THESIS

YOGA IMPROVES FUNCTIONAL GAIT AND HEALTH-RELATED QUALITY OF LIFE FOR ADULTS WITH DIABETIC PERIPHERAL NEUROPATHY: A PILOT STUDY

Submitted by

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In partial fulfillment of the requirements

For the Degree of Master of Science

Colorado State University

Fort Collins, Colorado

Summer 2015

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ABSTRACT

YOGA IMPROVES FUNCTIONAL GAIT AND HEALTH-RELATED QUALITY OF LIFE FOR ADULTS WITH DIABETIC PERIPHERAL NEUROPATHY: A PILOT STUDY

The object of this non-controlled pretest-posttest pilot study was to determine whether health-related quality of life (HRQOL) and functional gait improved after an eight-week yoga intervention among individuals with diabetic peripheral neuropathy (DPN), and whether HRQOL and functional gait were correlated in this sample of people with DPN.

This study was conducted at Colorado State University's Integrative Rehabilitation Lab. It included a sample of 15 participants with DPN, over the age of 18, recruited from Fort Collins and neighboring towns, who had self-reported having balance impairments. Each participant took part in an eight-week yoga intervention that met twice per week for one hour each session. Yoga sessions included physical postures, breathing exercises, and meditation. The yoga was modified for individuals with DPN and included seated, standing, and exercises laying on the floor.

The Neuro-QoL was used to assess HRQOL. Functional gait assessments included the Six-Minute Walk Test (6MWT), conducted to examine walking endurance, and the 10-Meter Walk Test to evaluate walking speed.

HRQOL and functional gait showed a fair correlation (6MWT, $r=0.487$; 10-Meter Walk Test, $r=0.420$). HRQOL improved by 8%. Both components of functional gait improved significantly, walking endurance by 15% ($p=0.014$) and walking speed by 23% ($p<0.001$).

The results demonstrate that yoga is a potential intervention to promote positive improvements in HRQOL and functional gait, including both walking speed and walking endurance, in individuals with DPN. Rehabilitation and medical professionals may consider this as a modality for helping individuals manage their DPN.

ACKNOWLEDGEMENTS

First and foremost, I would like to thank Dr. Arlene Schmid for her encouragement, guidance, and backing throughout the entire progression of my thesis. Thank you, Arlene, for introducing me to the incredible world of research and teaching me that research is fun. Secondly, I would like to thank Leslie Willis, for her partnership in this study and thesis process. Leslie's insight and feedback has helped me to refine my thesis to its current state. I would also like to thank Dr. Pat Sample and Dr. Brian Tracy, my committee members, for the direction and advice they gave me in the writing process. Additionally, I would like to thank the College of Health and Human Sciences Mini-Grant Program for providing the funding that sustained the Less Neuropathy After Yoga (LeNY) study. Assistance was provided for the yoga sessions and assessments by Dave Colangelo, Ruby Bolster, Katie Hinsey, and Carol Chop. I would also like to thank all the participants of the study who committed to the eight-weeks of yoga. Finally, I would like to thank my family and friends who gave me the encouragement to persist in the thesis process. Thank you to Anne, Ken, and Connor Phillips for your enduring backing and reassurance. Thank you to Alex Muntefering, Coach Scott Dahlberg, and Coach Art Siemers for your unparalleled support during my experience at Colorado State University that culminated in the completion of my thesis.

DEDICATION

To my beloved Grandpa Bryan Harry,

whose love of learning and former thesis

work at Colorado A&M inspired me to pursue a thesis

on the same college grounds. Thank you for your

overwhelming love, support, and belief in me.

I am forever grateful.

TABLE OF CONTENTS

LIST OF ABBREVIATIONS

CSU	Colorado State University
DM	Diabetes Mellitus
DPN	Diabetic Peripheral Neuropathy
HRQOL	Health-Related Quality of Life
ICF	International Classification of Functioning, Disability, and Health
MNSI	Michigan Neuropathy Screening Instrument
m/s	Meters per second
SPSS	Statistical Package for the Social Sciences
QoL	Quality of Life
6MWT	Six-Minute Walk Test

CHAPTER 1: INTRODUCTION

Purpose

The purpose of this study was to analyze whether an association exists between functional gait and health-related quality of life (HRQOL) for individuals with Diabetic Peripheral Neuropathy (DPN). Additionally, the study investigated the potential benefit of yoga on HRQOL and functional gait in individuals with DPN.

Background and Statement of Problem

Diabetes Mellitus (DM) effects roughly 29.1 million persons in the United States, of which up to 50% are estimated to be effected by DPN (Centers for Disease Control and Prevention, 2014; Poliakov & Toth, 2011). DPN is defined as a nerve disorder caused by DM that causes damage in the nerves of the arms and legs (Centers for Disease Control and Prevention, 2014). The negative effects of DPN include substantial pain, challenges to functional gait, and poorer quality of life (QoL) (Gore, Brandenburg, Hoffman, Tai, & Stacey, 2006; Mueller, Minor, Sahrmann, Schaaf, & Strube, 1994; Poliakov & Toth, 2011). These deleterious impacts on health have been associated with considerable consumption of health care costs, as well as a decline in work productivity for individuals affected by DPN (daCosta DiBonaventura, Cappelleri, & Joshi, 2011; Poliakov & Toth, 2011).

Type 2 DM is associated with a reduction in lower leg muscle strength. This loss in muscle strength is correlated with a loss of mobility. Declines in strength and mobility in Type 2 DM populations were found to be associated with a loss of HRQOL (IJzerman et al., 2012). However, at this time, no studies have been published that demonstrate a specific correlation between functional gait, a component of mobility, and HRQOL in individuals with DPN. As researchers continue to look at different therapy options for individuals with DPN and the effects on functional gait as well as HRQOL, the relationship should be investigated between these two outcome measures.

While no studies have been conducted to research the effects of yoga on DPN, researchers have looked at the effects of Tai Chi, a similar practice to yoga, on peripheral neuropathy (not specific to diabetes). The researchers found in a study of twenty-five participants with peripheral neuropathy, that individuals who participated in a long-term Tai Chi exercise program made substantial improvements in functional gait as well as physical well-being (Li & Manor, 2010). Yoga, like Tai Chi, has recently gained popularity in therapy settings; therefore, it seems appropriate that yoga should be investigated as a therapeutic option for individuals with DPN to engage in (Wayne & Kaptchuk, 2008).

The objectives of this study were to: 1) examine whether there was an association between functional gait and HRQOL in people with DPN; 2) determine whether there were changes in HRQOL in participants pre- and post-eight-week yoga intervention; and 3) examine whether there were changes in functional gait (walking speed and walking endurance) in participants pre- and post-eight-week yoga intervention.

Research Questions

1. Was there an association between functional gait and HRQOL in persons with DPN?
2. Was there a change in HRQOL after engaging in eight-weeks of yoga in persons with DPN?
3. Was there a change in functional gait after engaging in eight-weeks of yoga in persons with DPN?

CHAPTER 2: REVIEW OF THE LITERATURE

Conceptual Framework

This research was conducted with awareness of the World Health Organization's International Classification of Functioning, Disability, and Health (ICF)'s conceptual framework. This framework served as a guide, considering the ICF is aimed at providing a scientific understanding by which to analyze health, health-related states, health factors, and outcomes (World Health Organization, 2001). Figure 1 below provides a visual representation of this framework.

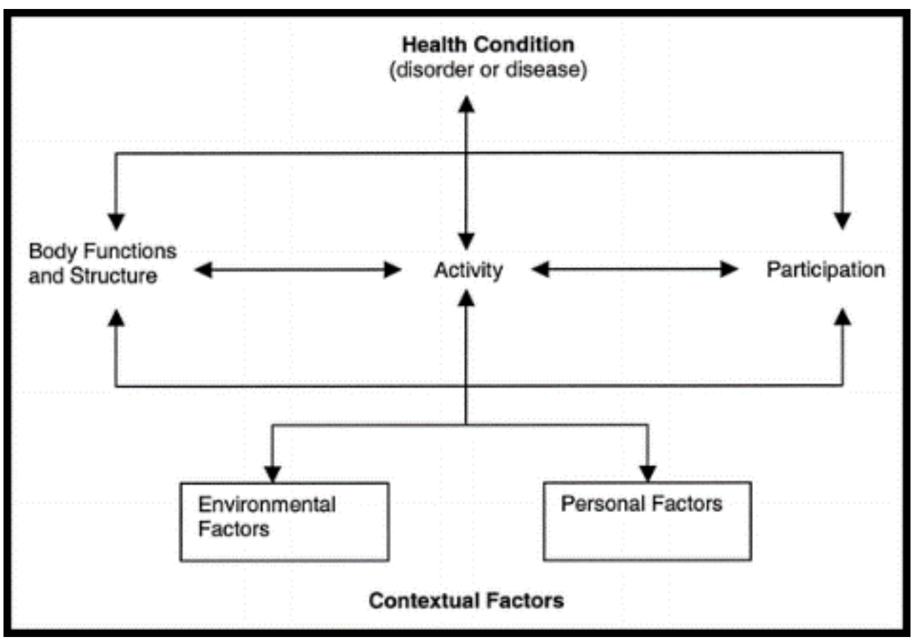

Figure 1: ICF conceptual framework.

While environmental factors are components not specifically measured by the outcomes of this study, the influence of these factors upon the research needs to be noted. Environmental factors are defined as the physical, social and attitudinal context in which a person carries out their life (World Health Organization, 2001). One such aspect of the environment influencing the development of the study was the fact that the research was conducted in Fort Collins, Colorado. The social environment of this college town is one that emphasizes healthy living and physical activity. Therefore, participants living in this environment may have been more willing to participate in this study because of the social values of the town that it was conducted in. Participation in yoga classes may not have been as readily welcomed and attempted by individuals in another region.

A fundamental requirement for participation in this research study was an individual's diagnosis of DPN. This was the health condition of primary importance in evaluating changes seen throughout the study. Additionally, there were components of participants' body functions and structure that allowed them to meet the eligibility requirements of the study and complete the study. For example, the individual had to have self-reported balance impairments, had to be able to walk 10 meters with or without a device, and had to have the ability to communicate with researchers (all body functions). They also had to be able to physically complete the yoga postures.

In relation to the outcomes of this study, functional gait and HRQOL, the ICF provides a clear framework by which to understand how changes in these two areas ultimately influences a person's engagement in occupations. Functional gait is included within mobility, which is defined by the ICF as an activity (World Health Organization, 2001). HRQOL will be addressed under personal factors, defined by the ICF as "particular background of an individual's life and living, and comprise features of the individual that are not part of a health condition" (World Health Organization, 2001).

Additionally, participation, or "involvement in a life situation", was an area of this framework not specifically measured in this study (World Health Organization, 2001). Yet, by engaging in a group yoga class for eight-weeks, individuals were involved in more than just a simple task or action. Participants became socially involved with other participants and emotionally invested in the pursuit of a yoga practice, engaging them not just in a task, but a broader experience. While that experience was not specially measured in this research study, it should be noted and understood for how it may have influenced the individual in their participation in the eight-weeks of yoga.

The six domains recognized in the ICF model are inseparable and changes or improvements in one area could likely lead to changes in the other areas addressed in the framework. While only specific areas of the ICF model were measured in our study, it is important to identify the close links between all six domains that could have led to other changes or improvements that we did not address or note.

Diabetic Peripheral Neuropathy

Definition.

DM refers to a metabolic disorder that is characterized by chronic hyperglycemia, as well as deficiencies in insulin secretion and insulin action (WHO Consultation, 1999). Diabetic neuropathies encompass a group of nerve disorders that are caused by DM (Centers for Disease Control and Prevention, 2014). Diabetic neuropathy is one of the most common problems associated with diabetes and results in pain, loss of mobility, and amputation (daCosta DiBonaventura et al., 2011). The cause of diabetic neuropathies includes many factors, most notably, exposure to continuous high blood glucose levels that cause nerve damage. Other factors that are thought to cause nerve damage in individuals with diabetes include: neurovascular factors, autoimmune factors, mechanical injury to nerves, inherited traits, and lifestyle factors (Centers for Disease Control and Prevention, 2014).

Peripheral Neuropathy, also known as sensorimotor neuropathy or symmetric neuropathy, is nerve damage specifically in the arms, hands, legs, and feet. In diabetic populations, peripheral neuropathy is the most common type of neuropathy (Centers for Disease Control and Prevention, 2014). The onset of DPN is typically gradual and can go unnoticed for a long period of time (Thomas, 1997). However, when symptoms begin to appear, they may include: numbness, tingling, and pain; wasting of the muscles of the feet or hands; indigestion, nausea, or vomiting; diarrhea or constipation; dizziness or faintness caused by a drop in blood pressure after sitting up or standing; difficulty urinating; erectile dysfunction in men and vaginal dryness in women; and general weakness (Argoff, Cole, Fishbain, & Irving, 2006). Additionally, symptoms often seen in individuals with DPN include depression and weight loss (Centers for Disease Control and Prevention, 2014). DPN typically presents itself distally and then proceeds proximally in affected limbs. Feet and legs are typically disturbed by nerve damage before hands and arms (Centers for Disease Control and Prevention, 2014; Vinik et al., 1992).

Incidence and prevalence.

It is estimated that there are approximately 29.1 million individuals in the United States who have DM (Centers for Disease Control and Prevention, 2014). Incidence of DPN is estimated to be approximately 8% in persons with diabetes at their time of diagnosis, and increases to 50% after 25 years of living with DM. Females and children with diabetes are less affected by this complication of DM (Harati, 1987). The highest prevalence of DPN is estimated in the elderly (Poliakov & Toth, 2011). In 1997, total direct costs for DM were estimated to be $44 billion, which was 5.8% of the total personal health care expenditure in the United States. Costs associated specifically with DPN annually total around $10.91 billion, roughly a quarter of the expenditure dedicated to DM (Gordois, Scuffham, Shearer, Oglesby, & Tobian, 2003). In addition to incurring overwhelming health care costs, DPN is also associated with considerable pain and morbidity (Argoff et al., 2006).

Impact of DPN related pain.

Pain symptoms associated with neuropathy are estimated to affect approximately 50% of individuals with DPN (Poliakov & Toth, 2011). The impact of chronic pain is associated with a lower QoL in persons with neuropathy (B. H. Smith, Torrance, Bennett, & Lee, 2007). The subjectivity of pain and its influence on mood, cognition, and emotion likely account for its negative effect upon QoL. Additionally, neuropathic pain has been found to impact: sleep efficacy; feelings of depression and anxiety; daily activities; and consumption of health care resources (Poliakov & Toth, 2011). Researchers have found that individuals suffering from pain associated with DPN demonstrate considerably more impairment and health care costs, and have a decreased QoL compared with individuals who have DM without DPN. Of the individuals who report pain symptoms, 80% reported that their pain was either moderate or severe. In addition, pain has been suggested to cause a loss of 1.4 hours of work productivity each week for individuals with painful DPN (daCosta DiBonaventura et al., 2011).

DPN and functional gait.

Functional gait includes walking speed and walking endurance (Graham, Ostir, Fisher, & Ottenbacher, 2008; Sciurba & Slivka, 1998). Walking speed is well studied in older adults and is typically measured in terms of meters per second (m/s). Decreased walking speed has been linked to increased likelihood of death in older adults and has been referred to as the "sixth vital sign", meaning that walking speed has the potential to be a primary indicator of function and health status within aging and diseased populations (Fritz & Lusardi, 2009; Peel, Kuys, & Klein, 2013; Studenski et al., 2011). Research on muscle strength and ankle mobility in diabetic neuropathies has demonstrated reductions in walking speed for people with DPN (Martinelli et al., 2013). Individuals with DPN also have been observed to be slower in executing walking tests (Volpato et al., 2012). Additionally, individuals with DPN demonstrate deficits in lower knee and ankle muscle strength, muscle power, and muscle quality (Martinelli et al., 2013). Muscle strength has been linked to stride length and walking speed in individuals with DPN (Martinelli et al., 2013). In research by Mueller et al. (1994) which assessed the differences in the gait characteristics of subjects with DPN with age-matched controls, the individuals with DPN demonstrated less ankle mobility, ankle moment, ankle power, velocity, and stride length during walking, which led to altered walking patterns in this population. Altered walking patterns resulted in a shorter stride and reduced walking speed and cadence during walking (Mueller et al., 1994).

DPN and quality of life.

Neuropathic pain is suggested to affect both individual functioning and QoL (Gore et al., 2006). When DPN is not treated or not treated properly, it has been associated with losses in several dimensions of QoL (Gore et al., 2006). Research on DPN and QoL by, Benbow et al. (1998), established that QoL was significantly more compromised ($P<.01$) in individuals with DPN than among individuals with DM alone. Furthermore, the researchers found that individuals with DPN were found to have more impairments in emotional reactions, energy, pain, physical mobility, and sleep (Benbow, Wallymahmed, & MacFarlane, 1998). QoL has also been shown to be reduced in persons with DPN due to impairments in sleep, enjoyment of life, mobility, employment, and recreational and social activities (Galer & Jensen, 1997).

Yoga

Definition.

The word ‘yoga’ comes from Sanskrit, meaning to yoke or join together (Field, 2011). The practice of yoga is an ancient practice that originated in India and was largely intended as a method of increasing self-awareness (Patanjali & Malhotra, 2001). Yoga is a mind-body medicine that combines a person’s mental, spiritual, and physical aspects to improve components of health (Woodyard, 2011). It is a practice that is recognized in improving aspects of health. In yoga, individuals perform a series of poses called ‘Asanas’. In Hatha yoga, these poses are practiced slowly and sequentially, and individuals concentrate on deep abdominal breathing accompanying each movement. Poses are typically held for four to five breaths (Field, 2011). There are many forms of yoga that exist, with Hatha yoga being the most popular form practiced in the west (Lynton, Kligler, & Shiflett, 2007). Our study used Hatha yoga, but will be referred to simply as yoga throughout the rest of this text.

Therapeutic yoga.

Yoga therapy refers to the method of empowering persons to progress toward improved health and freedom from disease with the implementation of the practice and philosophy of yoga (Mohan, 2013). The use of therapeutic yoga has been shown to promote: muscular strength; flexibility; respiratory and cardiovascular function; recovery from and treatment of addiction; and reduction in stress, anxiety, depression, and pain (Woodyard, 2011). Additionally, yoga has been shown to improve sleep patterns and overall well-being and QoL (Woodyard, 2011). While yoga is based in spiritual evolution, it increasingly has become a tool used for secondary health benefits (Telles, Kozasa, Bernardi, & Cohen, 2013). As a form of therapy, yoga has been shown to offer beneficial results for individuals with: heart failure; after stroke; chronic obstructive pulmonary disease; degenerative diseases like Parkinson's syndrome and muscular dystrophy; post-traumatic stress disorder; and certain psychiatric conditions (Bernardi et al., 2002; Hall, Verheyden, & Ashburn, 2011; Raupach et al., 2008; Schmid et al., 2012; Telles, Balkrishna, & Maharana, 2011; Telles, Singh, Joshi, & Balkrishna, 2010; Varambally et al., 2013). While there has been various research done on therapeutic yoga and its effects on different populations, including those with DM, to our knowledge, there is no existing research in regards to the possible benefits of therapeutic yoga for people with DPN (Posadzki, Lee, & Ernst, 2012; Sahay, 2007). While the yoga sessions in our study were led by a Registered Yoga Teacher, the yoga teacher collaborated with Certified Yoga Therapist to develop the yoga protocol for the study.

Yoga and DPN.

Currently, there have been no studies done to study the effect of yoga on people with DPN. The most relatable study on this topic was a study done that addressed the effects of Tai Chi on persons diagnosed with peripheral neuropathy; however, not specifically with a diabetic cause (Li & Manor, 2010). Tai Chi has many similarities to yoga, as it is a mind-body practice based on slow intentional movements, often coordinated with breathing and mental imagery. Like yoga, Tai Chi also has gained recent popularity in therapy settings (Wayne & Kaptchuk, 2008). Li and Manor (2010) found that a long-term Tai Chi exercise program for persons with peripheral neuropathy made significant improvements in functional gait, leg strength, and the individuals' physical well-being. Considering Tai Chi is a very similar practice to yoga and benefits have been observed through the implementation of a Tai Chi exercise programs, yoga should be studied to examine possible benefits it might have on populations with DPN.

Implications for Occupational Therapy

While yoga has been used to some extent in occupational therapy, the occupational philosophy of this practice seems to be generally overlooked. Yoga has been discussed as a practice of occupational regulation and warrants further study due to its potential ability to enrich occupational therapy practice (Mailoo, 2005). Yoga addresses occupational balance blending work, exercise, meditation and sleep with one's energy in mind. Additionally, yoga addresses feelings of occupational imbalance and occupational alienation by promoting self-acceptance and self-expression (Mailoo, 2005). Yoga's ability to promote numerous principles of occupational therapy makes it practical to include in interventions. The limited integration of yoga into occupational therapy up to this point makes it an even more appropriate area to further examine in regards to intervening with different populations in occupational therapy settings.

Summary

There is currently no research that exists that has established a correlation between functional gait and HRQOL in individuals with DPN. Examining whether there is a link between these two outcome measures will help to further understand the implications of affected gait patterns associated with DPN.

Additionally, no studies exist that address the impacts of yoga on individuals with DPN. Research has been conducted on individuals with peripheral neuropathy, studying the effects of Tai Chi, a similar practice to yoga, and has found many positive results supporting its use in neuropathic populations. Thus, yoga should be similarly studied to examine whether similar benefits are achieved through participation in yoga. Therefore, the objectives of this study were to: 1) examine whether there was an association between functional gait and HRQOL in people with DPN; 2) determine whether there were changes in HRQOL in participants pre- and post-eight-week yoga intervention; and 3) examine whether there were changes in functional gait (walking speed and walking endurance) in participants pre- and post-eight-week yoga intervention.

CHAPTER 3: METHODOLOGY

Research Design

These are planned primary analyses of a non-controlled pretest-posttest pilot study to understand the impact of yoga on functional gait and HRQOL in people with DPN.

Participants

This convenience sample was recruited from a pre-existing participant registry from past university research studies involving individuals with DPN, an approved recruitment flyer, diabetic and pain management support groups, a diabetic resource fair, and word of mouth. Inclusion criteria included: diagnosis of DPN as confirmed by self-report; age of 18+; ability to speak English; ability to converse/ answer questions/ communicate; and ability to walk 10 meters with or without a device. People were excluded if: they reported they had consistently engaged in yoga for more than one year; were unable to attend twice weekly yoga sessions for eight weeks; or had terminal illness with life expectancy of < 6 months. Human participants' approval was obtained from Colorado State University's (CSU) Institutional Review Board; all participants granted written informed consent to take part in the study.

Outcome Measures

All data were gathered and entered by trained research assistants. All components of the study were conducted at the CSU Integrative Rehabilitation Lab. Participants in the study completed a series of physical performance assessments and self-report questionnaires before and after the 8-week yoga intervention. Data collection included demographic information (age, gender, race, educational status) and DPN characteristics (type of DM, area of symptoms of DPN, DPN severity measured by Michigan Neuropathy Screening Instrument [MNSI]) (Moghtaderi, Bakhshipour, & Rashidi, 2006). We assessed HRQOL and functional gait.

Health-related quality of life.

The Neuro-QoL was used to measure HRQOL. It has been shown to fulfill specific requirements for both reliability and validity in assessing HRQOL specific to neurological disorders, including DPN (S. Smith, Lamping, & Maclaine, 2012). The test was developed to be applicable for a range of neurological conditions; therefore, the test manual specifies that researchers must consider which of the 17 domains are appropriate to assess within a specific disease population (Cella et al., 2012; National Institute of Neurological Disorders and Stroke (NINDS), 2010). Understanding the research by Benbow et al. (1998) that found that individuals with DPN specifically had more QoL impairments in terms of emotional reactions, energy, pain, physical mobility and sleep, helped us determine the test domains of the Neuro-QoL that would be appropriate to include for the participants in our study. We included the following seven 8-item domains: 1) ability to participate in social roles and activities; 2) depression; 3) fatigue; 4) lower extremity function (mobility); 5) satisfaction with social roles and activities; 6) upper extremity function (fine motor, ADL); and 7) anxiety.

Functional gait.

Functional gait encompasses both walking speed and walking endurance (Graham et al., 2008; Sciurba & Slivka, 1998). Assistive devices were used during the walking assessments if necessary. Walking speed was measured using the *10-Meter Walk Test*. This assessment requires individuals to walk as fast as they are comfortably able to for 10 meters. Time to walk the 10 meters were collected and then computed to meters/seconds (m/s) to determine the individual's walking speed (Graham et al., 2008).

Walking endurance was assessed using the Six Minute Walk Test (6MWT), which has been shown to be a valid and reliable measure. The test measures the number of feet walked on a level course in the specified six-minute period (Enright, 2003). Therefore, its use for persons dealing with the symptoms of DPN was appropriate. Additionally, the 6MWT has been noted as safer, easier to conduct, and better imitates activities of daily living than do other walking assessments (Enright, 2003).

Intervention

Individuals participated in eight weeks of yoga two times per week and one hour per session. The study included yoga, developed as a therapeutic intervention, for two groups of participants, one group of nine participants and one of six participants. Due to snow, there were a total of 15 sessions participants could have attended. Yoga sessions were led by a Registered Yoga Teacher who collaborated with a Certified Yoga Therapist to create the yoga intervention protocol. The protocol reflected the modified yoga plan presented in Table 1. See Table 1 on the following page for the yoga protocol that was used.

Table 1: Protocol for modified postures progressed throughout yoga intervention.

Position	Yoga Posture and Description
Chair Postures: Weeks 1-8	**2 to 1 breathing**: Slow, rhythmic breathing, with an extended exhale
	Bilateral eye movements and keeping eyes steady
	Different head and neck movements
	Receptive gesture: Scapular range of motion and arm movements
	Finger movements
	Cow, cobra, half moon, and fish king: spinal extension, flexion, lateral flexion, and rotation, respectively
	Pigeon pose: Hip, ankle, foot, and toe stretching/movement
	Alternate nostril breathing: Brain regulator
	Spinal twist: Hand to the opposite knee
Standing Postures: Weeks 2-8	**Mountain pose:** Standing with or without support of chair
	Chair pose: Knees squatting into a seated position, up & down on toes
	Locust pose: Hip extension with alternating legs while standing
	Warrior pose: Prolonged lunges while standing with or without support
	Awkward pose: Standing on toes or ball of foot, knees bent with flat feet
Supine Postures: Weeks 5-8	**Big toe pose:** Posterior leg stretches
	Bridge pose: Supine extensions with bridge lifts
	Energy releasing pose: Grasping knees into chest, separately then both
	Corpse pose: Supine relaxation with legs out or knees bent and feet flat
	Traveling through the corpse: Concentration, meditation, and relaxation

The yoga intervention addressed the following variables in relation to individuals' DPN: movements to gain awareness of lower and upper limbs; movements outside of their base of support; flexibility and strength at the hips, torso, and lower extremity joints; different head positions; reaching; and lunging. Yoga sessions included modified yoga poses for participants as well as deep breathing exercises and meditation that gradually progressed in difficulty throughout the eight weeks of the yoga intervention (all chair yoga that progressed to standing and floor yoga postures). The yoga intervention was delivered in a standardized progression allowing for the yoga to become more challenging and building upon prior skills.

Data Analysis

Data were entered into a Statistical Package for the Social Sciences (SPSS, Inc. Chicago) Version 22 database for management and analyses. Descriptive statistics were used to describe demographics and DPN characteristics with means, standard deviations, frequencies, and proportions as appropriate and compared from the baseline assessment to the eight-week assessment. Correlations were examined between the Neuro-QoL and functional gait scores (6MWT and 10-Meter Walk Test). A correlation was considered to demonstrate a fair degree of relationship if $r = 0.25\text{-}0.50$, a moderate degree of relationship if $r=0.50\text{-}0.75$, or an excellent degree of relationship if $r>0.75$(Portney & Watkins, 2000). The Shapiro-Wilk test was used to assess the normality of data. Paired *t*-tests (or Wilcoxon signed-rank test for non-normal data) were used to assess change between baseline and eight-week assessment variables. A Bonferroni adjustment was used to control for multiple comparisons for the three variables assessed ($\alpha = 0.05/3 = 0.0167$). We also calculated the percent change between baseline and eight-week assessments for each variable ([Time 1-Time 2]/Time 1) x 100. Additionally, due to our primary analyses and our interest in the HRQOL domains, we conducted post-hoc analyses to further investigate changes in the Neuro-QoL data from the baseline assessment to the eight-week assessment (Table 4). We completed paired *t*-tests (or Wilcoxon signed-rank test when appropriate) on the seven individual domain scores of the Neuro-QoL.

CHAPTER 4: MANUSCRIPT

Introduction

Diabetes Mellitus (DM) effects roughly 29.1 million persons in the United States, with up to 50% of people with DM estimated to be effected by Diabetic Peripheral Neuropathy (DPN) (Centers for Disease Control and Prevention, 2014; Poliakov & Toth, 2011). Diabetic neuropathies encompass a group of nerve disorders that are caused by DM (Centers for Disease Control and Prevention, 2014). Peripheral neuropathy is nerve damage specifically in the arms, hands, legs, and feet. Peripheral neuropathy is also the most common type of neuropathy that affects populations with diabetes. The negative effects of DPN include both declines in functional gait and decreased quality of life (QoL) (Gore et al., 2006; Mueller et al., 1994; Poliakov & Toth, 2011).

Benbow et al. (1998), established that QoL was significantly more compromised in individuals with DPN than among individuals with diabetes alone. Furthermore, the researchers found that individuals with DPN were found to have more impairments in emotional reactions, energy, pain, physical mobility, and sleep (Benbow et al., 1998). QoL has also been shown to be reduced in persons with DPN due to impairments in sleep, enjoyment of life, mobility, employment, and recreational and social activities (Galer & Jensen, 1997).

Type 2 DM is associated with a reduction in lower leg muscle strength (IJzerman et al., 2012). The loss in muscle strength is correlated with a loss of mobility (IJzerman et al., 2012). Declines in strength and mobility in Type 2 DM populations were found to be associated with a loss of health-related quality of life (HRQOL) (IJzerman et al., 2012). However, it is not currently known if there is a correlation between functional gait, a component of mobility, and HRQOL in DM populations.

Functional gait includes walking speed as well as walking endurance (Graham et al., 2008; Sciurba & Slivka, 1998). Decreased gait speed has been linked to increased likelihood of death in older adults and has been referred to as the sixth vital sign (Fritz & Lusardi, 2009; Studenski et al., 2011). Muscle strength and ankle mobility in people with DPN is associated with reductions in gait speed for people with DPN (Martinelli et al., 2013).

Yoga is an intervention that empowers persons to progress toward improved health and freedom from disease with the implementation of the practice and philosophy of yoga (Mohan, 2013). Yoga has been shown to promote: muscular strength; flexibility; respiratory and cardiovascular function; recovery from and treatment of addiction; improved sleep patterns; overall well-being and QoL; and a reduction in stress, anxiety, depression, and pain (Woodyard, 2011). As a form of therapy, yoga has been shown to offer beneficial results for individuals with: heart failure; stroke; chronic obstructive pulmonary disease; degenerative diseases like Parkinson's syndrome and muscular dystrophy; post-traumatic stress disorder; balance impairments; and certain psychotic conditions (Bernardi et al., 2002; Hall et al., 2011; Raupach et al., 2008; Schmid, Miller, Van Puymbroeck, & DeBaun-Sprague, 2014; Schmid et al., 2012; Schmid, Van Puymbroeck, & Koceja, 2010; Telles et al., 2011; Telles et al., 2010; Varambally et al., 2013).

While there has been various research conducted on yoga and its effects on different populations, including those with DM, to our knowledge, there is no research in regards to the possible benefits of yoga for people with DPN (Posadzki et al., 2012; Sahay, 2007). The only other mind-body intervention to be previously studied in populations with peripheral neuropathy was Tai Chi. However, according to a 2007 national survey on adults in the United States, conducted by Barnes et al. (2008), on the estimates of complementary and alternative medicine use, yoga was used at a rate almost six times that of Tai Chi. According to these statistics, yoga may be a more familiar and accessible mind/body intervention. Therefore, the objectives of this study were to: 1) examine the associations between functional gait and HRQOL (Neuro-QoL) scores in people with DPN; 2) determine the change in Neuro-QoL scores in participants pre- and post-eight-week yoga intervention; and 3) examine the change in functional gait measures (6-Minute Walk Test, 10-Meter Walk Test) in participants pre- and post-eight-week yoga intervention.

Methods

Design.

These are planned primary analyses of a non-controlled pretest-posttest pilot study to understand the impact of yoga on functional gait and HRQOL in people with DPN.

Recruitment and participants.

This convenience sample was recruited from a pre-existing participant registry from past university research studies involving individuals with DPN, an approved recruitment flyer, diabetic and pain management support groups, a diabetic resource fair, and word of mouth. Inclusion criteria included: diagnosis of DPN; age of 18+; ability to speak English; ability to converse/ answer questions/ communicate; and ability to walk 10 meters with or without a device. People were excluded if: they had consistently engaged in yoga for more than one year; were unable to attend twice weekly yoga sessions for eight weeks; or had terminal illness with life expectancy of <6 months. Human participants' approval was obtained from Colorado State University's (CSU) Institutional Review Board; all participants granted written informed consent to take part in the study.

Outcome measures.

All data were gathered and entered by trained research assistants. All components of the study were conducted at the CSU Integrative Rehabilitation Lab. Participants in the study completed a series of physical performance assessments and questionnaires before and after the 8-week yoga intervention. Data collection included demographic information (age, gender, race, educational status) and DPN characteristics (type of DM, area of symptoms of DPN, DPN severity measured by Michigan Neuropathy Screening Instrument [MNSI]) (Moghtaderi, Bakhshipour, & Rashidi, 2006). We assessed HRQOL and functional gait.

Health-related quality of life.

The Neuro-QoL was used to measure HRQOL. It has been shown to fulfill specific requirements for both reliability and validity in assessing HRQOL specific to neurological disorders, including DPN (S. Smith et al., 2012). The test was developed to be applicable for a range of neurological conditions; therefore, the test manual specifies that researchers must consider which of the 17 domains are appropriate to assess within a specific disease population (Cella et al., 2012; National Institute of Neurological Disorders and Stroke (NINDS), 2010). We included the following seven 8-item domains: 1) ability to participate in social roles and activities; 2) depression; 3) fatigue; 4) lower extremity function (mobility); 5) satisfaction with social roles and activities; 6) upper extremity function (fine motor, ADL); and 7) anxiety.

Functional gait.

Functional gait encompasses both walking speed and walking endurance (Graham et al., 2008; Sciurba & Slivka, 1998). Assistive devices were used during the walking assessments as necessary. Gait speed was measured using the *10-Meter Walk Test*. This assessment requires individuals to walk as fast as they are comfortably able to for 10 meters. Time to walk the 10 meters were collected and then computed to meters/seconds (m/s) to determine the individual's gait speed (Graham et al., 2008).

Walking endurance was assessed using the *Six Minute Walk Test (6MWT)*, which has been shown to be a valid and reliable measure. The test measures the number of feet walked on a level course in the specified six-minute period of time (Enright, 2003).

Intervention.

Individuals participated in eight weeks of yoga two times per week and one hour per session. The study included yoga, developed as a therapeutic intervention, for two groups of participants, one group of nine participants and one of six participants. Due to snow, there were a total of 15 sessions participants could have attended. Yoga sessions were led by a registered yoga teacher who collaborated with a certified yoga therapist to create the yoga intervention protocol.

The yoga Intervention addressed the following variables in relation to individuals' DPN: movements to gain awareness of lower and upper limbs; movements outside of their base of support; flexibility and strength at the hips, torso, and lower extremity joints; different head positions; reaching; and lunging. Yoga sessions included modified yoga poses for participants as well as deep breathing exercises and meditation that gradually progressed in difficulty throughout the eight weeks of the yoga intervention (all chair yoga that progressed to standing and floor yoga postures). The yoga intervention was delivered in a standardized progression allowing for the yoga to become more challenging and building upon prior skills.

The yoga protocol developed by the registered yoga teacher and certified yoga therapist are represented in the Table 1 on the following page. The table reflects how the yoga postures progressed for the participants throughout the eight-weeks of the intervention. See Table 1 for the yoga protocol that was used.

Table 2: Protocol for modified postures progressed throughout yoga intervention.

Position	Yoga Posture and Description
Chair Postures: Weeks 1-8	**2 to 1 breathing**: Slow, rhythmic breathing, with an extended exhale
	Bilateral eye movements and keeping eyes steady
	Different head and neck movements
	Receptive gesture: Scapular range of motion and arm movements
	Finger movements
	Cow, cobra, half moon, and fish king: spinal extension, flexion, lateral flexion, and rotation, respectively
	Pigeon pose: Hip, ankle, foot, and toe stretching/movement
	Alternate nostril breathing: Brain regulator
	Spinal twist: Hand to the opposite knee
Standing Postures: Weeks 2-8	**Mountain pose:** Standing with or without support of chair
	Chair pose: Knees squatting into a seated position, up & down on toes
	Locust pose: Hip extension with alternating legs while standing
	Warrior pose: Prolonged lunges while standing with or without support
	Awkward pose: Standing on toes or ball of foot, knees bent with flat feet
Supine Postures: Weeks 5-8	**Big toe pose:** Posterior leg stretches
	Bridge pose: Supine extensions with bridge lifts
	Energy releasing pose: Grasping knees into chest, separately then both at the same time
	Corpse pose: Supine relaxation with legs out or knees bent and feet flat
	Traveling through the corpse: Concentration, meditation, and relaxation

Data analysis.

Data were entered into a Statistical Package for the Social Sciences (SPSS, Inc. Chicago) Version 22 database for management and analyses. Descriptive statistics were used to describe demographics and DPN characteristics with means, standard deviations, frequencies, and proportions as appropriate and compared from the baseline assessment to the eight-week assessment. Correlations were examined between the Neuro-QoL and functional gait scores (6MWT and 10-Meter Walk Test). A correlation was considered to demonstrate a fair degree of relationship if $r = 0.25\text{-}0.50$, a moderate degree of relationship if $r = 0.50\text{-}0.75$, or an excellent degree of relationship if $r > 0.75$.(Portney & Watkins, 2000) The Shapiro-Wilk test was used to assess the normality of data. Paired *t*-tests (or Wilcoxon signed-rank test for non-normal data) were used to assess change between baseline and eight-week assessment variables. A Bonferroni adjustment was used to control for multiple comparisons for the three variables assessed ($\alpha = 0.05/3 = 0.0167$). We also calculated the percent change between baseline and eight-week assessments for each variable by taking ([Time 1-Time 2]/Time 1) x 100. Additionally, due to our preliminary findings and our interest in the HRQoL domains, we conducted post-hoc analyses to further investigate changes in the Neuro-QoL data from the baseline assessment to the eight-week assessment. We completed paired *t*-tests (or Wilcoxon signed-rank test when appropriate) on the seven individual domain scores of the Neuro-QoL.

Results

There were a total of 22 participants with DPN recruited for this study over a three month time period. All participants were recruited from Fort Collins, CO and the surrounding area and were screened and found to meet the eligibility criteria. Seven individuals who were recruited did not participate in the study because of conflicts that included: work schedules; lack of child-care; complications with co-morbid conditions; and surgery. Fifteen (68%) individuals participated in the study. The ages of participants ranged from 52-92 years, with the mean age being 66.5±11.34 years. The majority of the participants were female (53.3%), white (80%), and had at least some college education (73.3%). The majority of individuals had Type 2 Diabetes (86.7%) and reported a DPN severity of 6.13±2.56 on the MNSI participant questionnaire and 7.83±1.90 on the MNSI physical foot examination. As per the inclusion criteria, all participants reported DPN (100%), with 100% reporting DPN in their feet, and 60% of individuals reporting DPN symptoms in both their hands and feet. See Table 2 on page 28 for additional descriptive statistics and DPN specific characteristics.

All 15 individuals completed both baseline and eight-week assessments and the yoga intervention. Participants were physically able to complete all planned yoga activities, no injuries were sustained, and no adverse events were reported. Overall, the mean number of yoga sessions completed were 12.33±1.91, with a range of 9-15 sessions. Yoga sessions were missed because of sickness, family commitments, scheduling conflicts, doctors' appointments, and out-of-town travel.

A fair correlation was demonstrated between both the Neuro-QoL and the 6MWT, as well as the Neuro-Qol and the 10-Meter Walk Test (6MWT, r=0.487, p=0.065; 10-Meter Walk Test, r=0.420, p=0.119) (Portney & Watkins, 2000). Overall, the participants in the study demonstrated improvements in multiple variables. See Table 3 on page 29 for the changes in variables between baseline and 8 week assessment scores. Neuro-QoL overall scores, in which lower scores are reflective of better HRQOL, decreased by 8% demonstrating improvement after eight weeks of yoga (110.20±31.68 vs. 101.47±27.75, p=0.054). The number of feet walked in the 6MWT significantly increased by 15% (1018.48±406.99 vs. 1167.18±447.75, $p=0.014$) with an average improvement of 148.7 feet. In regards to the 10-Meter Walk Test, speed (m/s) significantly increased after eight weeks of yoga by 23% (0.74±0.25 vs. 0.91±0.28, $p<0.001$), with an average improvement of 0.17 m/s. Both walking endurance (6MWT) and walking speed (10-Meter Walk Test) remained statistically significant after the Bonferroni correction ($p<0.0167$).

Post-hoc analyses.

Since the Neuro-QoL overall scores were shown to improve from the baseline to eight-week assessments, we conducted post-hoc analyses on the individual Neuro-QoL domain scores. See Table 4 on page 30 for the changes from baseline to eight-week assessments in individual Neuro-QoL domain scores. While none of the domains were statistically significant, six of the seven domains demonstrated improvement. Anxiety was the only domain that did not show improvement.

Table 3: Demographics.

Variable	**All** **N=15**
Age (52-92 years)	66.43 ± 11.77
Gender (Female)	8 (53.3%)
Race (White)	12 (80%)
Education (Some college education)	11 (73.3%)
Type of Diabetes Mellitus	
Type 2	13 (86.7%)
Prediabetes	2 (13.3%)
5 or more years since Diabetes Mellitus symptom onset (Yes)	9 (60%)
Diabetic Peripheral Neuropathy (Yes)	15 (100%)
5 or more years since Diabetic Peripheral Neuropathy symptom onset (Yes)	5 (33.3%)
Severity of Neuropathy Symptoms	
MNSI participant questionnaire (13 point max)	6.13 ± 2.56
MNSI physical foot examination (10 point max)	7.83 ± 1.90
Area of Diabetes Peripheral Neuropathy symptoms	
Feet only	6 (40%)
Hands and feet	9 (60%)

Table 4: Change between baseline and 8 week assessment scores.

Variables	Yoga, N =15			
	Baseline	**8 weeks**	**P-value***	**% Change**
Neuro-QoL Overall Score	110.20 ± 31.68	101.47 ± 27.75	0.054	8%
Six-Minute Walk (feet)	1018.48 ± 406.99	1167.18 ± 447.75	0.014†	15%
10-Meter Walk (m/s)	0.74 ± 0.25	0.91 ± 0.28	<0.001†	23%

* As appropriate, p-values were calculated using Paired Sample T-tests for normal data and non-parametric Wilcoxon signed-rank test for non-normal data.

†Significant after Bonferroni correction (α=.05/3=.0167)

Table 5: Changes in Neuro-QoL domain scores.

Variables	Yoga, N =15			
	Baseline	**8 weeks**	**P-value***	**% Change**
Neuro-QoL Domain Scores				
Ability to Participate in Social Roles & Activities	15.00 ± 6.04	13.13 ± 3.83	0.054	12%
Depression	15.87 ± 7.60	13.07 ± 3. 61	0.072	18%
Fatigue	21.73 ± 7.24	20.27 ± 7.33	0.226	7%
Anxiety	14.53 ± 6.05	14.93 ± 6. 49	0.636	-3%
Satisfaction with Social Roles and Activities	19.07 ± 7.82	18.80 ± 7.47	0.838	1%
Lower Extremity Function	14.93 ± 6.05	12.73 ± 3.90	0.063	15%
Upper Extremity Function	9.07 ± 2.02	8.53 ± 0.74	0.380	6%

* As appropriate, p-values were calculated using Paired Sample T-tests for normal data and non-parametric Wilcoxon signed-rank test for non-normal data.

Discussion

In this group of individuals with DPN, we found a fair correlation between functional gait and HRQOL (Portney & Watkins, 2000). Our results demonstrated improvement, but no statistically significant change in HRQOL, as measured by Neuro-QoL overall scores. We report statistically significant improvement in functional gait measures, 6MWT and 10-Meter Walk Test.

While a correlation between HRQOL and functional gait has not been previously determined in DPN populations, researchers have shown that mobility is strongly correlated with HRQOL in older adults and suggest that interventions aimed at limitations to mobility may offer improvements in overall QoL (Groessl et al., 2007). Assessment of walking speed has been labeled as the “sixth vital sign”, meaning it has the potential to be a primary indicator of function and health status within aging and diseased populations (Peel et al., 2013). With the knowledge that functional gait is such an important determinant of health, it would be understandable that functional gait might influence HRQOL. While our results only demonstrated a fair correlation between functional gait and HRQOL, these results suggest that a link between functional gait and HRQOL may exist and should be further examined in DPN populations (Portney & Watkins, 2000). Perhaps a stronger correlation would be detected with a larger sample size or different QoL assessment.

To our knowledge, this is the first study to assess the effect of yoga on DPN. Overall, we found positive changes in HRQOL, walking speed, and walking endurance. Research by Benbow et al. (1998), established that QoL was significantly more compromised in individuals with DPN than in individuals with diabetes alone. They found that individuals with DPN specifically had more impairments in emotional reactions, energy, pain, physical mobility, and sleep. These findings helped us determine the test domains of the Neuro-QoL that would be appropriate to include for the participants in our study. The domains we chose looked at similar aspects of QoL that Benbow et al. (1998) had determined as being impaired in individuals with DPN (Benbow et al., 1998). We found improvements in all assessed domains of the Neuro-QoL except anxiety. These general trends toward improvement, while not significant, point to the promising effects that yoga may have on the adverse effects of DPN on HRQOL, though this relationship must be further examined.

While no studies have looked at the effects of yoga on DPN, limited research has looked at the effects of exercise interventions on DPN (Allet et al., 2010). One intervention that has been looked at for DPN is Tai Chi, a practice with some similarities to yoga. Tai Chi is also grounded in slow intentional movements, often coordinated with breathing and mental imagery (Wayne & Kaptchuk, 2008). Li & Manor (2010) looked at individuals with peripheral neuropathy (not specific to diabetes) and found that Tai Chi significantly improved individuals' walking endurance, as measured by the 6MWT (Li & Manor, 2010). Similarly, we found that individuals' performance on the 6MWT after eight-weeks of yoga improved significantly. In older adult populations, an improvement of 54 meters (177.17 feet) has been demonstrated to be a substantial meaningful change, while an improvement of 20 meters (65.62 feet) has been shown to be a small but meaningful change in the 6MWT (Perera, Mody, Woodman, & Studenski, 2006). On average, our participants improved by 148.7 feet which is more than double the 65.62 feet needed to demonstrate a small meaningful change. In addition to finding improvements in walking endurance, our study also demonstrated improvements in walking speed after eight-weeks of yoga. In older adult populations, a substantial meaningful change in the 10-Meter Walk Test has been demonstrated to be an improvement of 0.10 m/s or better

(Perera et al., 2006). Therefore, our change in m/s for the 10-Meter Walk Test after eight-weeks of yoga was 0.17, thus far exceeding the criteria for a substantial meaningful change.

Understanding that gait is such an important determinant of health, it is extremely promising to see that participants' walking speed and walking endurance both significantly improved after engaging in eight-weeks of yoga (Peel et al., 2013). Noting the fair correlation that we found between functional gait and HRQOL, it is also encouraging to see that six of the seven domains tested for HRQOL using the Neuro-QoL showed improvement after participating in yoga. While the improvements on the Neuro-QoL were not statistically significant, a study with more people could likely demonstrate results that are statically significant. The results of our study demonstrate early support that yoga can offer individuals with DPN improvements in both physical and mental capacities, and warrants further investigation.

Study limitations.

Several limitations must be acknowledged in this study. First, this was a relatively small pilot study; therefore we cannot generalize the findings of this study to the DPN population at large. Second, no control group was included; any future study should include a wait-list or randomized control trial design. Thirdly, participants missed sessions and had variable attendance, which may have affected results. One yoga class had to be completely canceled due to weather. Other classes were missed by individual participants due to doctors' appointments, co-morbidities, travel, family emergencies, and personal conflicts. Lastly, as there was only one group and everyone received yoga, the study was unblinded and the assessors were involved with the yoga intervention. Still, even with these acknowledged limitations, this study demonstrates that yoga may have positive benefits for individuals with DPN.

Conclusion

We conclude that yoga is a potential intervention to promote positive improvements in HRQOL and functional gait, including both walking speed and walking endurance, in individuals with DPN. While our results are only preliminary, they provide a hopeful basis by which further research on yoga should be conducted with this population. Rehabilitation and medical professionals may consider this as a modality for helping individuals manage their DPN.

CHAPTER 5: CONCLUSION

There is evidence that supports that DPN is a severe problem causing detrimental implications for individuals with DM (Gordois et al., 2003; Gore et al., 2006; Mueller et al., 1994; Poliakov & Toth, 2011). Specifically, individuals with DPN demonstrate declines in HRQOL and functional gait (Benbow et al., 1998; Gore et al., 2006; Martinelli et al., 2013; Mueller et al., 1994). The results of our study demonstrated a fair correlation between HRQOL scores from the Neuro-QoL and functional gait measures (6MWT and 10-Meter Walk Test). This can be understood in terms of the ICF model discussed in the Review of the Literature (World Health Organization, 2001). If all six areas of the ICF are interrelated, it is reasonable that impairments in one area, functional gait (activity), could influence another area, HRQOL (personal factors). Occupational therapists understand the complexities that influence an individual's occupational performance. It is understandable that impairments in functional gait, could influence one's ability to be mobile in their desired environment and engage in meaningful occupations. An inability to engage in preferred occupations could lead to occupational deprivation, thereby causing impairments in one's HRQOL.

Statistical analysis of the sample of participants in this study demonstrated that after engaging in eight-weeks of yoga, individuals' HRQOL and functional gait (both walking speed and walking endurance) improved. While this correlation between HRQOL and functional gait has been established in older adult populations, it has not be proven in populations with DPN (Groessl et al., 2007). However, the results of our study demonstrate initial findings that a similar link could exist between these two variables in persons with DPN, as does exist in older adults. Continued research should be examined in this area to establish a possible correlation.

Additionally, the statistical analysis of the sample in this study demonstrated improvements in overall HRQOL, walking speed, and walking endurance. These findings should be of interest to occupational therapists considering these variables all play a role in one's occupational engagement. If there are impairments in areas of HRQOL, walking speed, and walking endurance, one's occupational performance and engagement will ultimately be effected. Therefore, impairments in any of these areas should be of concern to occupational therapists and yoga should be considered as a safe and effective occupational therapy intervention to improve HRQOL and functional gait. This study underscores that the impacts of DPN on HRQOL and functional gait are widespread and further research must be conducted to find interventions to remediate these problems. Conducting future research to further understand the possibilities of yoga in benefitting this population is a hopeful place to start in helping individuals manage their DPN.

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