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Graduate Studies

THE IMPACT OF AN ONLINE, APPLIED EDUCATIONAL PROGRAM ON PAIN
INTENSITY, DISABILITY, AND HEALTH-RELATED QUALITY OF LIFE
(HRQOL) AMONG PATIENTS RECEIVING CHIROPRACTIC CARE

A Chapter Style Thesis Submitted in Partial Fulfillment of the Requirements for the
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By Lindsay H. Worley

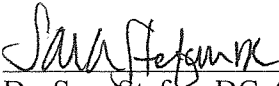
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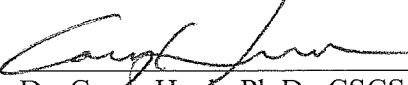
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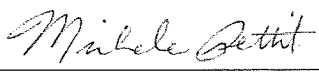
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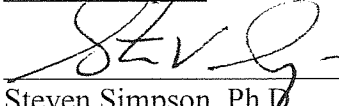
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ABSTRACT

Worley, L.H. The impact of an online applied educational program on pain intensity, disability, and health-related quality of life (HRQOL) among patients receiving chiropractic care. MPH, December 2016, 107pp. (G.D. Gilmore)

Chiropractic patients were selected as part of this research study because back pain has become a serious public health problem, impacting disability, medical costs, and an individual's quality of life. A double-blind pilot experimental design was conducted for the purpose of determining the effectiveness of an 8-week online educational self-management program, the *Healthy Back and Spine Challenge*, used in conjunction with chiropractic treatment. Self-reported levels of change on 3 specific outcomes were compared and analyzed on two study groups: an intervention group, referred to as the "challenge group" (group 1) and a usual care group (group 2). The 3 outcomes studied were pain intensity, low back pain disability, and overall health-related quality of life. Findings revealed no statistically significant differences in the changes of the mean scores reported between groups for all three outcomes, but within-group changes in the mean scores reported for both independent groups were significant at specific time points for all three outcomes. Recommendations include studying behavioral outcomes in alignment with the online program, utilizing other health education theories to identify specific constructs impacting behavior, and improving study design. This includes increasing sample size and recommending a health educator for further support with this form of delivery.

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CHAPTER I

THE BURDEN OF BACK PAIN

Introduction

The leading causes of death and noncommunicable diseases for adults in the United States are related to lifestyle-related behaviors to include physical inactivity, unhealthy diets, tobacco use, and overuse of alcohol (Mokdad, Marks, Stroup, & Gerberding, 2004). Lifestyle interventions have been recommended as a preventive approach by the World Health Organization to promote awareness and support self-management skills to reduce morbidity and mortality from chronic lifestyle-related diseases, such as cardiovascular disease, diabetes, and cancer (Kushner & Mechanick, 2015). Self-management, as defined by Barlow, Wright, Sheasby, Turner, and Hainsworth (2002) is “the individual’s ability to manage the symptoms, treatment, physical, and psychological consequences and lifestyle changes inherent in living with a chronic condition” (p. 173).

Self-management holds value because it trains patients to utilize relevant skills and carry out tasks to manage their conditions; it also bridges the gap between patients’ needs and available health services needed to meet those needs (Barlow et al., 2002). Kushner and Mechanick (2015) explain that interventions focusing on behavior change in the form of counseling require skills and competencies from practitioners. These skills include knowledge of the social determinants of health impacting individuals. This

includes, but not limited to, socioeconomic status, physical health, environmental conditions, genetics, and behavior status of an individual. Attention to these and other potential factors may impact an individual's behavior, and is important for practitioners to understand how barriers from these components impact one's desire to change a behavior. Interventions that address lifestyle behaviors have emerged as an innovative discipline, termed "lifestyle medicine".

The American College of Preventive Medicine (n.d.) defines lifestyle medicine "as the scientific approach that utilizes lifestyle-based interventions to decrease disease risk and illness burden by utilizing lifestyle interventions that activate self-management skills to promote healthy behaviors on nutrition, physical activity, stress reduction, and smoking cessation as a solution to combat preventable diseases from occurring" (para. 1). Modifying lifestyle-behavioral practices is important and shows promise in the management of chronic diseases, but also is becoming a new focus area and is being examined in chronic low back pain, because these same lifestyle changes and self-management approaches can prevent or even reverse many other conditions (Du et al., 2011; Geraghty, Stanford, Little, Roberts, Foster, Hill, et al., 2015; Woolf, Erwin, & March, 2012).

Background

A great deal of evidence reports that low back pain is a highly prevalent, multifaceted, and disabling condition that impacts people's health and quality of life, and is a result of a person's personal characteristics and lifestyle-related behavioral practices (Freburger, Holmes, Agans, Jackman, Darter, Wallace et al., 2009; Gore, Sadosky, Stacey, Tai, & Leslie, 2012; Manchikanti, Singh, Falco, Benyamin, & Hirsch, 2012;

Sheeran, Coales, & Sparkes, 2014). Health-related quality of life (HRQOL), as defined by the Centers for Disease Control and Prevention, is a multi-dimensional concept that includes domains related to physical, mental, emotional, and social functioning of an individual (Office of Disease Prevention and Health Promotion, 2016; CDC, 2011). Low back pain is an extremely common problem affecting at least 80% of all individuals at some point in their lifetime (Deyo, Cherkin, Conrad, & Volinn, 1991; Freburger et al., 2009; Grieves, Menke, & Pursel, 2009; Patrick, Emanski, & Knaub, 2016) and is the leading cause of disability in the world affecting all age groups (Freburger et al., 2009; Geraghty et al., 2015; Sheeran, Coales, & Sparkes, 2015; Vassilaki & Hurwitz, 2014). According to Gatchel, Polatin, and Mayer (1995), low back pain is the number one cause of disability in people less than 45 years of age, and the third-leading cause of disability for people over 45 years of age. In fact, Slater, Doctor, Pruitt, and Atkinson (1997) report that one percent of the US population is permanently disabled because of chronic low back pain conditions. Approximately 1 in 4 adults in the US have reported having low back pain resulting in a need for physician visits, hospitalization, and utilization of other health care services (Grieves et al., 2009; Martin et al., 2008; Patrick, Emanski, & Knaub, 2014). Furthermore, back and neck pain is the leading cause of sick leave, workers' compensation, and early retirement expenditures in the Western World (Linton, 1998). For example, Woolf, Erwin, and March (2012) reported that in the United States, 28% of workplace injuries and illnesses requiring time away from work in 2009 were due to musculoskeletal disorders. They also reported that the majority of productivity losses resulted from "reduced performance at work and reduced working hours rather than sickness absence" (p. 192).

Woolf, Erwin, and March (2012) defined low back pain (LBP) as non-specific and classified it according to duration and recurrence with acute back pain lasting less than 6 weeks, and chronic back pain lasting longer than 3 months. Although most cases of LBP resolve within 8 to 12 weeks (Gore et al., 2012), recurrence of LBP episodes range from 20%-44% within 1 year among working populations and lifetime recurrences are as high as 85%. Chronic LBP can result in periods of intense pain, significant limitations, and activity impairment (Freburger et al., 2009; Geraghty et al., 2015; Gore et al., 2012; Linton, 1997; Vassilaki & Hurwitz, 2014;). Martin et al. (2008) demonstrated that back pain also is a costly condition, leading to a significant financial and economic burden.

From a financial perspective, Martin et al. (2008) evaluated health care expenditures in the USA for treating neck and back pain problems. The research showed that direct and indirect costs for treating neck and back conditions ranged from approximately \$86 billion dollars to \$624.8 billion dollars and that healthcare expenditures for spine-related conditions among US adults increased by 65% between 1997 and 2005; physical functioning, mental health, and work also worsened during that time period. Freburger et al. (2009) also reported significant financial impacts of low back pain, with total costs estimated to be between \$100 and \$200 billion dollars annually. Woolf et al. (2012) reported that the United Kingdom National Health Service spends more than 1 billion dollars per year on back pain-related costs. They also reported that, between 2002 and 2004, the US spent \$193.9 billion dollars on annual direct medical costs for all spine-related conditions. Moreover, wages lost to spine-related conditions totaled \$14.0 billion dollars, thus impacting society considerably.

Research has demonstrated that back pain shares some of the same risk factors for chronic diseases, and some of these factors are modifiable (Vassilaki & Hurwitz, 2014). In fact, more than 100 risk factors have been identified for developing chronic back pain. These risk factors are related to the physical, emotional, and general health status of the individual, although findings are not consistent making chronic back pain a multifaceted condition (Giaquinto, Bruti, Dall'Armi, Gison, & Palma, 2010; Lucchetti, Oliveira, Mercante, & Peres, 2012; Manchikanti et al., 2012; Vassilaki & Hurwitz, 2014; Woolf & Pfleger, 2003;). Studies have reported that modifiable lifestyle-related risk factors for low back pain (LBP) include smoking, poor occupational conditions, physical inactivity, and poor diet (Manchikanti et al., 2012; Vassilaki & Hurwitz, 2014). Psychosocial factors such as stress, anxiety, and depression also are associated with greater rates of low back pain (Lucchetti et al., 2012; Patrick et al., 2016).

Considering lifestyle behavior change in the management of low back pain is less emphasized in guidelines for primary care because the mortality rate for low back pain is low (Woolf, Erwin, & March, 2012) and the condition generally is treated with medical interventions. However, literature is revealing medical interventions only are showing modest improvements and may also lead to overlooking mediating factors such as lifestyle-related behaviors (Deyo, Mirza, Turner, & Martin, 2009; Slater, Doctor, Pruitt, & Atkinson, 1997). Deyo et al. (2009) state that medical interventions such as surgeries, medications, and spinal injections are not the most effective or sustainable approaches for the management of chronic back pain, and that behavioral interventions and alternative medicines are being used as alternative approaches to traditional medical treatments (Deyo et al., 2009; Geraghty et al., 2015; Slater et al., 1997).

According to Parkinson, Sibbritt, Bolton, Rotterdam, and Villadesen (2013), chiropractors have been consulted regarding musculoskeletal pain with approximately 60-85% of their patients dealing with back pain. Chiropractic is a holistic profession dedicated to diagnosis, treatment, and prevention of disorders of the neuromusculoskeletal system (Parkinson et al., 2013). Doctors of Chiropractic (DCs) focus their care and treatment on the relationship between the spine and nervous system. In addition to their clinical role, DCs also advocate for health education, offering diet and lifestyle advice, coping strategies, and self-care approaches (Globe, Morris, Whalen, Farabaugh, & Hawk, 2008; Parkinson et al., 2013). Chiropractors provide manual techniques known as spinal manipulation, to move one or more parts of the body, and by treating the spine, it is the chiropractor's intention to restore and preserve general health and well-being of individuals. Parkinson et al. (2013) revealed that the efficacy of chiropractic treatment for low back pain remains unknown and that further research is needed to examine the impact of chiropractic interventions on the health and well-being of patients presenting with back pain.

Purpose of the Study

The purpose of the study was to explore the effectiveness of an online educational program used in conjunction with chiropractic treatment. The internet program was identified as the *Healthy Back and Spine Challenge*, and attempted to assist patients in taking control of their spine health by promoting awareness of lifestyle-related behaviors, and engaging patients in daily preventive activities related to physical activity, sleep, posture, nutrition, managing stress, and smoking cessation. The online program was designed to cultivate self-management skills for preventing the onset of back pain and

spine-related conditions. The program also sought to educate participants about healthy lifestyle-related behaviors to prevent noncommunicable diseases from occurring. Furthermore, the online challenge included strategies to help patients adopt and sustain healthy behaviors. These strategies included components from evidence-based behavioral theories. The Social Cognitive Theory, developed by Bandura (1953), explains the processes by which individuals learn behaviors within their environment. Concepts from this theory were used in the online challenge to help individuals achieve changes by providing education and positive reinforcement. The purpose of the Transtheoretical Model, developed by Prochaska and DiClemente (1979), is to assess an individual's readiness to change a behavior. The online challenge guided patients through the stages of change and provided strategies to encourage change. Specifically, goal-setting and Motivational Interviewing were used to determine if the individual was ready to change, and solution-focused therapies (e.g., exploration of personal values, series of questions that enhanced self-awareness on barriers inhibiting behavioral change, and preparation of an action plan to foster success) were used.

Statement of the Problem

Back pain has become a serious public health problem, significantly impacting disability, medical costs, and an individual's quality of life. Rising costs and the impact back pain has on an individual's quality of life underscores the need to reconsider and revise strategies that utilize multidisciplinary approaches. Approaches that foster self-management skills for the prevention of low back pain are encouraged to help manage and prevent the rising prevalence of back pain.

Need for the Study

In light of the impact and exorbitant costs associated with low back pain, there is a need to take a broader view of the management of back pain and further understand the value of self-management interventions. Supplementary approaches, like the *Healthy Back and Spine Challenge* are used in primary care settings, such as chiropractic clinics where people seek help for acute and chronic back pain conditions.

Research Questions

Three research questions were developed to address the problem and purpose for this study. Research Question 1: What is the self-reported level of pain intensity experienced by chiropractic patients participating in the *Healthy Back and Spine Challenge* as compared with an age and gender-matched control group during an 8-week period of time?

Research Question 2: What is the self-reported level of disability experienced by chiropractic patients participating in the *Healthy Back and Spine Challenge* as compared with an age and gender-matched control group during an 8-week period of time?

Research Question 3: What is the HRQOL experienced by chiropractic patients participating in the *Healthy Back and Spine Challenge* as compared with an age and gender-matched control group during an 8-week period of time?

Assumptions

Patients participating in the online lifestyle intervention program will be fully engaged in learning modules and will complete self-report surveys honestly.

Delimitations

Study participants were drawn from patients seeking care at Infinity Wellness and Chiropractic in Plover, Wisconsin. Subjects who were experiencing back pain or back-related issues, and who were seeking care for no longer than 6 months, were selected.

Limitations

A limitation of the study was that the combination of chiropractic care with the online intervention might have masked the participants' ability to fully ascertain the effectiveness of the online educational program. Another limitation of the study was that data were based on self-reported responses.

Definition of Terms

Acute- symptoms persisting for less than 6 weeks (Globe, Morris, Whalen, Farabaugh, & Hawk, 2008).

Chiropractic- "A profession dedicated to science-based, conservative health care approaches, like medicine, osteopathy, and other health professions, as opposed to a singular therapeutic procedure. Doctors of Chiropractic provide conservative, often "hands on" treatment, including, but not limited to, spinal manipulation, physiologic therapeutic modalities, exercise counseling, and also patient education to include diet and lifestyle advice, coping strategies, and self-care approaches" (Globe, Morris, Whalen, Farabaugh & Hawk, 2008, p. 652).

Chronic Low Back Pain- Chronic low back pain is defined as pain lasting longer than 3 months; such pain is intense and causes physical limitations, impacts functioning, and accounts for the majority of costs and disability attributed to back pain (Gore, Sadosky, Stacey, Tai, & Leslie, 2012).

Lifestyle Medicine- The scientific approach that utilizes lifestyle-based interventions to decrease disease risk and illness burden by utilizing lifestyle interventions that activate self-management skills to promote healthy behaviors on nutrition, physical activity, stress reduction, and smoking cessation as a solution to combat preventable diseases from occurring (American College of Preventive Medicine, 2011; Kushner & Mechanick, 2015, p. 38).

Health Promotion- “defined as health education and patient counseling aimed at behavior change in patients at risk for lifestyle-related illnesses, or who have diseases for which lifestyle modification can improve functioning or outcomes” (Duaso & Cheung, 2002, p. 473).

Health-Related Quality of Life- Health-related quality of life (HRQOL), as defined by the Centers for Disease Control and Prevention, is a multi-dimensional concept that includes domains related to physical, mental, emotional, and social functioning of an individual (Office of Disease Prevention and Health Promotion, 2016; CDC, 2015).

Self-Management Skills- “The individual's ability to manage the symptoms, treatment, physical and psychological consequences and lifestyle changes inherent in living with a chronic condition” (Du et al., 2011, p. 178).

CHAPTER II

REVIEW OF RELATED LITERATURE

Introduction

The choices individuals make regarding their lifestyles can have a significant impact on how their body expresses health. The World Health Organization (WHO) has defined lifestyle as “a way of living based on identifiable patterns of behavior which are determined by the interplay between an individual’s personal characteristics, social interactions, and socioeconomic and environmental living conditions” (Wai, Rodriguez, Dagenais, & Hall, 2008, p. 195). Evidence reported by the Centers for Disease Control and Prevention (CDC), World Health Organization (WHO), and National Center for Health Statistics (NCHS) suggests that lifestyle-related behaviors such as smoking, overuse of alcohol, poor diet, lack of physical activity, and inadequate relief from chronic stress are risk factors that contribute to the development of noncommunicable diseases (NCDs) (a.k.a., chronic diseases) (Danaei, Ding, Mozaffarian, Taylor, Rehm, Murray et al., 2009; Eyre, Kahn, Robertson, Clark, Doyle, Hong, et al., 2004; Milani & Lavie, 2015; Mokdad, Marks, Stroup, & Gerberding, 2004). NCDs are known to undermine health, shorten life expectancy, and contribute to high economic costs (Eyre et al., 2004).

Actual Causes of Death and Lifestyle-Related Risk Factors in the U.S.

Physical inactivity, unhealthy diets, tobacco use, and overuse of alcohol are noted as the four main lifestyle-related behaviors that contribute to the pandemic of chronic disease (Bauer, Briss, Goodman, & Bowman, 2014; Lianov & Johnson, 2010; Mokdad et al., 2004). According to Mokdad et al. (2004), such modifiable risk factors have been labeled as the “actual causes of death” compared to mortality from causes such as, infectious and toxic agents, firearm-related incidents, and motor vehicle accidents, because several improvements in the health system have led to a decline in mortality rates in the United States. Eyre et al. (2004) reported that these modifiable risk factors have led to an increase in the prevalence of other conditions such as, obesity and diabetes which rose to 65% between 1999 and 2000. Smoking, and physical inactivity were other lifestyle-related behaviors emphasized in 27th report of the National Center for Health Statistics, and pose significant risk for developing cardiovascular disease, diabetes, and cancer (Eyre et al., 2004).

Prevalence of Lifestyle-Related Diseases

The prevalence of chronic diseases among the population is concerning. According to Hyman, Ornish, and Roizen (2009), chronic diseases affect 160 million Americans, account for 78% of our healthcare costs, and are caused by lifestyle and environmental factors. Modifiable factors like these pose potential threats to one’s health and increase the chances of developing other chronic conditions, such as cardiovascular diseases, diabetes, and cancer, which account for nearly 2 of every 3 deaths in the United States (Eyre et al., 2004; Bauer et al., 2014; Mokdad et al., 2004). It is estimated that by the year 2030, NCDs may account for 52 million deaths worldwide (Milani & Lavie, 2015; WHO, 2015). Life

expectancy increased at a steady rate from 86.9% in 1998 to 92.2% in 2008, thus resulting in more people living with one or more chronic disease conditions (Bauer et al., 2014; Heidenreich, Trogon, Khavjou, Butler, Dracup, Ezekowitz, et al., 2011; Milani & Lavie, 2015). For example Milani and Lavie (2015), report that by the year 2020, it is estimated that 15 million Americans will be diagnosed with hypertension, 12 million will have diabetes, 4 million will have coronary heart disease, 2 million will be affected by stroke, and 2 million will have heart failure (Heidenreich et al., 2011). These diseases not only impact families, disability, and mortality, but they consequently place a heavy burden on the economy due to high escalating costs for treating or managing the conditions (Bryan, 2013). In 2011 alone, spending on healthcare was \$2.7 trillion dollars, and projected costs in the future for these conditions are expected to triple from total medical costs, reaching a total of \$818.1 billion dollars (Heidenreich et al., 2011; Moses, Matheson, Dorsey, George, Sadoff, and Yoshimura, 2013).

Lifestyle-Related Risk Factors

Lifestyle-related risk factors have received a considerable amount of attention because they often can be prevented by fostering healthy behaviors. The CDC leads US efforts to prevent and control chronic diseases and associated risk factors through the National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP). The organization provides a systematic approach to engage public health action, provides epidemiologic data to track chronic disease, builds infrastructure to improve community policies that encourage health promotion, and collaborates with healthcare systems to provide interventions and services to manage lifestyle-related conditions to address the burden of chronic diseases (National Center for Chronic Disease Prevention and Health

Promotion, 2015). Lifestyle-related risk factors and management for chronic disease have been a target for primary prevention and have become a specific focus area to reduce disability and premature mortality of chronic disease conditions (Bauer et al., 2014; Eyre et al., 2004; Heindenreich et al., 2011; Milani & Lavie, 2015). For example, the EPIC study published in the *Archives of Internal Medicine*, found that individuals who adhered to four simple behaviors--eating a healthy diet, exercising, not smoking, and maintained a healthy diet--prevented 93% of diabetes, 81% of heart attacks, 50% of strokes, and 36% of all cancers (Hyman, Ornish, & Roizen, 2009). This study documented the importance of how lifestyle interventions are more effective at preventing noncommunicable diseases than almost any other medical intervention and that lifestyle medicine is becoming the recommended foundational approach to preventing and treating many conditions in primary care settings.

Lifestyle Medicine

The American College of Preventive Medicine (n.d.) defines lifestyle medicine “as the scientific approach that utilizes lifestyle based interventions to decrease disease risk and illness burden by utilizing lifestyle interventions such as nutrition, physical activity, stress reduction, and smoking cessation as a solution to combat preventable diseases from occurring” (para. 1). Lifestyle interventions require skills and competencies in addressing multiple health risk behaviors, as well as building self-management skills for individuals to encourage and sustain healthy behaviors. However, guidelines encouraging lifestyle interventions as the first line of therapy in primary care are mixed and limited, and physicians often do not follow these recommendations (Kushner & Mechanick, 2015; Lianov & Johnson, 2010; Thande, Hursatk, Sciacca, & Giardina, 2008).

Deficiencies in Healthcare Delivery Model

Physician Time Demands

Milani and Lavie (2015) stated that the deficiencies in healthcare delivery primarily are due to certain factors. One factor includes physician time demands. The healthcare system is not structured to allow enough time to properly counsel and assess individuals to address the reasons why conditions are developing, creating gaps in healthcare delivery. For example, Milani and Lavie (2015) state that the median time for a physician visit is less than 15 minutes during which 6 varying topics are discussed, often resulting in the prescription of medication to treat health conditions that are created from poor lifestyles. Furthermore, they note that this consequently results in over-reliance on medication, causing medication-related events, which are now one of the top 5 causes of death, predominantly in the elderly population (Milani & Lavie, 2015).

Lack of Supporting Infrastructures for Lifestyle Modification. Another factor resulting in gaps in healthcare delivery is that there is lack of supporting infrastructures in the healthcare system. A primary care physician that has extra support such as a specialized non-physician, can bridge the gaps and provide the support needed for patients and help with monitoring and managing lifestyle-related practices (Milani & Lavie, 2015). In a study conducted by Duaso and Cheung (2002), patients were questioned to see if they could recall a time when lifestyle advice was received in a primary care setting. They found that the frequency in which lifestyle advice was given was low, yet patients expressed interest in receiving more health education; they also found that advice received was helpful. In addition, the lack of human and financial resources placed severe constraints on primary health services serving as a limitation in the general practice setting. Bauer et al. (2014)

stated that collaboration between health-care systems and public health is needed to address lifestyle-related risk factors through policy interventions, affordable access to healthy foods, environmental approaches to encourage physical health, and community clinical trials to support patients in managing their conditions through structured lifestyle programs.

Clinical Challenges. Healthcare providers are in a unique position where they can offer counseling, yet providers revealed from a survey conducted in 2006, that there are prominent barriers to facilitating effective counseling (Rao, Burke, Spring, Ewing, Lichtenstein, Cornier, et al., 2011). These barriers include lack of knowledge and skills, limited training and skills in preventive care, disbelief in preventive counseling, and perceived inability to change behavior (Lianov & Johnson, 2010; Milani & Lavie, 2015; Rao et al., 2011; Thande et al., 2008). According to Miliani and Lavie (2015), behavior change could be addressed in other ways, such as implementing innovative approaches to promote effective self-management skills and change lifestyle-related behaviors (Geraghty et al., 2015).

Self-Management Approaches

Self-management, defined by Barlow, Wright, Sheasby, Turner, and Hainsworth (2002) is “the individual’s ability to manage the symptoms, treatment, physical, and psychological consequences and lifestyle changes inherent in living with a chronic condition” (p. 173). Self-management holds value because it trains patients to utilize relevant skills and carry out tasks to manage their conditions and bridge the gap between their needs and health services available to meet those needs (Barlow et al., 2002). Lifestyle-based interventions provide the ability to deliver self-management approaches

that target all factors (i.e., biological, psychological and environmental) known to impact health. Modifying lifestyle-related factors is important and has shown promise in the management of chronic diseases; it also has become a popular new focus area for examining low back pain conditions because lifestyle changes can prevent or even reverse the recurrence of these conditions (Du et al., 2011; Erwin & March, 2012; Geraghty et al., 2015).

Burden of Back Pain

Previous literature reports that back pain is a multi-faceted problem that is highly prevalent and disabling, impacts people's health and quality of life, and is a result of a person's personal characteristics and lifestyle-related behavioral practices (Bergman, 2007; Dean & Soderlund, 2015; Freburger et al., 2009; Gore, Sadosky, Stacey, Tai, & Leslie, 2012; Manchikanti, Singh, Falco, Benyamin, & Hirsch, 2012; Sheeran, Coales, & Sparkes, 2014). Health-related quality of life (HRQOL), as defined by the Centers for Disease Control and Prevention, is a multi-dimensional concept that includes domains related to physical, mental, emotional, and social functioning of an individual (Office of Disease Prevention and Health Promotion, 2016; CDC, 2011).

Prevalence of Back Pain in the United States

Low back pain typically is defined as non-specific and is classified according to duration and recurrence, with acute back pain lasting less than 6 weeks, and chronic back pain lasting longer than 3 months (Erwin & March, 2012; Freburger et al., 2009; Gore et al., 2012; Woolf & Pfleger, 2003). Although most cases of LBP resolve within 8 to 12 weeks (Gore et al., 2012), recurrence of LBP episodes range from 20% to 44% within 1 year among working populations; lifetime recurrences are as high as 85% and can result in

periods of intense pain, significant limitations, and activity impairment (Freburger et al., 2009; Geraghty et al., 2015; Gore et al., 2012; Linton, 1997; Vassilaki & Hurwitz, 2014).

Incidence of Back Pain in the United States

Low back pain in the United States is an extremely common problem affecting at least 80% of all individuals at some point in their lifetime (Deyo, Cherkin, Conrad, & Volinn, 1991; Freburger et al., 2009; Grieses, Menke, & Pursel, 2009; Patrick, Emanski, & Knaub, 2014) it also is a leading cause of disability in the world (Freburger et al., 2009; Geraghty et al., 2015; Sheeran, Coales, & Sparkes, 2014; Vassilaki & Hurwitz, 2014). According to Vassilaki and Hurwitz (2014), in 2010, low back pain resulted in more disability than any other condition worldwide and was ranked 6th in terms of the overall disease burden. Khan, Akhter, Soomro, and Ali (2014) stated that low back pain is a major cause of disability in large populations around the world. Koes, Tulder, and Thomas (2006) stated that the reported lifetime prevalence varies from 49% to 70% and that five percent of the US population develop chronic low back pain and related disability.

Approximately 1 in 4 adults in the US have reported having low back pain, which is becoming one of the leading reasons for physician visits, hospitalization, and utilization of other health care services (Patrick et al., 2014; Grieses et al., 2009; Martin, Deyo, Mirza, Turner, Comstock Hollingworth, Sullivan, 2009; Deyo & Tsui-Wu, 1987). Furthermore, back and neck pain are the leading cause of sick leave, workers' compensation, and early retirement expenditures in the Western World (Linton, 1997). Woolf et al. (2012) reported that between 2002 and 2004, the US spent \$193.9 billion dollars on annual direct medical costs for all spine-related conditions. Moreover, wages lost to spine-related conditions totaled \$14.0 billion dollars, resulting in a significant financial and economic burden.

Magnitude of the Problem

Low back pain is one of the most prevalent and costly musculoskeletal conditions, and it has been reported that lifestyle practices, such as inactivity, poor sleep, overweight, and psychological factors can independently influence signs and symptoms of back pain (Darlow, Dean, Perry, Mathieson, Baxter, Dowell, 2015; Dean & Soderlund, 2015; Patrick et al., 2014; Vassilaki & Hurwitz, 2014). Back and neck pain is a more common reason for visits to primary care physicians and specialists, and is equally common among men and women (Deyo & Tsui-Wu, 1987; Grieves et al., 2009; Martin et al., 2008; Patrick et al., 2014; Xuemei, Pietrobon, Sun, Liu, & Hey, 2004).

Utilization of Healthcare Visits

According to a report by the *United States Bone and Joint Initiative*, an organization recognized by the World Health Organization to prevent musculoskeletal conditions, back and neck conditions resulted in increased healthcare visits from 32 million in 1998, to more than 50 million in 2010 (Bone and Joint Initiative, 2014). Gore et al. (2012) investigated pain-related treatment patterns of chronic low back pain patients, and the costs compared to patients without chronic low back pain. Results revealed that chronic low back pain patients had significantly higher usage of health care services compared to the control groups. For example, the total medical costs for the chronic low back pain group were significantly higher than the control group and differed by \$2502.87, and patients with chronic low back pain were prescribed significantly more pain-related medications compared to the control group. Additionally, the chronic low back pain group reported higher rates of depression, anxiety and sleep disorders compared to controls. Frebuger et al. (2009) conducted a population-based survey in North Carolina to determine

whether the prevalence of chronic low back pain and healthcare-seeking characteristics changed for the state during 1992-2006. In the 14-year time period, they reported a notable increase in the prevalence of chronic low back pain with it more than doubling from 3.9% to 10.2%. Along with an increased prevalence of chronic low back pain was surgical procedures. Surgical procedures increased per person among the North Carolina population and increased 157% from 1997 to 2005.

Increase in prescription medications and utilization of healthcare services.

Martin, Turner, Mirza, Lee, Comstock, and Deyo (2009) evaluated expenditures among those who sought healthcare services for spine problems in the United States for four major components including: inpatient care, outpatient care, pharmaceutical care, and emergency department care. Results revealed that the annual per-user expenditures for hospitalizations increased an average of 3.7% per year and prescription medication use increased from 1997 to 2006, which was more than any other service category. Inflation adjusted spine-related expenditures for prescription medication use increased an average of 10.2% per year from \$166 dollars in 1997 to \$397 per patient in 2006. From that same time period, there was a 660% increase in expenditures for opioid medications among people with spine problems from \$246 million in 1997 to \$1.9 billion dollars in 2006. Lastly, the research reported that the number of people who sought treatment for spine problems increased from 14.8 million in 1997 to 21.9 million in 2006, which equated to a 49% increase (Manchikanti et al., 2012).

Direct and indirect costs of back pain

Back pain is costly on the healthcare budget and represents one of the top 10 largest spending conditions, reaching a total of \$40.1 billion dollars in 2010 (Moses et al., 2013).

A study by Martin et al. (2008) evaluated health care expenditures in the United States for treating neck and back pain problems. The research showed that direct and indirect costs for treating neck and back conditions ranged from approximately \$86 billion dollars to \$624.8 billion dollars. In addition, healthcare expenditures for US adults for spine-related conditions increased by 65%, between 1997 and 2005, and that physical functioning, mental health, and work limitations were reported as specific domains that were affected from spine-related problems during this time period.

Freburger et al. (2009) also reported significant financial impacts of low back pain, estimating total costs between \$100 and \$200 billion dollars annually. According to national survey data sets, the direct costs for back pain reached \$12.9 billion dollars annually (Xuemei, Pietrobon, Sun, Liu, & Hey, 2004). Loss of work productivity costs alone is becoming a primary driver to the economic burden resulting in 149 million days of work per year lost because of low back pain (Freburger et al., 2009; Gore et al., 2012).

Leigh (2011) assessed data from 2007, and estimated the number and medical costs of nonfatal occupational injuries in the United States. He reported that injuries with 1 to 4 days away from work resulted in an average medical cost per injury of \$935 dollars. High patterns of expenses are seen internationally. For the United Kingdom, the direct annual costs for back pain have been estimated at 1.6 billion dollars, while also being a common reason for consultation visits detailing an annual rate of 591 people per 10,000 registered persons (Lewis, Jones, Barton, Whitehurst, Wathall, Foster et al., 2015). Direct and indirect healthcare expenses of back pain demonstrate that the condition is costly and creates a financial economic burden that impacts society considerably. Aside from the

indirect and direct costs of back pain, treatments and invasive therapies that have been sought out for relief of the condition also reveal substantial financial costs.

Healthcare Expenditures to Treat Back Pain

Healthcare treatments for back pain have expanded to include injections, surgical procedures, implantable devices, medications, and imaging (Martin et al., 2008). Over the past decade, efforts to better understand the medical costs and benefits of these treatments were analyzed.

Imaging for Low Back Pain

In the 2009 article, “*Overtreating Chronic Back Pain*,” Dr. Deyo stated that it is unclear if medical treatments and therapies yield improvements in the health status of individuals that have back or neck pain due to few high-quality trials assessing their efficacy and the fact that patients continue to experience pain and dysfunction (Deyo, Mirza, Turner, & Martin, 2009). According to Deyo et al. (2009), the use of lumbar magnetic resonance imaging (MRI) increased among Medicare beneficiaries by 307% during a 12-year period and surgery rates increased the highest in areas where high MRI rates were performed.

Weiner, Kim, Bonino, and Wang (2006) examined the rates of basic and advanced imaging utilization among Medicare beneficiaries with non-specific low back pain. Results from their study indicated that there was a 387.2% increase in total low back pain charges from 1991 to 2002. During the investigative time period, X-ray rates and charges increased by 4.1% and 19.3%, respectively, while MRI rates and charges increased by 40.5% and 72.5%. Charges related to low back pain have increased markedly, mostly due to the increased prevalence of low back pain. Weiner, Kim, Bonino, and Wang (2006) also

indicated that radiographic findings are poorly predictive of clinical symptoms, that low back pain is a complex clinical syndrome derived from many factors, and that physicians over-utilize advanced technologies that typically are not necessary. They stated that this is the result of physicians being poorly trained in pain management in general musculoskeletal assessment, and diagnostic testing frequently being relied upon for treatment. In addition, prescription usage of opioid use has been increasing steadily particularly among patients dealing with spinal disorders.

Increase in Opioid Prescription Usage. Data from the National Medical Expenditure Panel Survey, reported by Deyo et al. (2009) described a 108% increase in opioid prescriptions from 1997 to 2004, with trends increasing at a steady rate. He described that these trends likely are due to the under-treatment that occurs for patients dealing with chronic back pain. Even more concerning, deaths related to prescription opioids have increased, leading to 4451 deaths in 2002, and more than half of regular users of opioid prescriptions have back pain (Deyo et al., 2009). The efficacy and safety of long-term and short-term opioid use remain controversial, largely due to few high-quality trials examining and assessing the effectiveness of opioid use.

Controversy on opioid use for back pain management. Individuals exhibiting back pain have demonstrated that psychological consequences occur in patients dealing with chronic back pain, thus raising questions regarding opioid usage for patients (Deyo et al., 2009). Patients who experience depression and other psychiatric disorders often are excluded from opioid therapy trials because of the likeliness to misuse medication, yet opioids continue to be used as treatment for back pain despite controversy regarding their safety (Deyo et al., 2009; Koes, Tulder, Lin, Macedo, McAuley, and Maher, 2010; Weiner

& Nordin, 2010). Not only does the safety of opioids remain questionable, but adverse effects from opioid use can lead to potential risks such as changes in the brain and spinal cord, intensified sensitivity to pain, and reduced hormonal activity (Deyo et al., 2009). Due to the risks of opioid prescription use, a serious need exists not only to test the effectiveness of opioid prescriptions with more highly-controlled studies, but also to reassess and consider alternative, nonpharmacological therapies that can be implemented in clinical settings for managing back pain.

Surgical Treatments

Spine surgeries to treat back pain conditions also have increased and contribute to high costs and growth of health care spending in the United States. The frequency of back surgeries ranks behind Caesarean sections and back surgeries are a main reason for surgical hospitalizations. In fact, the likelihood of having back surgery in the United States was at least 40% higher compared to any other country (Cherkin, Deyo, Loeser, Bush, & Waddell, 1994). According to the U.S. Centers for Disease Control and Prevention, the top three surgical procedures in terms of overall cost in 2009 were: spinal fusion surgery (\$11.26 billion), balloon angioplasty of the heart (\$11 billion), and knee replacement surgery (\$10.36 billion) (CDC, 2012).

Birkmeyer, and Gust (2010) stated that the average total payments for inpatient back surgery was \$26,515 (Birkmeyer & Gust, 2010). The frequency of back surgery in the United States is the highest in the world, and spinal fusions increased by 40% between 1998 and 2004 (Vassilaki & Hurwitz, 2014). In previous years, lumbar spine fusion also rose at a rate of 220% from 1990 to 2001 and likely increased due to approval of a new type of surgical implant that became approved in 1996 (Deyo et al., 2009). Deyo et al.

suggested that surgical implants increase the risk of nerve injury, and can contribute to overall complications. Moreover, surgical implants have the potential of not improving pain or function from spine-related conditions, and the risks of surgery may outweigh the benefits, which has raised controversy.

When combined with surgical costs, medications, MRIs, and disability which contribute to decreased wages and lost productivity, spine conditions result in costing an estimated amount of \$100-\$200 billion dollars annually (Gatchel et al., 1995). These findings suggest that conventional approaches like surgeries, and/or opioid medications to treat and manage back pain are costly, and not guaranteed to produce any further improvements in preventing and managing back pain. Furthermore, research has demonstrated that psychological consequences occur in patients dealing with chronic back pain (Darlow et al., 2015; Freburger et al., 2009; Garbi, Hortense, Gomez, Silva Castanho, Sousa, 2014).

Personal and Societal Impacts of Back Pain

Research has shown that psychological consequences occur when patients are dealing with chronic back pain. Specifically, patients often experience depression and other cognitive-related disorders (Freburger et al., 2009). For example, Freburger et al. (2009) stated that individuals with major depression are likely to increase their risk for developing chronic pain and that depressive patients are 3 times more likely to develop episodes of chronic back pain within 2 years compared to non-depressive individuals.

Psychological Factors Resulting From Low Back Pain

Like Freburger et al. (2009), Darlow et al. (2015) examined the impact of psychological factors that occur from low back pain to include anxiety, vulnerability to

injury, depression, and uncertainty about one's ability to heal. Participants disclosed that the psychological consequences of dealing with back pain led to depression, feeling old, difficulty in decision making, feeling abrupt and irritable, and having strong negative beliefs about the ongoing effects of back pain.

Pain intensity, disability, and psychological outcomes. Garbi, Hortense, Gomez, Silva, Castanho, and Sousa (2014) measured pain intensity to identify disability and depression levels in people with chronic low back pain and found that high levels of pain were positively correlated with disability and depression. Similarly, Scholich, Hallner, Wittenberg, Hasenbring, and Rusu (2012) examined correlations between pain intensity, disability, and health-related quality of life and psychological outcomes for chronic low back pain patients in an orthopedic clinic from two points in time: during the first day after admission and 6 months after inpatient treatment ended. Results revealed strong positive correlations in psychological outcomes ($r=0.27$ to $r=0.48$) such as distress, anxiety and depression were found due to levels of pain intensity and disability. Furthermore, at 6 months, pain-related help-hopelessness, catastrophizing beliefs, and avoidance of behavior were positively related to pain, and disability had a negative relationship to health-related quality of life.

Non-surgical Care

The results from these studies indicate that psychological interventions should be integrated into back pain management as they play a role in pain and disability during the recovery period. Furthermore, Deyo et al. (2009) suggested that greater investment is needed in therapies and interventions that promote patient involvement, self-care strategies, social support, and activities. Deyo et al. also noted that it is important that

psychosocial, occupational, and lifestyle dimensions are not overlooked and are included in the treatment of chronic back pain. Similar suggestions were made by Vassilaki and Hurwitz (2014) who recommended that non-surgical interventions, such as supervised exercise, low-level laser therapies, and health promoting practices (e.g., physical activity, maintaining a healthy weight), may have protective effects on back pain and be more effective than other treatment. However, insufficient data exists on these types of therapeutic interventions. Approaches that feature multidisciplinary elements are few and should be further tested to determine the effectiveness for populations experiencing back pain symptoms. Despite limited research, the few studies assessing the effectiveness and utilization of multidimensional approaches for the prevention and management of back pain have shown encouraging results (Carson, Keefe, Lynch Carson, Goli, and Thorp, 2005; Morone, Greco, Moore, Rollman, & Weiner, 2016; Searle, Spink, Ho, & Chuter, 2015; Tilbrook et al., 2012).

Multidisciplinary Interventions for Treatment of Back Pain

Low back pain has a multifactorial etiology, and a variety of elements impact development of the condition. These elements include individual characteristics such as age, physical health, and psychosocial factors (depression, stress), as well as societal factors such as occupation and physical demands (Searle, Spink, Ho, & Chuter, 2015). Research has demonstrated that nonpharmacological treatments have produced positive results in chronic low back pain patients (Tilbrook, Cox, Hewit, Kangg, Chang, Jayakody, et al., 2011; Morone et al., 2016; Carson et al., 2005).

Yoga for Chronic Low Back Pain

Tilbrook et al. (2012) compared the effectiveness of yoga and usual care for chronic and recurrent low back pain patients. The 12-week yoga program incorporated relaxation techniques, and yoga poses targeted to improve mobility, strength, and posture. The findings revealed that individuals in the yoga group had better back function, and higher confidence in performing normal activities. Moreover, it was found that yoga is an effective strategy that clinicians should consider recommending for patients with a history of low back pain conditions (Tilbrook et al., 2012).

Mindfulness Meditation for Chronic Low back Pain. In addressing psychosocial factors, a randomized clinical trial performed by Morone, Greco, Moore, Rollman, and Weiner (2016), determined the effectiveness of an 8-week mind-body program aimed at increasing function and reducing pain in adults 65 years or older that presented with chronic low back pain. The intervention included a mindfulness-based stress reduction program that encouraged meditation practices such as a body scan, a walking meditation, and mindful stretching. Results revealed that mindfulness meditation techniques resulted in significant improvements in short-term physical functioning and resulted in improvement in the Numeric Rating Scale used to assess intensity of pain. As stated in the study, a recent meta-analysis found that higher levels of self-efficacy are associated with decreased impairment, emotional distress, and pain severity among patients with chronic pain. This study highlighted the importance of utilizing psychosocial components in interventions for chronic low back pain patients because such components can aid in improving function, self-efficacy, and quality of life.

Carson et al. (2005) found positive results among chronic back pain patients who were involved in a loving-kindness meditation intervention. The intervention included 8 weekly 90-minute group sessions that were led by a clinical psychologist and health educator who had the skills and training to teach loving-kindness meditation with the goal to encourage an emotional shift in patients dealing with back pain. Specifically, patients recalled a time when they felt a very positive connection and reflected on the actual feelings of love and kindness that were elicited in that moment. The intervention also involved employing mental phrases to direct positive feelings towards oneself, including presentations on loving-kindness meditation, gratitude exercises, and homework assignments to practice loving-kindness strategies.

Findings from the study revealed that the intervention was helpful in improving patients' pain. Specifically, the more patients practiced loving-kindness meditation, the less likely they were to experience anger and tension when practicing these techniques. This study provided evidence of the potential efficacy of utilizing multiple strategies in a population of persons having persistent pain, as well as providing preliminary support for holistic approaches to integrate meditation into the treatment of patients with persistent pain.

Self-Management programs for chronic back pain

Korff, Moore, Lorig, Cherkin, Saunders, Gonzalez, Laurent, Rutter, and Comite (1998), undertook a randomized trial incorporating a self-management program for people with chronic back conditions enrolled in a health maintenance organization in Western Washington. The intervention included goal planning and problem-solving techniques that engaged participants in identifying problems and activity limitations related to back pain.

It also included exercise, and information about proper posture, and the impact of positive and negative self-talk in managing back pain. Results from the study found that, compared to traditional care patients, those enrolled in the self-management group had favorable outcomes that included better attitudes toward back pain self-management, reduced worry from three to six months, and a 50% or greater reduction in severity of impairment and limitation of activities due to back pain.

Similar results were found in a study evaluating the effectiveness of a self-management program for chronic low back pain among elderly Americans. The program had a positive effect on emotional well-being, provided social interaction for discussing back problems and solutions, and resulted in a 6-month improvement in functional disability (Haas, Group, Muench, Kraemer, Brummel-Smith, Sharma, et al., 2005). In a similar study, Schulz, Rubinell, and Hartung (2007) tested the efficacy of using the internet as a strategy for enhancing self-management for chronic low back pain patients. When compared to the control group, the participants in the internet intervention group reported a decrease in intensity of back pain, an increase in physical activity levels, a reduction in painkiller usage, and an increase in knowledge (e.g., causes of back pain, pain perception, increase an exercise, correct postures, and wrong movements). This study suggests that an online educational intervention led to positive results, but further research is needed on larger scales.

Findings from these studies suggest that engaging patients in problem solving to overcome activity limitations, and enhancing confidence in self-care, may be important components in engaging patients in the management of back pain. However, there is insufficient evidence to demonstrate the effectiveness of self-management programs and

there is a pressing need for further research for improving pain and disability among acute and chronic back pain patients (Du et al., 2011). Vassilaki and Hurwitz (2014) stated that interventions like this are few and finding data regarding their effectiveness in preventing recurrences of back pain are limited, yet interventions such as these have yielded more promising results for those who have back pain, compared to medical treatments that often are performed. Priority has been placed on research to further investigate self-care and self-reliance strategies for persons with chronic or recurrent back pain.

The Need to Address Back Pain

Research has demonstrated that back pain shares some of the same risk factors for chronic disease. In fact, more than 100 risk factors have been identified for developing chronic back pain; these risk factors are related to the physical, emotional, and general health status of the individual, making chronic back pain a multifaceted conundrum (Giaquinto, Bruti, Dall'Armi, Gison, & Palma, 2010; Lucchet, Oliveira, Mercante, & Peres, 2012; Manchikanti et al., 2012; Vassilaki & Hurwitz, 2014; Woolf & Pfleger, 2003). Considering lifestyle behavior change in the management of back pain is less emphasized in guidelines for primary care because, unlike chronic diseases such as cancer and heart disease, mortality rates for back pain conditions are low (Woolf, Erwin, & March, 2012). In fact, back pain usually is treated with medical interventions, such as surgery, prescription usage, and/or diagnostic testing such as magnetic resonance imaging (MRI). However, this review of literature revealed that medical interventions for the treatment of back pain conditions have shown modest improvements and could lead to overlooking mediating factors such as lifestyle-related behaviors, which are known to influence and impact the onset of back pain (Deyo et al., 2009; Slater, Doctor, Pruitt, & Atkinson, 1997).

Despite improvements in therapeutic strategies for back pain, use of medical services has risen, and limited studies exist to prove that medical interventions such as surgeries, medications, and spinal injections are the most effective approach for the prevention and management of patients who are suffering from chronic back pain conditions (Briggs, Jordan, O’Sullivan, Buchbinder, Burnett, Osborne, Straker, 2011; Deyo et al., 2009).

Clinical Guidelines in the Management of low back pain in primary care settings

Korff et al. (1998) mentioned that healthcare for back pain pays inadequate attention to enhancing patients’ abilities to carry out self-management tasks, and that further research is needed to investigate interventions that activate self-management for back pain in primary care settings. In addition, back pain and the reoccurrence of back pain problems still continue and are having significant impacts on disability, medical costs, and individuals’ quality of life. Koes, Tulder, Lin, Macedo, McAuley, and Maher (2010) reported that guidelines for the management of acute and chronic back pain have been established by a multidisciplinary team of primary care physicians, physiotherapists, orthopedic surgeons, and occupational and rehabilitation therapists. The guidelines encourage health-promoting recommendations such as, incorporating regular exercise, practicing cognitive behavioral therapies, and employing self-care for individuals dealing with back pain. Focusing on health promotion recommendations such as these, may empower patients with knowledge and self-care strategies for managing back pain. (Haas et al., 2005; Koes et al., 2010).

Future Directions. The single greatest opportunity to improving population health lies in lifestyle-related behavioral risk factors (National Center for Chronic Disease Prevention and Health Promotion, 2015). Strategies that include a multidisciplinary

prevention program for patients exhibiting back pain related conditions may be important to help manage and prevent the rising prevalence of back pain. In addition, further research is needed to assess the efficacy of lifestyle behavior change interventions and their impact on patients who are dealing with back pain and other lifestyle-related conditions known to impact back health.

CHAPTER III

METHODS AND PROCEDURES

Introduction

There is a need to take a broader view of the management of back pain and further understand the value of self-management interventions like the *Healthy Back and Spine Challenge*, used as supplementary approaches in primary care settings. The *Healthy Back and Spine Challenge* was implemented in a chiropractic setting, *Infinity Wellness and Chiropractic Clinic*, located in Plover, Wisconsin, where people seek help for acute and chronic back pain conditions.

Researchers suggest that greater investment is needed in therapies and interventions that promote patient involvement, self-care strategies, social support, and health promotion activities (e.g. counseling, education, behavior change strategies). It also has also been suggested that psychosocial, occupational, and lifestyle dimensions are included. It is encouraged that these components are not overlooked and are included in the treatment of chronic back pain. This is because low back pain is understood to have a multifactorial etiology (Brunner, De-Hert, Minget, Baldew, & Probst, 2013; Deyo et al., 2009; Geraghty et al., 2015; Haas et al., 2005; Koes et al., 2010). Implementing innovative approaches that can be used to promote effective self-management skills may be a key strategy. It also may be an important concept to include for the management of back pain (Crowe, Whitehead, Gagan, Baxter& Panckhurst, 2010).

Similar suggestions were made by Vassilaki and Hurwitz (2014) when they discussed the likelihood that supervised exercise, low-level laser therapies, and health-promoting recommendations, such as physical activity, and maintaining a healthy weight, may have protective effects on back pain. However, insufficient data exist regarding these types of therapeutic interventions, due to a paucity of reported approaches that feature multidisciplinary elements. It has been recommended that these therapeutic interventions be further tested for effectiveness among those with lower back pain (Deyo et al., 2009; Du et al., 2011; Korff et al., 1999; Schulz, Rubinell, & Hartung, 2007; Vassilaki & Hurwitz, 2014).

Study Design

A pilot study, with a double-blind experimental design, was conducted to explore the feasibility and effectiveness of an online, applied-educational program, *Healthy Back and Spine Challenge* (active approach) compared with an information-only (passive approach) control group. The online program was developed by Wellness Professors, LLC, an online company that offers credible wellness courses, challenges, and programs for niche population groups, and is designed to cultivate self-management skills. The *Healthy Back and Spine Challenge* often is referred to as the “online challenge.” The purpose of the online challenge was to identify the level of pain intensity and level of disability during an 8-week period of time among patients participating in the challenge compared with an age and gender-matched control group. Patients in the intervention group who received the online challenge in addition to chiropractic treatment (active approach) were compared to patients in the age and gender-matched control group who did not receive the online challenge (passive approach). In addition, Health-Related

Quality Of Life (HRQOL), as measured by 8 domains, was compared between chiropractic patients participating in the online challenge and an age and gender-matched control group during an 8-week period of time. The 8 domains included physical functioning, bodily pain, role limitations due to physical health, role limitations due to personal or emotional health, emotional well-being, social functioning, energy/fatigue, and general health perceptions. The research was approved by the Institutional Review Board of the University of Wisconsin- La Crosse, WI. Participants were recruited solely through the *Infinity Wellness Chiropractic Clinic*, and signed written informed consent forms to participate in the study.

Subject Selection

All participants in this pilot study were recruited in a two-week timeframe from a chiropractic clinic, *Infinity Wellness and Chiropractic Clinic*, in Plover Wisconsin. Dr. Stefan, clinical director and chiropractor (DC), reviewed her patients' health records and identified all participants who were eligible for participation in the study based upon the established eligibility criteria (see eligibility criteria below). The chiropractor referred patients to the investigator, who then used a script for recruitment in order to assure the consistency of the request (see Appendix A) either over the phone or during in-person interactions within the clinic.

Eligibility Criteria

Participants were considered eligible if they had exhibited back pain or spine-related ailments and had not received chiropractic care for more than 6 months, or had been identified by Dr. Stefan as having major disabilities due to factors other than low back pain, conditions requiring individual medical or surgical treatment, or physical

activity restrictions or injuries which prohibited participation in exercise. Participants who rated their pain at a numerical value of 10, which is the worst imaginable pain, on the Numeric Pain Rating Scale (NPRS; see Appendix B), were not included in the study. Participants exhibiting a high level of pain were considered unable to participate due to the participants being unsupervised when exercises were performed. For that reason, those participants were excluded to prevent participants from being injured due to the physical disability inflicted from pain. Pain intensity was measured using the Numeric Pain Rating Scale, an instrument commonly used in clinical work and used by the chiropractor in this setting (Ares, Prado, Verdecho, Villanueva, Hoyos, Herdman, Lugilde, & Rivera., 2014; Kahl & Cleland, 2005).

Inclusion criteria also included participants' age (i.e., equal to or greater than 25 years of age up to 57 years of age). The age range was set at this level because of the usual age range of the patients being seen at this clinic. Additionally, those who did not receive Dr. Stefan's recommendation to participate in the study, and/or those whose physical health status for participating in exercise was a concern, needed to sign a physician release and clearance form from their primary doctor to participate in the *Healthy Back and Spine Challenge*. A completed informed consent form also was returned to the investigator (see Appendix C). Intervention participants had to have provided their email address and had to have access to technical requirements, such as a tablet, smart phone, or personal computer that allowed access to the internet and speakers or headphones that enabled use of online audio files. All participants who met the criteria were invited to volunteer their participation in the study. The total number of participants in the study numbered 23.

Procedures for Group Formation

The investigator had a major responsibility throughout the recruitment process. Specifically, the investigator was the designated person responsible for tracking all eligible participants selected from the overall patient pool from the clinic. This ensured that the investigator had access to the patient population at *Infinity Wellness and Chiropractic Clinic*, where the sample was being taking from, and also protected patient information. The investigator recorded names and collected email information for the participants who agreed to participate in the study and placed the identification contact information on a Microsoft Office Excel 2013 spreadsheet. Column A included participants number assignment, column B included email information, column C included gender, and column D included age.

A number was assigned to each participant by the health and wellness professional and then each participant was matched according to those characteristics. After 23 participants were recruited, a column titled “Number Assignment” was created in column A. Each participant was assigned a designated number between 1 and 23 by the health and wellness professional (see Appendix D). Numbers, rather than names, were assigned to protect patient information. The sample was collected by the investigator only, and information was recorded for the next critical step, which was random assignment for the two groups performed by a separate individual. Random assignment was completed by a health and wellness professional. For the sake of remaining blind as to group alignment the investigator did not have any involvement during the randomization process of placing participants in the groups. After the sample was achieved, and the information was recorded on the Excel spreadsheet by the

investigator, the investigator emailed to a wellness professional the final spreadsheet which included participants' email contact information, gender, and age. This was the final time the investigator was involved in formation of the two study groups. The investigator did not have any knowledge of which participants were assigned to what group to eliminate potential bias.

The wellness professional had a separate role from the investigator. The wellness professional completed the random allocation of participants and distributed participants evenly among the two groups on behalf of the Wellness Professors, LLC for the online challenge. Randomization was completed by the health and wellness professional, an Academic Professor in the College of Professional Studies (CPS) at the University of Wisconsin-Stevens Point (UWSP), and also the Program Developer of the online challenge. The allocation alignments were concealed from the investigator and the chiropractor performing the clinical services.

After receiving the spreadsheet, the wellness professional recorded all members from the sample on a piece of paper using the assigned number and included gender and three specific age groups so that matching participants' characteristics could occur between the two groups. To ensure that participants were balanced between the two study groups, gender and age were considered. The age categories were assigned as followed: 25-35 years of age, 36-46 years of age, and 47-57 years of age. Three age ranges were established in order to achieve an equal representation of age in the intervention group, and the traditional care group. A total of 13 participants in the age group 25-35 years of age were randomly assigned to either the intervention group or the usual care group. Hereafter, the comparison group will be referred to as the "usual care group." A total of 5

participants each in the age group 36-46 years of age and 47-57 were randomly assigned to the intervention group or the usual care group to ensure the best balance possible. As a side note, 2 males in the age range of 25-35 were randomly assigned to either the intervention group or the usual care group and placed in their specific age group. The clinic primarily sees females. Even though the proportion of males to females was exceptionally small, males were included because they potentially may have responded differently to the intervention compared to females, and it was important not to lessen the sample size. After sample selection, the wellness professional placed each one of the pieces of paper in the appropriate categorized container. After all participants were placed in the appropriate categorized containers, they were shuffled to ensure the pieces of paper were well mixed. Thereafter, the wellness professional performed a simple random sampling technique known as the “Fishbowl technique without replacement” (Cottrell & Mckenzie, 2011). The wellness professional randomly drew one piece of paper at each time from each categorized container, randomly assigned the participants to one of the two study groups -the intervention group (group 1) or the usual care group (group 2)-and recorded the information on a Microsoft Excel spreadsheet until he reached the designated number (12) chosen for the intervention group (group 1) with one extra person randomly assigned to the intervention group in case one declined continual involvement at some point during the 8-week period. The mean age of participants in the intervention group was 37.58 years. The usual care group (group 2) reached the designated number (11), and the mean age was 37.45 years. Each participant was assigned a unique number between 1 and 23 that was generated by the health and

wellness professional. These numbers were used for participant identification during data collection.

Intervention

The intervention group received free and unlimited access to content material for the *Healthy Back and Spine Challenge* at a location where they had access to the internet, in addition to receiving standard chiropractic care and services from Dr. Stefan.

Participants in the usual care group did not receive any access to content material for the *Healthy Back and Spine Challenge*. However, they did receive information from Internet sources selected by the investigator regarding the importance of lifestyle enhancement, along with the usual chiropractic care and services from Dr. Stefan (see Appendix E for the Health Articles at the Clinic Available to all Study Participants). All the participants were encouraged to read these resources and be aware of the health-related articles. This represented a more passive approach for the usual care group. At the beginning of implementation, an introduction/welcome letter was sent to all participants that were participating in the study by email, from the health and wellness professional. The welcome letter informed participants that the program had begun. The intervention time period was 8-weeks. Participants in the intervention group only, received a separate email from the health and wellness professional notifying them that they were selected and instructing them to enroll in the *Healthy Back and Spine Challenge*. The email informed intervention participants how to enroll in the *Healthy Back and Spine Challenge* and notified the intervention participants of their assigned study number. Instruction was given to intervention participants about the name of the website to gain access to the challenge, as well as how to login to the challenge using a login identification (email

address) and password assigned by the health and wellness professional. Participants were notified that they could change their password at any time during the 8 weeks if preferred. After login id and password information was set by each intervention participant, participants in the intervention group used that information to gain access during the 8-week challenge. If intervention participants did not register one week from the first invitation, a reminder email was sent from the health and wellness professional about enrolling. The investigator received all assessments that each participant sent in for both groups, while remaining unaware throughout the study with which group a participant was aligned.

Healthy Back and Spine Challenge. The *Healthy Back and Spine Challenge* was an 8-week online challenge offered through Wellness Professors, LLC, an online company that provides credible wellness courses, challenges, and programs for niche population groups. All courses were designed by wellness professionals with appropriate licensure or credentials (Doctor of Physical Therapy D.P.T., Doctor of Chiropractic D.C., Certified Wellness Practitioner C.W.P., Certified Strength and Conditioning Specialist C.S.C.S., Licensed Psychologist). The core of this program provides courses that are preventive in nature promoting the adoption and sustainment of healthy behaviors for participants specific to the goals of each challenge. Each course fostered three main components: foundational knowledge, skill development and practice, and behavior change strategies.

Foundational knowledge and skill development are important components used in the online challenge to induce self-management skills by providing tools and resources. This approach assists participants in acquiring skills and confidence to manage their

conditions. By routinely assessing problems and accomplishments in the learning modules, along with guidance from credible wellness professionals, participants learned how to master each skill and build knowledge.

Behavior change strategies were included from behavior change theories as a guide to influence health behaviors derived from internal and external factors. Internal factors include an individual's cognitions, beliefs, emotions, neurological challenges, illnesses, or physical disabilities. External factors can include environmental, societal, and psychological factors such as interactions with other people (e.g., friends, family, and the community), the area in which an individual resides, the economy, health policies and laws such as nutrition labeling to prevent obesity and promote healthy living. These internal and external factors can provide a better understanding of the complex influences on human behavior (Glanz, Rimer, & Lewis, 2008). Internal and external factors were included to assist individuals in changing behavior and enhancing self-motivation and self-efficacy. Self-efficacy is defined as "the conviction that one can successfully execute the behavior required to produce the outcomes" (Glanz, Rimer & Viswanath, 2008, p. 49). Self-motivation, often referred to as intrinsic motivation, is defined as doing an activity because of one's own satisfaction or interest, without external control of others (Ryan & Deci, 2000).

The online program was designed to cultivate self-management skills and provide educational advice regarding pain and low back pain-related topics. The online program also was designed to prevent the onset of back pain and spine-related conditions. Finally, it promoted a holistic approach in encouraging and educating participants about healthy lifestyle-related behaviors to prevent noncommunicable diseases from occurring. The

online challenge was set up to release content at specific time intervals. This meant that the first 4 weeks of the online challenge were made available to intervention participants at the start of the program.

Intervention participants had unlimited access to all of the educational content of the online modules allowing participants to complete the first 4 weeks at their own pace. Content from the modules included, but were not limited to, important topics such as postural health, mindfulness, nutrition, strength training exercises, sleep considerations, and stress management techniques. Furthermore, it included special features such as, instructional how-to videos to promote back health, provided tips for achieving success, and included quizzes to test and build knowledge. Lastly, it included weekly online support and praise that was given by email, from the health and wellness professional. It also included an online discussion forum whereby participants in the intervention group could contact the health and wellness professional at any time during the intervention regarding questions and/or comments on any of the material from the *Healthy Back and Spine Challenge*.

The discussion forum was made public, therefore anyone assigned to the challenge was able to see the comments and questions, and was able to respond or contribute to the online forum. The wellness professional response occurred in an asynchronous manner. After successful completion of the first 4 weeks of the online challenge, participants had access to the final remaining 4 weeks of the challenge which focused more on strength training and exercise programming. If completion of the first 4 weeks was not accomplished, participants could not advance or have access to the latter

content of the online challenge. Furthermore, the online challenge included strategies to help patients adopt and sustain healthy behaviors.

These strategies included components from evidence-based behavioral therapies. The Social Cognitive Theory, developed by Bandura (1953), explains the processes by which individuals learn behaviors within their environment. Concepts from this theory were used in the online challenge by promoting self-management to help individuals achieve changes and by providing them with education and positive reinforcement. The Transtheoretical Model, developed by Prochaska and DiClemente (1979), assesses an individual's readiness to change a behavior. The online challenge guides patients through the stages of change and provides strategies to encourage change. This process included goal-setting and motivational interviewing (MI) to determine if the individual was ready to change, and provided solution-focused therapies.

Motivational interviewing, as defined by Rollnick and Miller (2013), is a directive, client-centered counseling style for eliciting behavior change by helping clients to explore and resolve ambivalence. By combining these above features and providing a highly accessible intervention with in-depth feedback for participants experiencing back pain in addition to usual chiropractic care that was performed, the study explored and assessed the following areas of change: the level of improvement in components of health-related quality of life as detailed in research question three, the level of pain intensity as detailed in research question one, and the level of disability as detailed in research question two.

Comparison Group Written Material. The written material on lifestyle was derived from Internet sources, included a variety of health-related topics, and was

intended to be read by the participants in the comparison group at their own inclination. Both groups had access to this material. At the beginning of every week, health-related information was retrieved from Internet sources by the investigator and was displayed during the 8-week period. The health-related articles were displayed on the counter at the clinic. As each participant checked out, the investigator, along with other staff, asked or reminded each participant to be sure to check the health-related resource article for the week to heighten awareness of the materials. This was considered to be a more passive approach to receiving information and support about lifestyle choices for the usual care group (see Appendix E for the list of health articles).

Outcome Measures

Baseline assessments were taken at the start of the experimental study. The primary outcome that was measured was based on self-reported pain intensity. Pain intensity was assessed using the Numeric Pain Rating Scale (NPRS) at baseline, during the intermittent exam that was scheduled at 4-weeks, and then the 8-week follow-up (Ares et al., 2015; Kahl & Cleland, 2005). Participants were asked to mark a scale from 0 to 10, where a lower score indicated no pain and 10 indicated the worst imaginable pain. This scale commonly is used in clinical work and was the scale that the chiropractor used in the setting. Pain rating scales have a fundamental place in clinical practice, and evidence suggest that patients are able to use them to communicate their pain experience and their response to treatment, and is an appropriate measurement to use. This scale has been explored in research and is a reliable and valid measurement (Williamson and Hoggart, 2005).

The Oswestry Disability Index (ODI) is a self-administered, 10-item questionnaire used to assess disability (Monticone, Baiardi, Vanti, Ferrari, Pillastrini, Mugnai, & Foti, 2012). The first section rates intensity of pain and the others describe its disabling effect on typical daily activities. The score for each item ranges from 0 to 5, and the sum of 10 scores is expressed as a percentage and ranges from 0 indicating no disability to 100 indicating maximum disability. This is an important questionnaire used to measure a patient's permanent functional disability in relation to pain intensity and is considered the "gold standard" of low back functional outcome tools (Fairbank & Pynsent, 2000).

Secondary outcomes was assessed using the SF-36 general health questionnaire developed by Ware and Sherbourne, (1992). The SF- 36 assessed eight domains over the past four weeks at baseline, at 4-weeks, and again at the 8-week follow-up. The eight domains included physical functioning, bodily pain, role limitations due to physical health, role limitations due to personal or emotional health, emotional well-being, social functioning, energy/fatigue, and general health perceptions. Scores for each domain range from 0-100 with higher scores indicating a better self-reported health. Scores of participants in the intervention group were compared to scores of participants in the non-intervention group to assess statistically significant differences. The SF-36 survey was constructed to provide a comprehensive overview to measure general health concepts of each one of the domains assessed and has accumulated evidence for validity and reliability (McHorney, Ware, and Raczek, 1993). It is a useful measurement to include in establishing guidelines for each domain, and is an appropriate measurement to use across diverse groups.

Clinical observations from Dr. Stefan's clinical notes were examined and used as an additional measure to provide further insight to answer the research questions. Specifically, the following observations were noted: additional changes and improvements in physical functioning, bodily pain, role limitations for physical and emotional health, well-being, social functioning, energy/fatigue, and general health perceptions.

Data were measured for all participants at the start of the intervention (June 29, 2016), at week 4 during the intermittent exam, and at the 8-week follow-up onsite at the clinic (August 17, 2016). Outcome measures were collected by the investigator using the same scales for each time point. Outcome measures were stored in a locked file cabinet onsite at the clinic for the protection of human rights.

Potential Barriers (Limitations)

One potential barrier to the study is that some individuals in the intervention group may not have had the health literacy level regarding internet usage or proper equipment to use the intervention effectively. Gender differences also posed a barrier because there was not an equal gender balance in each group. This was due to the nature of the practice and its setting, and the fact that the clinic treated more females than males. This may affect generalizability of results when findings are disseminated. Another barrier to the study potentially occurred when the principal clinician (Dr. Stefan) was on maternity leave for 2 weeks, and the replacement clinician may have adjusted participants differently. Another barrier to the study was that the time when the intervention took place may have affected the sample size. The timeframe when the challenge was implemented was during the summer season when screening opportunities and marketing

of events for the opportunity to increase patient load was limited. The sample size potentially may have been larger if the challenge was implemented around the times when patient load was likely to increase due to the influx of new patients coming in to seek care.

Statistical Treatment

Statistical analysis was performed using the Statistical Package for Social Sciences (SPSS Inc., Chicago, IL) version 23. The variables of interest were pain intensity, disability, and improvements in physical functioning, bodily pain, role limitations for physical and emotional health, well-being, social functioning, energy/fatigue, and general health perceptions as measured from the SF-36. The Mann-Whitney U, a nonparametric test was used to assess and test statistically significant differences in disability between the intervention and control groups. In order to assess disability, the 10-item questionnaire known as the Oswestry Disability Index questionnaire was administered to the two groups. The test was used because the data that were collected did not meet the four assumptions and the guidelines required to run a parametric test (Frost, 2015). Specifically, there was a small sample size ($n=23$), the data were ordinal, and the data gathered from the Oswestry Disability questionnaire were not normally distributed. The nonparametric test was selected to determine if the level of disability improved in the group that was receiving online challenge (active treatment). This was achieved by testing for differences between two independent groups on the intervention and comparing the median scores that were collected from the assessments to find if statistical difference occurred between the two groups.

Pain intensity was assessed using the NPRS and its level of measurement was ratio. For this outcome measure it was given the independent samples t-test. An independent samples t-test was performed to examine pain intensity because the following assumptions for running a parametric test were met: the sample size was greater than 20, the data collected were not normally distributed, and the data involved a ratio level of measurement. The independent t-test was used to examine statistically significant differences between the means for the two groups.

The 8 domains of HRQOL obtained from the SF-36 were interval level data that were normally distributed and thus, an independent samples t-test was used. The eight domains of HRQOL were explored and examined to establish the significance of change between the intervention group and control group. HRQOL domains included physical functioning, bodily pain, role limitations due to physical health, role limitations due to personal or emotional health, emotional well-being, social functioning, energy/fatigue, and general health perceptions as measured by the SF-36.

CHAPTER IV

RESULTS AND DISCUSSION

Introduction

In this chapter, the results of the data analysis are presented. This pilot study explored the feasibility and evaluated the effectiveness of an online educational program, known as the *Healthy Back and Spine Challenge* used in conjunction with usual chiropractic treatment. The study was implemented at Infinity Wellness and Chiropractic, located in Plover, Wisconsin, where participants were randomly assigned to one of the two study groups: an intervention group, also referred to as the “challenge group” (group 1) and a usual care group (group 2). The purpose of the study was to identify the self-reported level of pain intensity and self-reported level of disability experienced by chiropractic patients participating in the *Healthy Back and Spine Challenge* as compared with an age and gender-matched control group during an 8-week period of time. In addition, responses from the Health-Related Quality Of Life (HRQOL) instrument were explored among the 8 domains experienced by challenge group participants in comparison with the control group over the same period of time. In this chapter, the findings and statistical techniques used to analyze the data for this pilot study are presented.

Demographic Data

Descriptive statistics were reported to illustrate the central tendency alignment for patient characteristics at baseline for both groups. The participants' mean age in the challenge group was 39.5 years, compared with 35.4 years for the usual care group. Since the sample sizes were small and the data were not normally distributed, a nonparametric test, Mann-Whitney U, was used to examine statistical significance between groups for patient characteristics (i.e., age, gender, and patient visits) at baseline. No statistically significant differences were found between groups, indicating that groups were well-matched. The p-values are listed in Table 4.1.

Table 4.1. Infinity Wellness and Chiropractic Patient Demographics, 2016

Category	Group	N	Mean	P Value
Age	1.0	10	39.500	.429
	2.0	7	35.429	.429
Sessions	1.0	10	38.200	-
	2.0	7	44.000	-
Numeric Pain Rating Scale	1.0	10	5.800	.941
	2.0	7	5.714	.943
Oswestry Questionnaire	1.0	10	13.0	.811
	2.0	7	11.43	.787
Health-Related Quality of Life	1.0	10	85.80	.583
	2.0	7	82.86	.593
Bodily Pain	1.0	10	76.00	.959
	2.0	7	75.429	.956

Notes:

The P value column was observed to examine statistical significance between groups for patient characteristics at baseline.

Group 1= Challenge Group (Group that received the *Healthy Back and Spine Challenge* in addition to usual care)

Group 2= Usual Care Group (Group that received standard chiropractic care only)

Initially, twenty-three participants were recruited for the study, but only 17 were included in the data analysis, since six participants were dropped from the study because of incomplete data. There was one participant that did not sign up for the challenge and missed multiple clinic appointments during the time the challenge took place. Two

participants had care plans that ended, and they did not schedule a follow-up appointment to continue care. One participant had a medical emergency and was unable to continue, and two other participants were absent from care at the time the doctor took a leave of absence for maternity leave, and were lost to follow-up. Therefore, ten participants were included in the challenge group (group 1), and seven participants were included in the usual care group (group 2).

Patient visits also were important characteristics to consider. The reason that the number of patient visits was included as an eligibility criterion was because newer patients come to the clinic more frequently. Care for newer patients also is more intensive compared to the long-term patients who are seen once or twice every other week, along with long-term patients who experience minimal pain, and thus are more likely to come in for wellness maintenance. Patient visits could not exceed 60 visits for the reasons stated above. The average number of patient visits per participant for the challenge group was 38 visits, and for the usual care group, the average was 44 patient visits per participant. Both groups had at least one male to allow for groups to be evenly matched by gender and age. To ensure that males were selected in each group, the names of two males were kept separate and set to the side during the random assignment of both groups. After the initial random assignment was completed, the two males were randomly placed in either the challenge group or the usual care group.

Findings

Research Question 1: What is the self-reported level of pain intensity experienced by chiropractic patients participating in the *Healthy Back and Spine Challenge* as compared with an age and gender-matched control group during an 8-week period of time?

During the 8-week intervention, data were collected simultaneously from both groups by self-report questionnaires (i.e., the Oswestry Low Back Pain questionnaire, the Health-related quality of life (SF-36) questionnaire, and the Numeric Pain Rating Scale (NPRS)) at baseline, 4 weeks, and 8 weeks. Pain intensity was assessed using the Numeric Pain Rating Scale (NPRS) at baseline, at 4-weeks, and then at an 8-week follow-up. The NPRS was used to answer Research Question 1. A Wilcoxon Signed-Rank Test revealed that the challenge group had statistically significant differences of change within the group when observing the means for level of pain intensity for all three time points: from baseline to week 4 ($p = .005$), week 4 to week 8 ($p = 0.048$), and baseline to week 8 ($p = 0.005$). For the usual care group, statistically significant differences of change within the group were found only at 2 specific time points when observing the average scores for pain intensity, baseline to week 4 ($p = 0.018$) and baseline to week 8 ($p = 0.018$) (see Table 4.2).

Table 4.2. Observing the within-group Mean Scores and Significance Values from the Self-Reported Numeric Pain Rating Scale Ratings, 2016

Time Interval	Group	N	Mean	P Value
Baseline to 4 weeks	1.0	10	5.800	.005*
	2.0	7	5.714	.018*
4 weeks to 8 weeks	1.0	10	2.650	0.048*
	2.0	7	1.429	0.785
Baseline to 8 weeks	1.0	10	.900	0.005*
	2.0	7	1.357	0.018*

Notes:

The mean column was observed and its associated significance level (the p value column) for both independent groups to test for statistically significant differences within groups.

* $p \leq 0.05$ level of significance

Group 1= Challenge Group (Group that received the *Healthy Back and Spine Challenge* in addition to usual care)

Group 2= Usual Care Group (Group that received standard chiropractic care only)

There were no statistically significant differences of change from week 4 to week 8 ($p = 0.785$) in the usual care group, since the change in the average score for pain intensity remained minimal. When observing the reduction in pain intensity during the duration of the study, results revealed that both groups experienced self-reported levels of reduction in pain intensity from baseline to week 8 (see Figure 4.1).

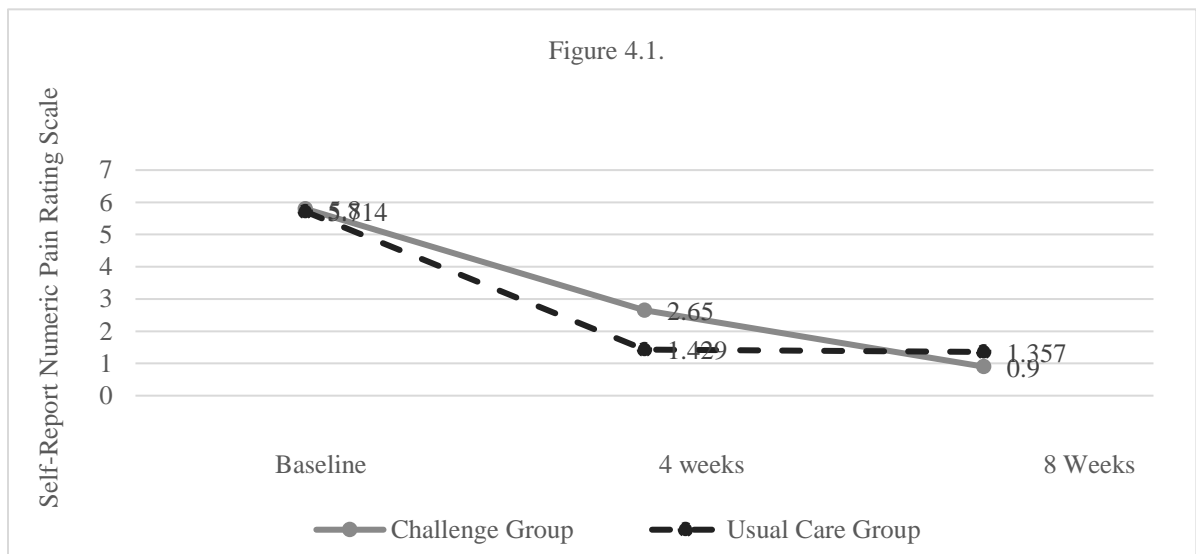


Figure 4.1. Measuring Level of Pain Intensity During an 8-Week Period for 2 Independent Groups Using Self-Report Numeric Pain Rating Scale (NPRS), 2016.

To test for differences between the two independent groups (i.e., pain intensity), a Mann-Whitney U test revealed no statistically significant difference in the means of change between groups for pain intensity at week 8 ($p = 0.669$). Both groups received the same chiropractic treatment which is much more hands-on and likely played a large role on pain reduction as compared to the Challenge program itself. For example, participants in the online challenge were asked to complete an evaluation survey. There were six participants out of the 10 who participated in the challenge who responded that they developed new skills in their ability to practice healthy behaviors, and also reported either a lot or some motivation to adopt new lifestyles.

Research Question 2: What is the self-reported level of disability experienced by chiropractic patients participating in the *Healthy Back and Spine Challenge* as compared with an age and gender-matched control group during an 8-week period of time?

The Oswestry low back pain questionnaire was used to answer Research Question 2. Due to the low sample size and given that the data were not normally distributed, non-parametric tests needed to be used.

To test for differences between the two independent groups, a Mann-Whitney U Test revealed no statistically significant difference in the means of change between groups for low back pain as measured by the Oswestry Low Back Pain questionnaire at week 8 ($p = 0.669$). A Wilcoxon Signed-Rank test was used to analyze the mean changes for low back pain disability within each group between the three specific time points (baseline to week 4, week 4 to week 8, and baseline to week 8). The baseline measure for

low back pain disability for the challenge group was ($M = 13.40$) and the baseline measure for the usual care group was ($M = 11.43$).

The results from the Wilcoxon Signed-Rank Test indicated that both groups exhibited a significant reduction in low back pain disability from baseline to week 4 ($p = .0018$ for the challenge group, and $p = .0017$ for the usual care group) and from baseline to week 8 ($p = 0.017$ for the challenge group, and $p = 0.017$ for the usual care group; see Table 4.3). The self-reported level of low back pain disability also decreased in the 8-week time for both groups (see Figure 4.2).

Table 4.3. Observing the within-group Mean Scores and the Significance Values from the Self-Reported Oswestry Disability Index (ODI) Ratings, 2016

Time Interval	Group	N	Mean	P Value
Baseline to 4 weeks	1.0	10	13.40	0.018*
	2.0	7	11.43	0.017*
4 weeks to 8 weeks	1.0	10	6.40	0.161
	2.0	7	5.14	0.891
Baseline to 8 weeks	1.0	10	3.20	0.017*
	2.0	7	5.14	0.017*

Notes:

The mean column was observed and its associated significance level (the p value column) for both independent group to test for statistically significant differences within groups.

* $p \leq 0.05$ level of significance

Group 1= Challenge Group (Group that received the *Healthy Back and Spine Challenge* in addition to usual care)

Group 2= Usual Care Group (Group that received standard chiropractic care only)

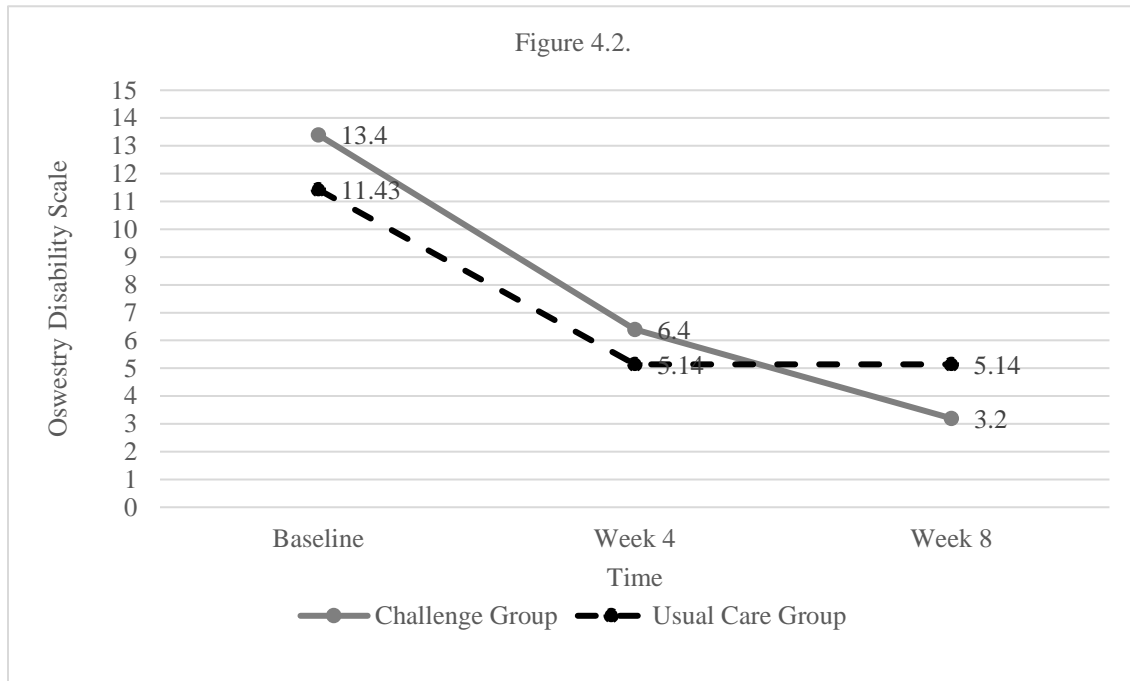


Figure 4.2. Measuring Level of Low Back Pain Disability During an 8-week Period for 2 Independent Groups Using Self-Reported Oswestry Disability Index (ODI) Questionnaire, 2016.

In addition, both the challenge group and the usual care group did not have statistically significant differences from week 4 to week 8, which is illustrated in Table 4.3. Interestingly, nearly the same significant value was observed by the investigator for both groups from baseline to week 4, and the same significant value was observed from baseline to week 8 where the results revealed statistically significant differences, and reductions of low back pain disability occurred for both groups (see Table 4.3).

Research Question 3: What is the Health-Related Quality Of Life experienced by chiropractic patients participating in the *Healthy Back and Spine Challenge* as compared with an age and gender-matched control group during an 8-week period of time?

Analyses were performed to explore and answer Research Question 3. An independent samples t-test was used to compare the mean score for two independent

groups to test whether there were statistically significant differences in the mean scores between the two groups. The independent samples t-test assumes that a difference in the mean score from all three assessments (i.e., NPRS, ODI Questionnaire, and SF-36) would occur in one of the two independent groups because of the influence of the independent variable, in this case the online challenge group. This test along with the Mann-Whitney U test were included in the analysis to determine if that occurred. There were no statistically significant differences in the change between groups for the 7 domains assessed, except one domain, “bodily pain” revealed statistical significance for both independent groups. A Mann-Whitney U test was used to examine any differences between the two independent groups, and revealed no statistically significant differences between group changes for bodily pain at week 8 ($p = .740$). Both of these tests were used to clarify differences between groups and both were run to ensure accuracy.

Results from a Wilcoxon Signed-Rank Test revealed that only the usual care group had a statistically significant difference in the self-reported average of the scores for bodily pain as measured by the SF-36 questionnaire that occurred within the group from baseline to week 4 ($p = 0.026$). In addition, both groups demonstrated statistically significant differences of change within groups when observing the means for bodily pain at one specific time point--baseline to week 8 ($p = 0.028$ for the challenge group, $p = 0.039$ for the usual care group, see Table 4.4). Both groups by the end of 8 weeks, reported improvements in bodily pain in the 8-week timeframe, and reported almost the same percentage for bodily pain by the end of 8 weeks (see Figure 4.3.).

Table 4.4. Observing the within-group Mean Scores and the Significance Values from the Self-Reported Health-Related Quality of Life (HRQOL) Ratings for Bodily Pain, 2016

Time Interval	Group	N	Mean	P Value
Baseline to 4 weeks	1.0	10	76.000	0.196
	2.0	7	75.429	0.026*
4 weeks to 8 weeks	1.0	10	79.700	0.206
	2.0	7	84.857	0.461
Baseline to 8 weeks	1.0	10	87.400	0.028*
	2.0	7	88.000	0.039*

Notes:

The mean column was observed and its associated significance level (the p value column) for both independent group to test for statistically significant differences within groups.

* $p \leq 0.05$ level of significance

Group 1= Challenge Group (Group that received the *Healthy Back and Spine Challenge* in addition to usual care)

Group 2= Usual Care Group (Group that received standard chiropractic care only)

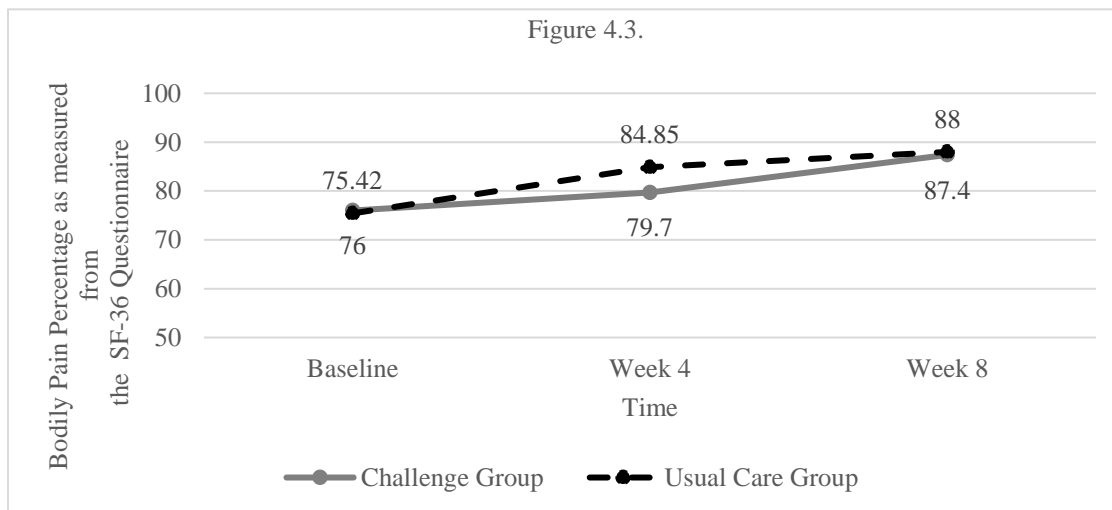


Figure 4.3. Measuring Bodily Pain During an 8-week Period for 2 Independent Groups Using the Self-Report Short Form-36 Questionnaire, 2016.

Both groups received the same chiropractic care which indicates that the care alone provided to patients, such as exercises to rehabilitate the spine, the spinal adjustments, and traction might have led to the self-reported decreases in bodily pain.

Discussion

Overall, while not completely consistent, the participants receiving the online program *Healthy Back and Spine Challenge* did not report better outcomes or outperform the usual care group in the outcomes that were studied, which included pain intensity,

low back pain disability, and general health-related quality of life. There were no statistically significant differences in the changes between groups for all three outcomes studied, but some statistically significant findings occurred within each group for all three outcomes for both groups at specific time points.

For pain intensity, as measured by the Numeric Pain Rating Scale, there was no statistically significant difference in the means of change between groups at week 8 ($p = 0.669$). There were statistically significant differences of change within both groups that occurred at specific time points. Within the challenge group, statistically significant findings of pain reduction were found from baseline to week 4 ($p = 0.05$), week 4 to week 8 ($p = 0.048$), and from baseline to week 8 ($p = 0.005$). For the usual care group, statistically significant findings of pain reduction were found from baseline to week 4 ($p = 0.018$) and from baseline to week 8 ($p = 0.018$), but not from week 4 to week 8 ($p = 0.785$). Of interest, results revealed statistically significant differences for pain intensity that occurred within group changes from week 4 to week 8 for the challenge group compared to the usual care group which did not have statistically significant findings. Although the distinction is small, and significant findings were found in all 3 time points for the challenge group only, for this specific outcome, assessing other outcomes (such as motivation, readiness to change, and self-efficacy) that align directly with the *Healthy Back and Spine Challenge* could be of value.

For low back pain disability, there were no statistically significant differences in the means of change between groups at 8 weeks ($p = 0.669$). Additional findings indicate that there were significant differences within groups for both groups for low back pain disability during specific time points, and that both groups exhibited a significant

reduction in low back pain disability from baseline to week 4, and from baseline to week 8 ($p = .0018$ for the challenge group, and $p = .0017$ for the usual care group). The self-reported level of low back pain disability also reduced in the 8-week period for both groups. These findings implied that patients receiving chiropractic care in addition to receiving the online intervention did not show a statistically significant decreased effect on low back pain disability when compared to the group receiving standard care only. A potential factor playing a role in assessing the reduction of low back pain may have been the assessment process used for this outcome in this study which primarily focused on one body site (i.e., back pain) versus several other body sites (e.g., neck pain and/or headaches). Another factor may be that the online challenge was not substantial enough to bring about change, but may be useful to provide as a supplementary tool.

Since the results revealed that both groups had nearly the same or exact statistically-significant values from baseline to week 4 and baseline to week 8, and both groups did not show any significant differences that occurred from week 4 to week 8, these findings might be indicative of the assessment not being the most complete assessment, due to this consistency across all three time points. These findings also may have been impacted by the possibility that the self-report Oswestry questionnaire may not have been the appropriate measurement to use in terms of assessment sensitivity. For example, both groups of patients did not report high levels of functional disability throughout the intervention. To establish any statistically significant change for this outcome would be difficult to quantify with scores being on the low end from the beginning of the study along with the small sample size. The following considerations were noted by the investigator: a) there was a similarity of comments that were offered

by both groups; b) there was a small sample size; c) there was a relatively short intervention time (8 weeks); and d) the data were self-reported (i.e., The data were based on self-reported responses and the similarity of comments being reported from both groups about the assessments being more comprehensive, and not being limited to only back pain, may indicate that these assessments may not be an accurate measure for the outcomes studied), and e) most importantly, Dr. Stefan's usual treatment modality during the study was comprehensive in nature. Dr. Stefan's treatment included education, suggested exercise prescription and rehabilitation exercises performed at the office, exercise demonstrations provided at the clinic by staff, and workshops and seminars that were available on a quarterly basis at the clinic. These treatment components all might have impacted the assessed outcomes.

Findings from the general health-related quality of life assessment revealed that there were no statistically significant differences in the 7 domains of general health between groups at week 8 ($p = .740$). Findings revealed that both groups had statistically significant differences of change within groups for bodily pain as measured by the SF-36, from baseline to week 8 ($p = 0.028$ for the challenge group, $p = 0.039$ for the usual care group). Bodily pain was one of the 8 domains assessed by the Health-Related Quality Of Life instrument. The usual care group only had statistically significant differences of change from baseline to week 4 ($p = 0.026$). By the end of 8 weeks, both groups reported almost the same percentage for bodily pain. The average was 88.0 for the usual care group, and 87.4 for the challenge group.

Overall, the findings revealed that the changes in the means within each group were small, and since both groups received the same high level of chiropractic care, the

online challenge did not appear to enhance or have an impact on improving other general health domains compared to standard care only given the similarity of self-reported commentary regarding bodily pain. One factor that may lead to improvements in bodily pain, as measured by the SF-36, may be the care the participants received from the clinic. The data demonstrated that the usual care group had statistically significant differences at two time points compared to the challenge group data that revealed statistically significant differences only from one specific time point, baseline to week 8. Since both groups were receiving the same high level of chiropractic care from the clinician and groups of staff, these findings indicated that the care being delivered from this clinic was comprehensive for these participants.

CHAPTER V

CONCLUSIONS AND RECOMMENDATIONS

Summary

In this chapter, the summary of the thesis research conclusions, along with recommendations for future actions are discussed. A double-blind experimental pilot study was conducted for the purpose of determining the effectiveness of the online educational program, the *Healthy Back and Spine Challenge*, as a treatment adjuvant to usual care. The overall purpose of the study was to compare self-reported levels of change related to three specific outcomes on an intervention group, referred to as the “challenge group” (group 1) and a “usual care group” (group 2). Both groups were matched in accordance with gender and age. The three outcomes studied were pain intensity, low back pain disability, and overall health-related quality of life. There were three questionnaires that served as the instrumentation for data collection, with 17 participants from the sample of the patient population who served as study respondents. The newly-developed online educational challenge program was used as a supplementary approach in addition to usual chiropractic treatment, as implemented at the Infinity Wellness and Chiropractic Clinic in Plover, Wisconsin. A pilot study was conducted to assess the degree to which the online self-management program offered in conjunction

with usual chiropractic treatment could serve as a therapeutic adjuvant in enhancing patient health status as measured by the three study assessments.

Conclusions were derived from clusters of findings emerging from the comparison of mean differences of patient scores for self-reported levels of pain intensity, lower back pain disability, and health-related quality of life, at three points in time. These assessments included the Numeric Pain Rating Scale (NPRS), which assessed pain intensity, the Oswestry Disability Index (ODI), which assessed low back pain disability, and the SF-36 General Health-Related Quality of Life assessment, which assessed 8 domains for quality of life.

Conclusions

Conclusion 1

Overall, pain intensity decreased during the 8-week time period in both the challenge and the usual care groups in a similar manner. For self-reported levels of pain intensity, both groups' reduction in change decreased and small differences from baseline to week 8 occurred within the two groups. The findings cited for pain intensity revealed the *Healthy Back and Spine Challenge* used as an adjuvant to chiropractic treatment did not appear to enhance or strengthen this health outcome compared to the group receiving usual care only. However, it was observed from the findings that pain intensity within group reductions occurred more in the challenge group compared to the usual care group for reasons that are unknown and were not further explored by the investigator.

Conclusion 2

Overall, both groups' self-reported levels of low back pain disability reduced during the 8-week time period, and reductions appeared consistent across all 3 time

points for both groups. The mean scores demonstrated that the health status among the participants involved in this study improved during the 8-week time period for both groups, but of greater interest are the consistencies that were found across all time points for both groups from the self-reported low back pain questionnaire. The consistencies in the responses to the low back pain questionnaire for both groups were not further explored by the investigator.

Conclusion 3

Overall, across the eight domains evaluated for general health, both groups demonstrated improvements for “bodily pain” only during the 8-week time period in a similar manner. For health-related quality of life, the self-reported average scores for bodily pain were observed for groups and the similarities of self-reported scores between all-time points were discovered. These findings indicated that the clinic delivered high levels of comprehensive care for the participants, and the procedures and standard of care received from this clinic might have led to decreases in bodily pain, but the reasons are unknown and were not explored by the investigator in this study.

Conclusion 4

Specifically, there was a small sample size, the timeline of the intervention, and the collection of self-reported data may have impacted the results. The results from the pilot study cannot be generalized to the entire patient population because the sample was not fully representative of the total patient population. The length of the intervention may not have been a sufficient timeframe. The investigator conducted the pilot study and chose the sample from one chiropractic clinic in a specific location where a large representative sampling frame was not possible during the study timeframe.

Recommendations

The following recommendations for future actions are in alignment with each one of the above-mentioned conclusions.

Recommendation 1. There is a need to conduct further studies of the behavioral outcomes in alignment with the online program along with pain intensity.

The outcomes selected for this research study may not have been the most appropriate outcomes to examine in conjunction with the online program. Since the *Healthy Back and Spine Challenge* was a program to facilitate adoption of healthy behaviors, future studies assessing other outcomes such as patient motivation, knowledge, and readiness to change in addition to pain intensity would be further encouraged in order to identify if behavioral components such as these were impacted to a greater extent in the group receiving the online challenge in addition to usual care. It also would be of importance to identify if those behavioral outcomes, such as patient motivation, knowledge, or readiness to change had an impact in the reduction for level of pain intensity. Overall, no specific behavioral components were analyzed for this research study.

Also, examining other outcomes related to an individual's belief, such as self-efficacy and exploring other constructs from theoretical frameworks, such as the Health Belief Model (HBM) is encouraged. Utilizing recognized health-related theories would assist in identifying one's personal beliefs and perceptions regarding health status, thus providing further insights into changing human behavior. The HBM is a widely used psychotherapy approach that is used for health behavior research, and could be used as a guide for examining behavior change interventions (Glanz, Rimer, & Viswanath, 2008).

Utilizing health education theories such as these could allow for a better understanding of additional impactors, and might provide effective strategies to sustain behavior change over time.

Recommendation 2. Utilizing a more comprehensive assessment that measures various body sites and provides insights to other symptomatic complaints is recommended.

Using a comprehensive assessment that measures additional symptomatic outcomes, along with low back pain disability, such as neck pain, and/or headaches, is recommended. Usually, people seeking care at chiropractic clinics often have other complaints in addition to experiencing back pain, and a more comprehensive assessment would be necessary for more in-depth evaluation. The assessment used for this study only focused on one type of pain-low back pain. The Oswestry questionnaire may not have been the most appropriate measurement to use because it relates to only one body site, limiting insights into other symptoms. In addition, the similarity of written commentary from the two study groups regarding the one-site specificity noted by the investigator from the participants during the study needs to be taken into consideration for future research.

Recommendation 3. Patient educational resources along with comprehensive care may have improved health-related quality of life (HRQOL) domains.

The results of this study may indicate that the standard of care and treatment alone provided at Infinity Wellness and Chiropractic led to improvements in the areas assessed for health-related quality of life for patients. Also, this study included additional resources for patient education regarding health promotion recommendations on lifestyle behaviors and spine health. This consideration may imply that offering comprehensive

treatment or health promotion activities and engaging patients with health education resources may further impact domains related to health-related quality of life (HRQOL).

Patient educational resources is important because it allows patients to engage in additional resources that are provided. Information that was provided in the challenge group were also brought out in the patient educational materials that were given to all patients at the clinic. It was important to include patient educational resources in this study for the purpose of maintaining usual clinical practice, and to also address the importance of patients having access to health educational materials.

Recommendation 4. If this study is replicated in the future, strengthening the study design (e.g., establishing a fully representative sample) for the purpose that findings of the future study could be generalized to the patient population.

Lastly, a key limitation resulting from this pilot study may have been the study design. Two elements of the study design may have impacted the study and those elements were the sample size, self-reported data, and having a fully representative sample. The pilot study consisted of a small sample size from the patient population and the results cannot be generalized to the entire population because the sample was not representative of the population. Collecting a larger representative random sample from other chiropractic clinics is suggested. Also, the data collected were self-reported. One disadvantage with self-reported data solely is that responses vary and are subjective. Incorporating more objectivity into the study design is recommended. This could be achieved by adding in clinical observations from the chiropractor and/or staff. Clinical observations or clinical notes from the chiropractor and/or staff observing patients' behavior and recording improvements in their diagnoses as an example. Also, adding in

clinical assessments to bring more objectivity into the study design is recommended. An example of this is including physical examinations, or other clinical examinations that further explores the body of a patient for signs of complaints.

The timeframe for the intervention took place over 8-weeks. This timeline may not have provided a sufficient amount of time to facilitate change related to the outcomes studied, and/or for future studies that are testing health outcomes related to behaviors. Lastly, since this online program was focused on providing behavior change strategies, keeping the clinician not blind would be recommended, or having a health educator available. This is recommended for the reason that the clinician or health educator could be used as an adjuvant to the online challenge, and bring more interaction and connectivity to the program. Health educators could play a vital role to the delivery of the program because when involved, they can be more aware of the experiences that the participants had and understand the feelings that were felt when the online challenge took place. They could also serve as a liaison to follow-up with participants, which may assist with accountability for participants to ensure that participants are staying engaged during the entire time the online challenge is taking place.

Lastly, including a process evaluation to further determine the online program strengths and weaknesses. This may allow for better understanding of the elements included in the program that may need to be strengthened or improved. A process evaluation can also allow more participant involvement and provide opportunities for them to share their feelings and experiences of how they felt the challenge went and the impact it may or may not have had.

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APPENNDIX A
RECRUITMENT SCRIPT

RECRUITMENT SCRIPT

Hello, (insert name). In addition to my work here at Infinity Clinic, I am a graduate student at the University of Wisconsin-La Crosse focusing on Community Health Education. At Infinity, we are always seeking ways to encourage and further support you in your efforts in becoming the healthiest person you can be. The project I am involved in is designed to foster a healthier lifestyle. May I speak with you in more detail about our optional upcoming efforts to assist you?

- Over the next two months, we will be attempting to discover the best methods of providing additional support for our patients to practice healthier lifestyles.
- In order to make the most objective assessments, we will be randomly assigning those who agree to be involved in the project into one of two groups. Both groups will receive some support for healthy lifestyles while we continue to provide our usual high-quality clinical care.
- For objectivity, we in the clinic setting will not know which of the additional methods of support those who participate will receive.
- For this project, the additional methods of support will be provided by the Wellness Professors, LLC.
- Brief assessments will be sent to the participants during the 8-week period.

The reason for offering these options is to assist you in building a healthier lifestyle along with preventing back-pain related conditions from reoccurring. Does this sound like something you would be interested in doing? (Response from participant) Great! Here is the informed consent form that provides more detailed information about the program and your signature for participating. Thank you for your involvement and being a part of this project. We will be in further communication with you shortly.

APPENDIX B

NUMERIC PAIN RATING SCALE

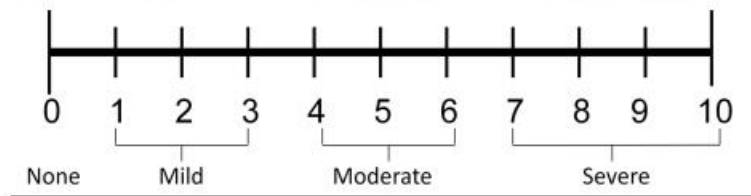
The Numeric Pain Rating Scale Instructions

General Information:

- The patient is asked to make three pain ratings, corresponding to current, best and worst pain experienced over the past 24 hours.
- The average of the 3 ratings was used to represent the patient's level of pain over the previous 24 hours.

Patient Instructions (adopted from (McCaffery, Beebe et al. 1989):

"Please indicate the intensity of current, best, and worst pain levels over the past 24 hours on a scale of 0 (no pain) to 10 (worst pain imaginable)"



Reference:

McCaffery, M., Beebe, A., et al. (1989). Pain: Clinical manual for nursing practice, Mosby St. Louis, MO.

APPENDIX C
INFORMED CONSENT GUIDELINES

Informed Consent Guidelines

Title: Study Protocol: *Healthy back and Spine Challenge*: Impact of an online, applied educational program on Health-Related Quality of Life (HRQOL) in patients receiving chiropractic care.

Researcher: Lindsay H. Worley
Masters of Public Health, UW-La Crosse
1725 State St, La Crosse, WI 54601
(307)575-1044
worley.lind@uwlax.edu

Emergency Contact: Lindsay H. Worley
(307) 575-1044

- 1. Introduction Purpose/Procedure of Research:** Dear potential participant. You are being asked to participate in a research study to explore the feasibility of testing the effectiveness of an online-applied educational program, known as *Healthy Back and Spine Challenge*. The online program was designed to cultivate self-management skills with applied education from wellness professionals to prevent the onset of back pain and spine-related conditions, as well as promote a holistic approach in encouraging healthier lifestyle-related behaviors. The challenge will be implemented in a clinical setting, in conjunction with chiropractic care to investigate and compare differences among two study groups: an intervention group and a control group. Data will be analyzed to determine if the online-educational program aids in improving pain intensity and disability outcomes as well as identify if greater improvements are made in physical functioning, bodily pain, role limitations due to physical health, and role limitations due to personal or emotional health, emotional well-being, social functioning, energy/fatigue, and general health perceptions, compared to the control group that will be receiving chiropractic care only. Study participants' are

drawn from only patients that are seeking care at Infinity Wellness and Chiropractic, in Plover, Wisconsin. Back pain in general is becoming a public health problem and back pain and the reoccurrence of back pain problems still continue. There is a need to take a broader view in the management of back pain and further understand the value of self-management interventions and need to be considered, to assist in managing and preventing the rising prevalence of back pain, to improve overall quality of life.

- 2. Risks and discomforts to you if you take part in this study:** Your participation in the study will put you at no greater risk. For participants' in the experimental group, we ask only of your time to participate in the online-applied educational challenge and be fully engaged in the learning modules and complete self-report surveys honestly.
- 3. The benefits to you of taking part in this study:** The benefits for participating in the study as a result of regular and consistent participation is an increase in knowledge regarding health-related activities and discover strategies that will aid in the prevention of back pain. It may also help adopt and sustain healthy behaviors that aid in improving quality of life and health and well-being. Professional feedback and support will be given throughout the challenge to answer questions or concerns.
- 4. Alternate Procedures:** No alternate procedure will take place for this study.
- 5. Specific things you should understand about confidentiality:** All the information gathered for the study, including the results from assessments will be kept confidential with regard to individual identity. A random number will be

assigned to you at the beginning of the study and only that number will be used for collecting data. All data will be collected by the investigator and data will be kept in a secure location onsite at the clinic in a locked file cabinet. Data will then be destroyed once the study is complete and published. Participants' will be randomly assigned to either the control group (usual chiropractic care) or the experimental group (online challenge) by a health and wellness professional, who is the Program Developer of the online challenge, and is an Academic Professor in the College of Professional Studies (CPS) at the University of Wisconsin, Stevens Point (UWSP). Information regarding which participants' were in which group, will be concealed from the investigator and the chiropractor who is performing the services.

- 6. What to do if you decide you want to withdraw from the study:** You may withdraw from the study at any time and your participation in this study is completely voluntarily. No penalties will be assigned towards you if you discontinue participation at any time. However, if you decide to leave the study, please let the Program Developer of the online challenge know. You are not giving up any legal rights by signing this consent document and taking part of this research study. If you have questions regarding the rights as a research participant, the following person may be contacted: Dr. Gary Gilmore, Professor and Director of Graduate Community Health/Public Health Programs, University of Wisconsin, La Crosse, (608) 785-8163.

7. **What are the costs and payments for taking part in this study:** There will be no additional costs or payments involved in this research study. You will not be paid to participate in the research study.
8. **Thank you for your time and consideration of this request and for your interest in this study.**

Investigators:
Lindsay H. Worley
worl.lind@uwlax.edu
Masters of Public Health- UW La Crosse, WI
Department of Public Health
(307)575-1044

I give my consent to participate in the research project entitled: “*Healthy back and Spine Challenge: Impact of an online, applied educational program on Health-Related Quality of Life (HRQOL) in patients receiving chiropractic care*”. The researcher has discussed the research project with me and I have read the description of the project. I have also had a chance to ask any questions about the study and they have been answered to my satisfaction. I understand that I will receive a copy of this consent form to keep for my future references.

Participant’s Name Printed

Participant’s Signature

Date

APPENDIX D

STUDY PARTICIPANTS CODED AND MATCHED

Study Participants Coded and Matched

A	B	C	D	E
number	email	Gender	Age	Match
5		F	25	4
4		F	26	5
1		F	28	16
2		F	46	3
3		F	50	2
6		F	40	10
7		F	51	14
9		F	33	8
8		F	34	9
15		F	25	21
23		M	35	
12		F	43	20
17		F	31	13
14		F	54	7
18		M	27	11
19		F	57	22
20		F	46	12
16		F	26	1
11		M	32	18
22		F	55	19
21		F	29	15
10		F	36	6
13		F	34	17

APPENDIX E
HEALTH ARTICLES AT THE CLINIC AVAILABLE
TO ALL STUDY PARTICIPANTS

Health Articles at the Clinic Available to all Study Participants

HEALTH ARTICLES

1. Junk Food and Junk Science
2. The Danger of Muscle Imbalances and the Importance of Symmetry
3. Do You Really Believe You Can Change?
4. Cultivating Health During Crisis
5. Exercise Can Lower Your Risk of a Dozen Cancers by 20 Percent
6. Squats Are a Great Daily Exercise for People of All Ages
7. You Are Not Your Illness: Do Not Become Your Aches and Pains
8. Expert Answers: Safe Rotational Exercise

APPENDIX F

EMAIL TEMPLATE FOR ASSIGNED GROUP ALLOCATION

Email Template for Assigned Group Allocation

Research Participant,

Thanks for agreeing to participate in Lindsay Worley's masters thesis study with Dr. Sara Stefan and myself, Dr. Corey Huck. This study will assess the impact of an online, applied educational program on health-related quality of life with patients receiving chiropractic care. The online educational program titled, "The Healthy Back and Spine Challenge," was recently developed by a newly emerging company called, Wellness Professors LLC.

All participants were given a code number, were matched by gender and age, and then randomly assigned into the online challenge group or the usual care group.

YOU are number:1 and were assigned into the: usual care group.

This means you will continue your chiropractic care with Dr. Sara Stefan as usual, and you will not be asked to do any additional tasks or requirements for the entire duration of the study (8 weeks).

When your participation in this study is completed and all data has been collected, you will receive complimentary (free) access to the online challenge (Healthy Back and Spine Challenge)! Until then, try to live your life as you normally do.

Please do not tell Dr. Sara or Lindsay which group you are in or how the challenge is going... they are both to remain blinded throughout the duration of the study.

If you ever have ANY questions or concerns during or after the study, please don't hesitate to contact me. My e-mail address and cell phone number are listed below.

Thanks again,

-Corey
[\(715\) 570-5204](tel:(715)570-5204)
Corey@WellnessProfessors.com

Research Participant,

Thanks for agreeing to participate in Lindsay Worley's masters thesis study with Dr. Sara Stefan and myself, Dr. Corey Huck. This study will assess the impact of an online, applied educational program on health-related quality of life with patients receiving chiropractic care. The online educational program titled, "The Healthy Back and Spine Challenge," was recently developed by a newly emerging company called, Wellness Professors LLC.

All participants were given a code number, were matched by gender and age, and then randomly assigned into the online challenge group or the usual care group.

YOU are number:1 and were assigned into the: online challenge group.

This means you will continue your chiropractic care with Dr. Sara Stefan as usual, plus you will be invited (highly encouraged) to complete the online challenge, "Healthy Back and Spine Challenge."

You will receive an e-mail (from me) later this week with instructions on how to get signed up for the challenge.

Please do not tell Dr. Sara or Lindsay which group you are in or how the challenge is going... they are both to remain blinded throughout the duration of the study.

If you ever have ANY questions or concerns during the challenge, please don't hesitate to contact me. My e-mail address and cell phone number are listed below.

Thanks again,

-Corey
[\(715\) 570-5204](tel:7155705204)
Corey@WellnessProfessors.com

APPENDIX G

EMAIL INSTRUCTION FOR *HEALTHY BACK AND SPINE CHALLENGE*

Email Instruction for *Healthy Back and Spine Challenge*

Research Participant,

Thanks for agreeing to participate in Lindsay Worley's ~~masters~~ thesis study with Dr. Sara Stefan and myself, Dr. Corey Huck. This study will assess the impact of an online, applied educational program on health-related quality of life with patients receiving chiropractic care. The online educational program titled, "The Healthy Back and Spine Challenge," was recently developed by a newly emerging company called, Wellness Professors LLC.

All participants were given a code number, were matched by gender and age, and then randomly assigned into the online challenge group or the usual care group.

You are research participant number 2 and in the online challenge group. I signed you up for the Wellness Professors website under that code name. Now you need to log-in and enroll in the Healthy Back and Spine Challenge. Don't worry, it's really easy!

Steps:

- 1) Go the website: www.wellnessprofessors.com
- 2) Click on the Log-in button (upper right side of your screen)
- 3) Enter you log-in information

Your email address: [XXXXXXXXXXXXXXXXXX](#)

Your temporary password: gethealthy2016

4) ~~click~~ on the Healthy Back and Spine Challenge and enroll.

5) ~~follow~~ online instructions to move through the challenge.

The study duration for the total challenge is 8 weeks. You will receive access to the last two components of the challenge after 4 weeks, so please complete what you can in the first 4 weeks.

Please remember not to tell Lindsay or Dr. Sara that you are in the challenge, they are to remain blinded throughout the study.

Again, let me know if you have any questions or concerns!

Thanks for participating and enjoy!

To confirm that you received and understand this message, please reply "ok."

Corey Huck, PhD, CSCS
Owner / Chief Wellness Prof
Wellness Professors LLC
c: [XXX-XXX-XXXX](tel:XXX-XXX-XXXX)
www.wellnessprofessors.com
wellnessprofessors@gmail.com