3-2015

Effect of Tai Chi Exercise Combined with Mental Imagery in Improving Balance

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School of Allied Health Professions
in conjunction with the
Faculty of Graduate Studies

Effect of Tai Chi Exercise Combined with Mental Imagery in Improving Balance

by

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A Dissertation submitted in partial satisfaction of
the requirements for the degree
Doctor of Science in Physical Therapy

March 2015

Each person whose signature appears below certifies that this dissertation in his/her opinion is adequate, in scope and quality, as a dissertation for the degree Doctor of Science.

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ACKNOWLEDGEMENTS

I would like to thank Loma Linda University for offering me the opportunity to pursue my doctoral degree in physical therapy. My journey was not limited to academics; during this journey, my administration skills have strengthened and my leadership skill have been honed. I had the opportunity to establish and chair the Saudi Students Club at Loma Lina University for two years. This position enriched my knowledge and experience by communicating regularly with Loma Linda University officials and the Saudi Arabian Cultural Mission.

Special thanks is due to my committee chair, Jerrold Petrofsky, who spent endless hours with me, answering questions, guiding me, and providing me with excellent recommendations. He is a generous, open hearted person and his door was always open. Working in his lab, I felt supported, encouraged, and motivated. Dr. Petrofsky carefully reviewed and evaluated my work, providing me with valuable comments that helped to shape this dissertation. I want to acknowledge and appreciate his professional mentorship during my journey. I will keep him in my mind for any help, support or further collaboration work.

I would like to express my deepest gratitude to Noha Daher who was supportive of me and wife during my journey. I have learned from her the importance of accuracy in all phases of the research process. She offered me a huge amount of guidance in the statistical analysis for my research project and guided me in the writing of my dissertation. She treated my wife and me with kindness and treated us as members of her family.

I would like to gratefully and sincerely thank Everett Lohman, Program Director for the Post-professional Physical Therapy Programs, for his advice. He was my academic advisor and helped me achieve my academic goals that will one day lead to a respected academic professorship. Despite his busy academic obligations, Dr. Lohman supported me in establishing the Saudi Students' Club at LLU. He believes that student activities' can help prepare tomorrow's leaders. I appreciate his special belief in my skills to lead and develop the club as president. I have learned from this man the real meaning of leadership and communication and I consider him my academic mentor and role model.

Also, I would like to extend my thanks to Edward Balbas, M.D., who advised and guided me in using the H-reflex and nerve conduction velocity test in my study, and as a certified expert in the field, helped me interpret the results. I am very grateful to Micheal Laymon for helping me develop the main idea in this study. Special thanks go to the Tai Chi (TC) instructor Mr. Harvey Kurland and his assistant, Ms. Myra Allen, for handling the TC classes throughout the study in such a professional manner. Also, I will not forget the program coordinator, Sondra Caposio, who was so modest, helpful, and kind in all the administration processes during my academic life at LLU.

Special thanks go to my wife, Shroog Alsubaihi, who was one of the most important factors in completing my doctoral degree. She was always there to offer me all means of comfort and keep me fully prepared for studying despite during her own studies as a PhD student and the care of our two children, , Danah and Naif. Also, I will not forget my parents who, though they supported my wish to be educated in the U.S., kept asking when I was going to finish and come back home! I'm sure that seeing me get my degree at the graduation ceremony would make them the happiest people in the world. I owe them a great debt and promise to make up for my time away by spending more time with them in the future.

I would extend my thanks to my government of Saudi Arabia for offering me this scholarship through King Saud University, and to my advisors at the Saudi Cultural Mission to the United States (SACM) for their sponsorship and guidance. I would like to acknowledge a unique and pioneering leader at SACM, Samar Al-Saggaf, the director of medical programs at SACM, for her important role in my educational and professional endeavors. She was always available to help me solve any problems and facilitated the processing of any academic requests. She never hesitated to offer her kind assistance and support.

Finally, I will not forget King Abdullah Al-Saud, who established the scholarship program in 2005, and his support of the education abroad program. To our deep sorrow and grief, he passed away on January 23, 2015. I am deeply saddened by his loss. I will keep him in my prayers and I hope to achieve his goals, visions, and dreams when I return to Saudi Arabia.

CONTENT

FIGURES

TABLES

ABBREVIATIONS

DM	Diabetic Mellitus
TC	Tai Chi
BMI	Body mass index
HbA1C	Hemoglobin A1C
ABC	Activities-specific Balance Confidence
OLS	One leg standing test
FRT	Functional reach test
WHO	World Health Organization
MI	Motor or mental imagery
APTA	American Physical Therapy Association
CSM	Combined Sections Meeting
IRB	Institutional Review Board
LLU	Loma Linda University
FAEC-FIRM	Feet apart, eyes closed and firm surface
TEO-FIRM	Tandem standing, eyes opened and firm surface
TEC-FIRM	Tandem standing, eyes closed and firm surface
FAEO-FOAM	Feet apart, eyes opened and foam surface
FAEC-FOAM	Feet apart, eyes closed and foam surface
TEO-FOAM	Tandem standing, eyes opened and foam surface
TEC-FOAM	Tandem standing, eyes closed and foam surface
NCV	Nerve Conduction Velocity studies
μV	microvolts
ms	milliseconds
m/s	meter per second
EMG	Electromyography

ABSTRACT OF THE DISSERTATION

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by

Abdulrahman Alsubiheen

Doctor of Science, Graduate Program in Physical Therapy
Loma Linda University, March 2015
Dr. Jerrold Petrofsky, Chairperson

Background: One of the effects of diabetes mellitus (DM), peripheral neuropathy, affects feet sensation and can increase the chance of falling. The purpose of the study was to investigate the effect of 8 weeks of Tai Chi (TC) training combined with mental imagery (MI) on improving balance in people with diabetes and an age matched control group.

Methods: Seventeen healthy subjects and 12 diabetic sedentary subjects ranging from 50-80 years of age were recruited. All subjects in both groups attended a Yang style of TC class, two sessions per week for 8 weeks. Each session was one hour long. Measures were taken using a balance platform test, an Activities-specific Balance Confidence *(*ABC*)* Scale, a one leg standing test (OLS), and a functional reach test (FRT). These measures were taken twice, pre and post-study, for both groups. Additional measurements for the DM group were hemoglobin A1C (HbA1C), H-reflex and nerve conduction velocity test.

Results: This study showed that both groups experienced significant improvements in ABC, OLS, FRT ($P < 0 .01$) after completing 8 weeks of TC exercise, with no significant difference improvement between groups. Subjects using the balance platform test demonstrated improvement in balance in all different tasks with no significant difference between groups. There was no significant change in HbA1C among people with diabetes. For the H-reflex, there was a significant increase in amplitude (μV) after completing 8 weeks of TC exercise (1226.9±320.8 vs. 1815.6±478.8, p=0.02). There were significant improvements in the sural nerve in terms of velocity (m/sec) (30.9±3.6 vs. 33.8±3.9, p=0.01), amplitude (μV) (18.2±4.1 vs. 7.6±1.2, p=0.01), and latency (ms) (3.7±0.4 vs. 3.4±0.4, p=0.01). In the superficial peroneal nerve, significant improvements were observed in velocity (m/sec) (p=0.02) and latency (ms) (p=0.01) but not in amplitude (μV) (p>0.05).

Conclusion: Combining TC with MI for 8 weeks resulted in an improvement in balance in the diabetic and the control groups; however, no significant difference between the groups was observed.

Keywords: Tai Chi exercise, balance, aging, diabetes, H-reflex and nerve conduction velocity test.

CHAPTER ONE

INTRODUCTION

Diabetes mellitus (DM) is a chronic disease with life-threatening complications, which has been dramatically increasing in prevalence worldwide expected to continue to affect more people in coming years. DM is characterized by silent symptoms, since most people are not aware they have the disease until they begin experiencing complications or advanced symptoms[1]. According to the World Health Organization (WHO), more than 347 million people worldwide have diabetes, and the prevalence is expected to double or even triple that number by the year 2030[2]. Diabetes prevalence is rising faster in some countries than in the United States; for example, the highest prevalence is in the Middle East[3-5]. One of the effects of diabetes mellitus (DM) is peripheral neuropathy, which affects sensation in the feet, disturbing balance increasing the risk of falls[6].

Peripheral neuropathy is a result of demyelination, which slows nerve conduction and due to the loss of axons, the nerve action potentials is slower as well[7]. The distal sensory fibers of the feet are usually the first to be affected, in what is known as the dying-back phenomenon[8-10]. The sural and superficial peroneal nerves are usually assessed in neuropathy using a series of clinical measurements called nerve conduction velocity (NCV) studies[11]. In this study, both sural and superficial peroneal nerves were evaluated before and after engaging in Tai Chi (TC) exercise. The sural nerve supplies sensation to the lateral aspect of the foot, heel, and ankle, in addition to the posterolateral aspect of the distal third of the leg. The superficial peroneal nerve supplies sensation on the dorsum of the foot, except for the web space between the hallux and second digit. Nerve conduction velocity (NCV) studies involve three specific parameters for analysis:

amplitude in microvolts (μV), measured from baseline to peak and which reflects the number of active nerve fibers; latency in milliseconds (ms), the time it takes from the electrical stimulus to the onset of an evoked response and conduction velocity in meter per second (m/s), which is measured as the distance between stimulation and the recording electrodes, divided by latency[12]. One of the tests used to measure sensory motor function is the H-reflex. This test measures sensory motor function by comparing the electrical activity of the muscle with direct stimulation of the motor nerve to reflex stimulation through spinal cord (monosynaptic). When motor nerve is stimulated, the nerve impulse goes in two directions, one impulse goes directly to the muscle causing it to contact and the other stimulate the sensory fibers from muscle spindle causing a monosynaptic reflex. If the reflex amplitude was exactly the same as the direct muscle stimulation, the ratio will be %100. Therefore, two different electrical amplitudes called M wave from the direct muscle stimulation and H-wave from monosynaptic reflex through spinal cord are measured. The normal H/M ratio is 50% in adults with no sensory impairment[13-15]. The difference in H-reflex before and after the exercise intervention can be used as an indicator of spinal plasticity as a result of motor learning[14].

Balance stability is controlled by the central nervous system, which integrates afferent information from the vestibular, visual, and somatosensory systems[6,16,17]. Sensory impairment starts in the distal lower extremities[18], among DM patients, usually both small and large nerve fibers are affected. The small fibers are responsible for pain and temperature sensation while large fibers are used for proprioception and light touch[18-20]. In addition to the normal age-related increases in the risk of falling, DM further increases this risk[21]. Aging and living with diabetes over a long period results in decreasing proprioception, which affects balance and protective reflexes[22]. The autonomic nervous system maintains blood flow for proper muscle and organ function, and aging and DM can diminish blood flow to these tissues[23]. This, in turn, can reduce the effectiveness of all three balance system components and, as a consequence, lead to somatosensory loss (proprioception), as well as vestibular system and vision impairments[6,16,17]. During activities which require balance, blood flow increases to the somatic and central nervous systems to help control balance[24-26]. Both aging and DM can lead to poor peripheral circulation[6,16,17]. General muscle weakness is common in people with diabetes, which reduces their ability to maintain their center of gravity in a stable position over their base of support without falling[27]. Decreasing somatosensory information from the foot and ankle causes postural instability, leading to foot injuries, foot ulcers, and possibly lower limb extremity amputation[17,28-31]. It is estimated that more than 60% of non-traumatic lower-limb amputations are related to DM[6,16,17,29,32]. Falling is a predicted result of postural instability and is considered a major problem in older people and people with DM[21]. Previous studies have shown that balance training such as Tai Chi (TC) exercise can improve balance control[33-41]. Other studies have demonstrated an increase in balance with mental or motor imagery (MI) [42,43].

Tai Chi is a cultural Chinese exercise that improves balance and postural control. It is called a body-mind technique because the person uses his or her mind while accomplishing the exercise[44]. TC as exercise consists of weight shifting, postural alignment, and slow coordinated movements with synchronized deep breathing[45,46]. This combination involves many different mental and physical elements, such as quiet concentration on the movement, following the instructor’s example to achieve the proper form to improve muscle elasticity, while tying the movement to deep breathing in order to enhance cardiac output and support the muscles with sufficient blood flow[47,48].

Tai Chi differs from any other types of exercise such as running, because the complex series of movements requires the individual to concentrate while performing each movement. Concentration also is important in re-learning or re-conditioning a damaged nervous system. In many patients with diabetes, the feet provide false (signal) information to the brain about ground reaction forces. In TC, subjects move slowly, visualizing the movement while concentrating on how each movement feels; this helps people to become more aware of sensation. Previous studies have showed the role of mental or motor imagery in terms of re-learning or re-conditioning[49,50].

Some studies have shown that 12 weeks of TC intervention has positive results in elderly people in terms of improving the H- reflex[51,52]. Many studies have shown that TC has positive results in elderly people in terms of minimizing the risk of falls and improving balance[33-37,53-57], proprioception[47,58], circulation[59,60] and blood pressure[38]. In a majority of the studies, program interventions were lengthy, varying between 4 months to 5 years[33-35,37,39-41,47,56,58,61,62]. Both elderly people and the diabetic population had somatosensory impairments, and while aging adds its own impairments, the neuropathic and circulatory damage associated with diabetes further reduces somatosensory function.

Motor or mental imagery (MI) is defined as "the mental representation of movement without any movement[49]. It is a process of imagining an action without executing it. The subject relies on memory to understand the process of the action. During mental practice, the subject repeats the imagined acts to master the actual performance of the movement[49]. The combination of physical and mental practice helps restore successful movement. In this process, the person mentally and explicitly rehearses the order of action required while doing the task. The focus and planning increases awareness of the required task[49,50,63]. In a transcranial magnetic stimulation (TMS) study, the motor imagery of gait and foot movement caused corticospinal excitability[64].

The purpose of this clinical trial study was to examine the effect of 8 weeks of TC training, combined with mental imagery, on improving balance in people with diabetes and an age matched control group. In this study, it was hypothesized that focusing on mental imagery approaches during TC training would help optimize and improve balance and sensation in a shorter treatment time.

The main focus of this study was to examine the role of combining of Tai Chi (TC) exercise with mental imagery (MI) in improving balance, circulation, and nerve testing in people with diabetes and an age matched control group. In Chapter Two, we look at the effect of 8 weeks of TC training, combined with mental imagery, on improving balance in people with diabetes and an age matched control group. Chapter Three focuses on the effect of 8 weeks of TC training combined with mental imagery MI on soleus H-reflex and nerve conduction velocity (NCV) tests for sural and superficial peroneal nerves in people with diabetes.

Diabetes mellitus is a disease which causes many complications, and prevalence is increasing dramatically[2], making it a worldwide health threat. One of the effects of diabetes mellitus (DM), peripheral neuropathy, affects the peripheral nerves and circulation; it also impairs somatosensory information from the ankle and feet which are important in control balance[65]. Demyelination slows nerve conduction and the loss of axons also decreases nerve action potential [7]. Balance is affected as we age, and this is particularly true for diabetics over age 60. These losses occur slowly, with reflexes becoming more sluggish over time[21,30,31,66]. Despite the aging increases the risk of falling, diabetes further increases the chance of falling[21]. Exercise and diet are important factors in controlling diabetes and age related impairments.

The primary purpose of this prospective clinical study was to examine the effect of 8 weeks of TC exercise and mental imagery in improving balance, balance self-confidence, H-reflex and NCV tests in a group of diabetics compared to age matched controls. To our knowledge, this was the first study using TC that focused on MI strategies. In this clinical trial, we hypothesized that TC exercise for 8 weeks combined with focusing on mental imagery would improve balance control and lessen fears about falling and balance.

The Activities-specific Balance Confidence (ABC) scale was used as the percent change variable meaning a smaller percent indicates more improvement. In this clinical trial, although the diabetic group had more balance impairment at baseline compared to the control group, both groups showed significant improvement and identical results. For the functional reach test (FRT), measurements were similar at baseline for both groups, and both groups showed significant improvement in similar amounts. For the one leg standing test (OLS), the amount of time that the diabetic group could stand at baseline was lower than in the control group; however, there was significant improvement in both groups. This result was consistent with the other balance outcome measures in this study that showed more improvement in the diabetic group since their impairment was more significant at baseline.

Similarly, both groups improved in the balance platform tasks, with no significant difference between them; this indicates that TC exercise was beneficial for both groups. The three altered sensory factor tests (TEC-FOAM), which are considered the most difficult, showed significant improvement in both groups.

The amplitude of soleus H-reflex significantly improved, which is related to more nerve fibers recruited after TC exercise. The results of the sensory nerve conduction velocity tests of the sural and superficial peroneal nerves showed significant improvement in velocity and latency onset after completing the 8 week TC intervention. Using mental imagery during TC exercise aided in “re-learning” the movements, enhancing the somatosensory system and helping restore some functions lost due to aging and /or diabetes. The improvement was demonstrated in different ways such as understanding the sequence of the movement from the instructor, doing the movement in front of the mirror, feeling each sequence of movement, and doing the exercise with no shoes or socks on thick foam to make it more challenging. Together these elements help increase muscle flexibility and postural stability in a wider base of support. Also, combining TC with mental imagery concepts may increase peripheral blood circulation warm the skin, which increases nerve conduction. This in turn improves touch sensation, or proprioception, which helps the foot recognize abnormal forces on the ground, minimizing the chance of falling. Moreover, increasing peripheral circulation helps to supply tissues with adequate blood flow, which ultimately increases muscle control and balance. Practicing TC for years has demonstrated improvement in the peripheral microcirculation[59,60].

In this study, both groups showed significant improvement in balance after the 8 week intervention. Similar improvements were noticed in both groups but since the diabetic group had more balance impairment at baseline, this group saw more benefit. Other studies have shown that TC improves balance, however, in those studies the exercise program was longer than 8 weeks [33-37,39-41,56,58,61,62] or was more intense on a daily basis[53,55,67]; in our study, participants did TC exercise twice a week for 8 weeks. Using concepts of mental imagery shortened the length of the TC program to get the same result, making the TC more effective over a shorter period. Practicing TC for years has been shown to induce changes in brain structure (brain morphometry) [68]. In previous studies, researchers found that TC improves the H-reflex; however, in those studies, the programs were 12 weeks long [51,52] or over a period of years [69]. In this study, H-reflex and NCV tests for sural and superficial peroneal nerves demonstrated improvement after 8 weeks of TC intervention using mental imagery. The use of mental imagery made the 8 week program both efficient and beneficial.

This study explored the use of TC -- both duration and intensity -- together with the use of mental imagery to accelerate the "re-learning" process and improve function. The findings of this study showed an improvement at 8 weeks with mild intensity TC exercise (1hour/2times/week), while most studies used similar or longer duration interventions or more intense daily programs. The study had some limitations. Measurements were not taken at the mid-point of the study (4 weeks) to check the subjects' progress. Also, 40% of the diabetic group dropped out due to scheduling conflicts. However, this attrition might also be seen as reluctance to exercise on the part of sedentary participants unused to such activity[70]. Increasing peripheral circulation (microcirculation) is a possible reason for the improvement in the H-reflex and NCV tests. Future studies should measure blood flow peripherally before and after exercise.

Based on this findings of this study, physical therapists are encouraged to recommend and integrate Tai Chi in physical therapy practice as a therapeutic intervention to improve balance and general wellness among their diabetic and geriatric patients[71,72]. The results of this study suggested that teaching patients to focus on mental imagery while doing TC exercise is the best way to promote and accelerate the "re-learning" process to improve balance.

CHAPTER TWO

EFFECT OF TAI CHI EXERCISE COMBINDED WITH MENTAL IMAGERY THEORY IN IMPROVING BALANCE IN A DIABETIC AND ELDERLY POPULATION

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Abstract

Background: Diabetes mellitus (DM) is a disease that threatens the health of people worldwide due to its widespread prevalence and many complications, including loss of balance.

Objective: To investigate the effect of 8 weeks of Tai Chi (TC) training combined with mental imagery (MI) on improving balance in people with diabetes and an age matched control group.

Design: Pre- and post-test on a diabetic group compared to the control group.

Subjects: Seventeen healthy subjects and 12 diabetic sedentary subjects ranging from 50-80 years of age with no history of TC exercise were recruited for this study. They did not have any orthopedic, neurological, or cardiovascular conditions or back pain. Subjects were not taking any medication that could affect balance. Their body mass index (BMI) was between 10 and 35 kg/m^2. In the diabetic group, subjects were included if they had a history of type 2 diabetes for 2-20 years and had a hemoglobin A1C (HbA1C) between 6 and 10. Subjects had no foot ulcers.

Intervention: All subjects in both groups attended a Yang style of TC class, two sessions a week for 8 weeks. Each session was one hour long.

Outcome Measures: Measures were taken using a balance platform test, an Activities-specific Balance Confidence (ABC) Scale, a one leg standing test (OLS), functional reach test (FRT) and HbA1C. These measures were taken twice, pre and post-study, for both groups.

Results: This study showed that both groups experienced significant improvements in ABC, OLS, FRT (P <0 .01) after completing 8 weeks of TC exercise with no significant difference between groups. Subjects using the balance platform test demonstrated improvement in balance in all different tasks with no significant difference between groups. There was no significant change in HbA1C for the diabetic group after completing the exercise program.

Conclusion: Combining TC with MI for 8 weeks resulted in an improvement in balance in the diabetic and the control groups; however, no significant difference between the groups was observed. Since the DM group had more problems with balance impairment at baseline than the control, the diabetic group showed the most benefit from the TC exercise.

Keywords: Tai Chi exercise, balance, aging, diabetes and falling.

Introduction

Diabetes mellitus (DM) is a silent systematic disease that threatens world health. It can be present for a few years with no symptoms, and most people do not know that they have the disease until they experience complications or advanced symptoms. In addition, most people with DM do not notice the onset of symptoms such as frequent urination or extreme thirst because these symptoms increase gradually over a period of years, making it difficult for patients to notice the changes[1]. According to the World Health Organization (WHO), more than 347 million people worldwide have diabetes, and prevalence will increase to double or even triple that number by the year 2030[2]. Diabetes prevalence rises faster in some countries than in the United States; for example, the Middle East has one of the highest diabetes prevalence rates in the world, and it is also considered to have the highest incidence rate, or number of new cases, of diabetes[3-5]. Some causes include a change of lifestyle in the Middle East, especially dietary habits. One of the effects of diabetes mellitus (DM), peripheral neuropathy, affects the feet sensation which can increase the chance of falling[6].

The central nervous system integrates the afferent information from the vestibular, visual and somatosensory systems to control balance[6-8]. The autonomic nervous system maintains blood flow for proper muscle and organ function[9]. During activities that require balance, blood flow increases to help the somatic and central nervous systems control balance by providing sufficient blood flow to somatosensory organs[10-12]. The combination of aging and living with DM can impair blood flow to tissues. This, in turn, can reduce the effectiveness of all three balance system components and, as a consequence, leading to somatosensory sensation (proprioception), vestibular system and vision impairments[6-8]. After a few years, a patient's muscles become weaker, reducing their ability to maintain their center of gravity in a stable position over their base of support without falling[13]. As somatosensory information from the foot and ankle is affected, it causes postural instability, leading to foot injuries, foot ulcers, non-healing wounds and possibly lower limb extremity amputation[8,14-18]. It has been estimated that more than 60% of non-traumatic lower-limb amputations are related to DM[14]. Falling is an expected result of postural instability and considered a major problem in older people and people with DM[8,16,17,19,20]. Studies have shown that balance training such as Tai Chi (TC) exercise can improve postural stability[21-30]. Other studies have shown an increase in balance with motor imagery[31,32].

Tai Chi (TC), as a traditional exercise regimen, has been practiced in China to improve balance and postural control. It is called a body-mind technique because the person uses his or her mind while accomplishing the exercise[33]. TC is a combination exercise involving weight shifting, postural alignment, and slow coordinated movements with synchronized deep breathing[34,35]. This combination involves many different mental and physical elements, such as calm concentration on the movement, following the instructor's example to achieve the proper form to improve muscle elasticity (stretching), while tying the movement to deep breathing in order to enhance cardiac output and support the muscles with adequate blood flow[36,37].

Tai Chi (TC) differs from other forms of exercise such as running, because the complex series of movements requires the individual to concentrate while performing each movement. Concentration also is important in re-learning or re-conditioning a damaged nervous system. In many patients with diabetes, the feet provide false (signal) information to the brain about ground reaction forces. In TC, subjects move slowly, visualizing the movement while concentrating on how each movement feels; this helps people to become more aware of sensation. Previous studies have supported the role of mental or motor imagery in terms of re-learning or re-conditioning[38,39].

Many studies have shown that TC has positive results in elderly people in terms of minimizing the chance of falls and improving balance[21-25,40-44], proprioception[36,45], circulation[26,46] and blood pressure[27]. In a majority of the studies, program interventions were lengthy, varying between 4 months to 5 years[21-23,25,28-30,36,43,45,47,48]. Both elderly people and the diabetic population had somatosensory impairments, and while aging adds its own impairments, among diabetics, neuropathic and circulatory damage further reduce somatosensory function.

Motor or mental imagery (MI) is defined as “the mental representation of movement without any movement” [38]. It is a process of imagining an action without executing it. The subject relies on memory to understand the process of the action. During mental practice, the subject repeats the imagined acts to improve the actual performance of the movement[38]. The combination of physical and mental practice helps to restore successful movement. In this process, the person mentally and explicitly rehearses the sequence of movements required while doing the task. The focus and planning increases awareness of the required task[38,39,49]. In a transcranial magnetic stimulation (TMS) study, the motor imagery of foot movement and motor imagery of gait resulted in corticospinal excitability[50].

Although TC is an ancient form of exercise used in China and other countries, it has recently attracted researchers’ interest. Currently, researchers are conducting clinical trials to examine information in Chinese history books that addresses the multiple benefits of TC exercise, including balance improvement. In addition, some clinical sites have started to provide TC as a therapeutic intervention[51-53]. Lately, physical therapists have become interested in the uses of tai chi to improve balance and co-ordination. Between 2012 and 2015, The American Physical Therapy Association (APTA) has conducted workshops and education sessions on the use of TC as an intervention at the annual Combined Sections Meeting (CSM) in sections such as neurology, geriatrics, and women's health. The purpose of this current study was to investigate the effect of 8 weeks of TC training, combined with mental imagery, on improving balance in people with diabetes and an age matched control group. In this study, it was hypothesized that focusing on mental imagery strategies during exercise with TC would help in optimizing and improving balance and sensation in a shorter treatment time.

Methods

Study Design

A prospective study on a diabetic group and an age-matched control was conducted. The study's design was a pre- and post-test longitudinal design. After screening for inclusion and exclusion criteria, all subjects were tested twice, at baseline and again after the completion of an 8-week TC class which met twice a week for an hour per session (total 16 hours of TC exercise). Both groups received the same intervention of TC exercise classes.

Subjects

This study was approved by the Institutional Review Board (IRB) at Loma Linda University (LLU) and conducted at the Physical Fitness Laboratory at the School of Allied Health Professions (SAHP), Department of Physical Therapy. Subjects were recruited from the Drayson Fitness Center and the Diabetes Treatment Center at LLU. All subjects read and signed the informed consent form before they began the study.

The study subjects were 50 to 80 years of age and recruited using several methods. Study flyers were placed on the main bulletin board of the School of Allied Health Professions and the Drayson Fitness Center (main gym) in LLU (APPENDIX A). This flyer was also sent via email to all faculty and students in the School of Allied Health Professions. The Diabetes Treatment Center at LLU assisted by referring interested diabetic patients to the study research team and providing them with the study flyer if they felt they met the study criteria.

The following inclusion/exclusion criteria were used to determine eligibility for enrollment in the study. Inclusion criteria included: 1) had not practiced TC; 2) did not exercise more than once per week; 3) body mass index (BMI) between 10 and35 Kg/m^2; 4) normal or controlled blood pressure; and 5) functional range of motion, at least 5/5 muscle power bilateral. Subjects were excluded if they: 1) took medications which could affect balance; 2) had a history of frequent falling; 3) had vision problems; and 4) had orthopedic/ neuromuscular/ cardiovascular impairments that restricted exercise. A researcher determined eligibility for inclusion through telephone interviews to match the inclusion/exclusion criteria. Those who met the inclusion criteria were divided into two groups, control or diabetic.

A convenience sample of 40 subjects, 20 of them diagnosed with Type 2 diabetes and 20 subjects who were in the control group (Figure 1). Eleven subjects withdrew due to conflicts with the TC class schedule. Data analysis was based on the remaining 29 subjects who completed the study. Twelve were diagnosed with Type 2 diabetes and 17 were in the control group.

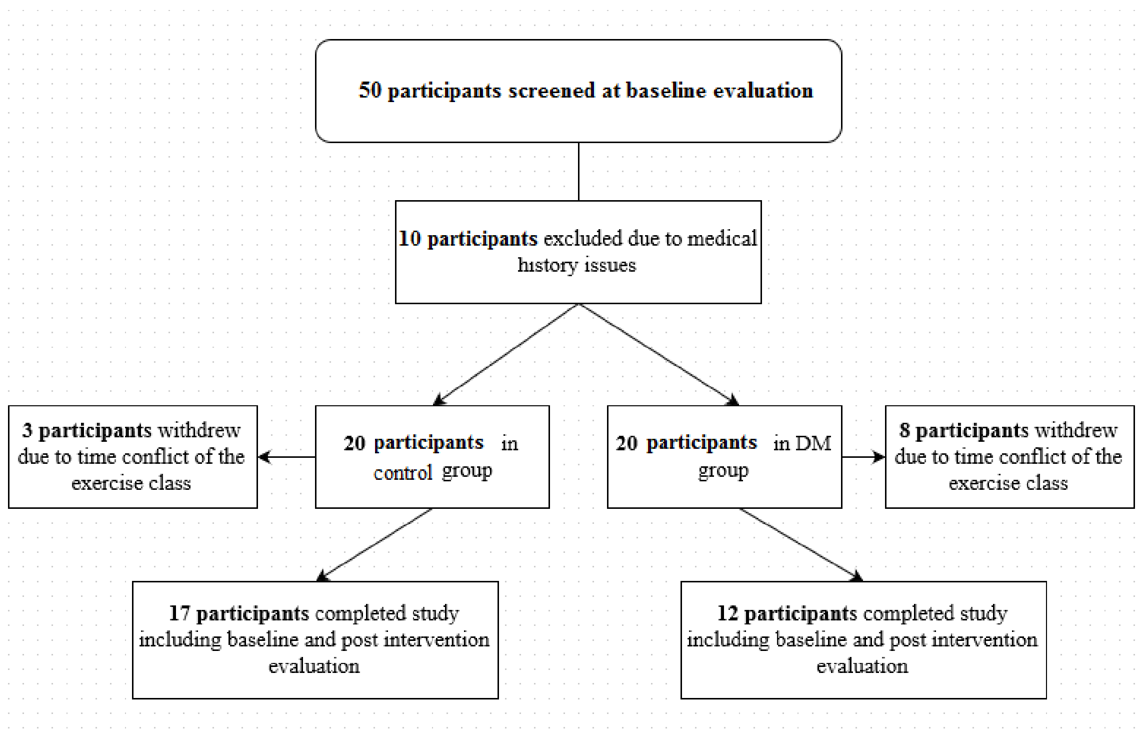

Figure 1. The Progression of Subjects during the Study

Outcome Measures

In this study, the following tools were used before and after the intervention.

Balance Platform Test

The balance platform used in this study was developed by Petrofsky et al. (2009) and has been validated in a previous study[54]. This device consisted of four stainless steel bars mounted at four corners of the platform (TML Strain Gauge FLA-6, 350-17, Tokyo, Japan). The output of the strain gauge bridge was amplified by four BioPac 100C low-level bio-potential amplifiers and recorded on a BioPac MP 150 system through a 24-bit A/D converter. The sampling rate was 2000 samples per second (Figure 2).

During the test, a gait belt was placed around the subject's waist as a safety precaution and a researcher remained nearby to prevent falls. Each subject stood over the platform while performing eight different tasks, or positions. Each position was executed with eyes opened and closed. At the beginning, the subject was asked to keep their eyes fixed on a target on the wall, with arms crossed on the chest and standing quietly on the platform with feet apart for 10 seconds. The center of mass provided weight distribution among the four sensors. The device recorded sway. The subjects were asked to perform the eight tasks in random order for 10 seconds each with one minute rest time between each task. The eight tasks were: 1) Feet apart, eyes opened and firm surface (this task used as referent for each subject); 2) Feet apart, eyes closed and firm surface (FAEC-FIRM); 3) Tandem standing, eyes opened and firm surface (TEO-FIRM); 4) Tandem standing, eyes closed and firm surface (TEC-FIRM); 5) Feet apart, eyes opened and foam surface (FAEO-FOAM); 6) Feet apart, eyes closed and foam surface (FAEC-FOAM); 7) Tandem standing, eyes opened and foam surface TEO-FOAM); and 8) Tandem standing, eyes closed and foam surface (TEC-FOAM) [55]. The basic task was to stand with feet apart on a firm surface with eyes open. For each subject, this task was used as referent for all tasks. This test was used to alter and challenge different sensory systems. In this study, three factors were used, both singly and in combination, to investigate the effect on balance (Table 3). These factors were: 1) base of support; 2) surface challenge; 3) vision. The mean coefficient variation was calculated to compare pre- and post-test results using the basic task as a referent for each subject.

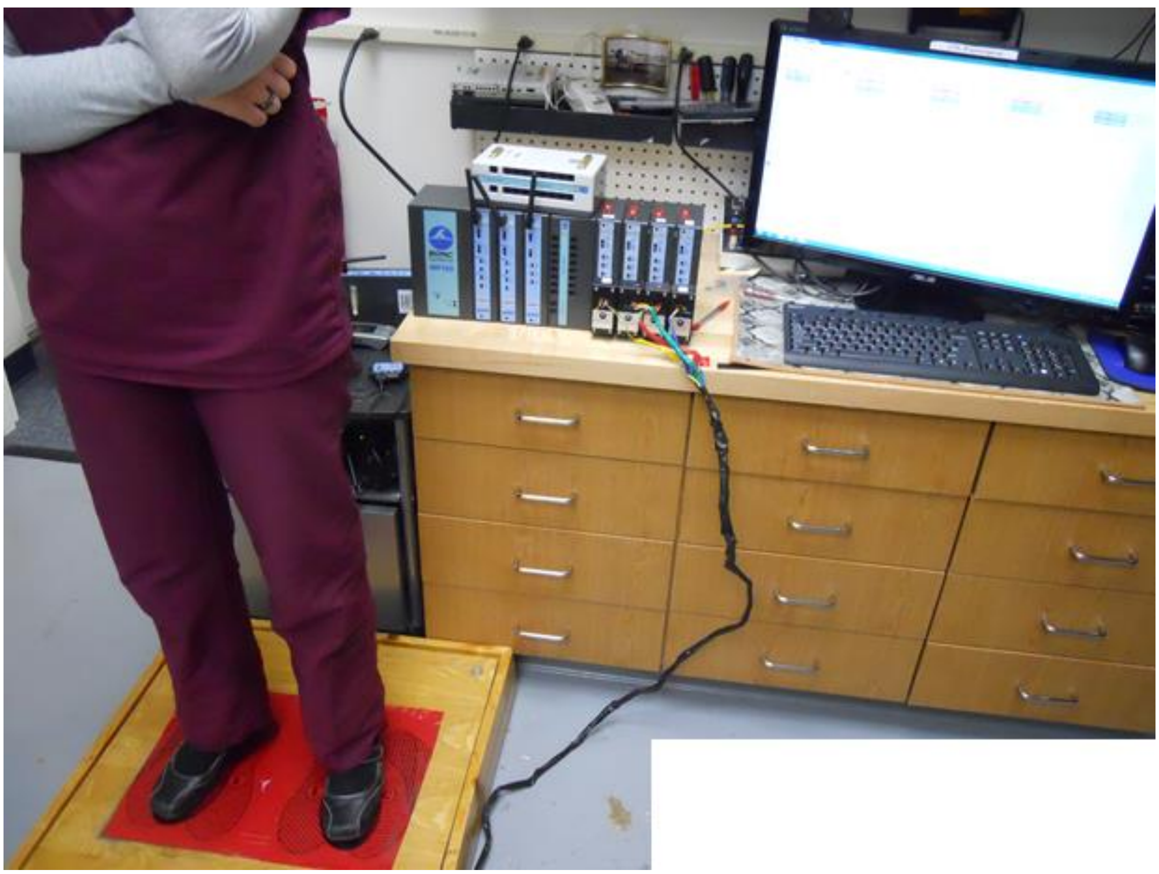

Figure 2. Balance Platform System.

The Activities-specific Balance Confidence *(*ABC*)* Scale

Subjects completed the 16-item Activities-specific Balance Confidence (ABC) scale (APPENDIX B)[56] that subjectively quantifies patient confidence when performing mobility tasks Among the elderly, researchers demonstrated that the ABC scale has excellent test-retest reliability (r=0.92, p<0.001)[56]. Furthermore, a previous study had shown that the ABC scale has adequate criteria and construct validity[57]. The ABC score was calculated as following:

$$\frac{\text{sum of the 16 questions} - 1600}{1600} \times 100$$

Functional Reach Test (FRT)

The FRT was used to assess dynamic balance[58]. A yardstick was placed on the wall at shoulder level and the subjects were asked to stand with their dominant shoulder next to the wall without touching or leaning on the wall and then elevate their arm to 90 degrees of shoulder flexion parallel to the wall. The investigator recorded the starting position at the distal end of the third metacarpal head on the yardstick. The subject then was asked to reach forward as much as possible without taking a step forward, and the maximum reaching point was recorded. The investigator demonstrated the task and asked the subject repeat it as to ensure that the subject performed the test correctly. The subject performed the task three times and the average was recorded. The FRT has excellent test retest reliability (ICC= .92) and inter rater reliability (ICC=.98) [58]. Previous studies indicated that FRT has good criterion validity[59,60] and responsiveness[61].

One Leg Standing Test (OLS)

This test was performed to assess static balance[62,63]. The subject was asked to stand on one leg with eyes open and arms on the hips. The length of time was recorded from when the patient's foot was off the floor until it touched the floor again. The investigator demonstrated the task and asked the subject to perform it. The subject then performed the task three times and the average was recorded. Researchers have found that the OLS has a good interclass correlation coefficient (ICC range=0.95 to 0.099) and within the rater interclass correlation coefficient (ICC= 0.73 to 0.93) [64].

The HemoglobinA1C for Diabetic Group

The hemoglobin A1C (HbA1C) is the most common measure of long term glycemic control[65,66]. This is a blood test to measure the average concentration of blood glucose over the last 3 months indirectly through glycated hemoglobin. Approximately 5µL of blood (from finger stick) was obtained and used to measure the HbA1C with a Food Drug Administration (FDA) approved device called the DCV Vantage analyzer (SIEMENS®, Tarrytown, NY, USA). (Figure 3). The HbA1C test is not affected by eating, thus, blood samples for this test can be taken without regard to when food was last eaten[65,66].

Figure 3. HbA1C Analyzer

Intervention

All subjects in both groups underwent the same TC exercise program. A certified TC instructor handled the class for the entire program which involved 2 sessions a week for 8 weeks. Each session was one hour. TC has many styles, and we determined that the Yang style was the most appropriate because it had the important characteristics relevant to motor imagery and somatosensory enhancement. These characteristics included slow coordinated movement, weight shifting with wide steps, a one-leg stance, stretching, and mental concentration. The exercise was conducted on a thick mat and with shoes off for greater sensory enhancement and challenge as indicated in previous studies[67,68]. In this study, subjects were asked to concentrate on sequence of each movement in TC. Also, they were asked to mentor the exercise visually from the TC instructor before they executed any movement. Then, they were instructed to do and feel the movement sequence while watching themselves in front of the mirror; this was done with supervision from the instructor to correct any movement if needed to achieve better outcomes as reported in a previous study[69].

Procedures

An appointment was scheduled for baseline testing with subject who met the inclusion/exclusion criteria. Subjects were provided with detailed information regarding the purpose of the study, procedures and tests, potential risks and scheduled time of the TC exercise. If the subject agreed to proceed, he/she signed the informed consent form as approved by the IRB (APPENDIX C) before proceeding to testing and taking measurements.

A researcher took all subject measurements. Baseline measurements were taken to assess balance using the following tools: 1) balance platform test; 2) the activities-specific balance confidence *(*ABC*)* Scale, 3) one leg standing test (OLS), and 4) function reach test (FRT). In addition, HbA1C blood test was done for the diabetic group only. Both diabetic and control groups received the same intervention for the TC exercise.

Subjects participated in 1 hour sessions, 2 times a week for 8 weeks. Each session consisted of 15 minutes of warming-up exercises, including stretching, loosening the muscles, and breathing exercises, and followed by 45 minutes of TC exercise, Yang style (Figure 4).

Normal and diabetic subjects were recruited into the appropriate groups. Subjects had an interview for the inclusion and exclusion criteria as screening tools for the study requirements. Subjects were given a consent form to read and sign. All subjects had the same type intervention of TC exercise. The first test was conducted during the informed consent process, and then outcome measures taken after the subjects completed the 8-week TC exercise intervention. The measurements took around 2-3 hours to complete each measure.

The measurements were taken at the Physical Therapy Research Laboratory, Nichol Hall, Loma Linda University, Loma Linda, CA. The TC class was held at Drayson Fitness Center, Loma Linda University.


Figure 4. Participants during Tai Chi class

Data Analysis

Data were analyzed using SPSS for Windows Version 22.0. The demographic characteristics of the subjects were compared between the diabetic and control groups using independent t-test for the quantitative variables and Chi-square for independence for categorical variables. The normality of the outcome variables at baseline and post intervention was examined using the One-sample Kolmogorov-Smirnov test. Since the distribution of these variables was not approximately normal, the baseline scores and differences between post and pre measures for ABC, FRT and OLS were compared between the two groups using the Mann-Whitney U test. In each study group, comparisons between post and pre measures after the TC exercise were assessed using the Wilcoxon Signed rank test. For the different balance tasks, changes between post and pre measures were examined using paired t-test and between diabetic and control groups using an independent t-test. The level of significance was set at $p \leq 0.05$.

Results

Twenty nine subjects completed the study, 12 (41.4%) diabetics and 17 (58.6%) controls. The distribution of age, gender, and BMI were similar in both study groups (Table 1). Among subjects with diabetes, the average duration of the disease was 10.8±5.4 years with a mean A1C of 6.8±0.8. (Table 1)

Table 1. Demographic Characteristics of Subjects (N=29)

Characteristic	**Diabetic (n=12)**		**Control (n=17)**		***P* value [a]**
	Mean (SD)	n (%)	Mean (SD)	n (%)	
Age (years)	63.8 (8.1)		63.6 (6.5)		0.91
Gender (Female) [b]		8 (66.7)		13 (76.5)	0.43
Weight (Kg)	86.8 (17.2)		77.4 (17.4)		0.16
Height (m)	1.8 (0.1)		1.7 (0.1)		< 0.01
BMI (Kg/m^2)	27.9 (5.5)		27.1 (4.3)		0.66
Duration of diabetes (years)	10.8 (5.4)				
A1C at baseline	6.8 (0.8)				

Abbreviation: SD, standard deviations; BMI, body mass index.
a *P* value from Independent t-test
b Chi square

The mean ABC score improved significantly in both groups. Among subjects with diabetes, the average dropped from17.7±3.3 to 6.5±1.3 ($p<0.01$) and from 7.5±2.8 to 3.5±1.1 in the healthy controls ($p<0.01$). However, there was no significant difference found between the two groups (p=0.17). Similar findings were observed for the FRT and the OLS test. In the diabetic group, the mean FRT distance increased from11.2±0.5 to 12.8±0.6 inches (p<0.001) and from 11.7±0.4 to 13.3±0.5 inches in the controls (p<0.01) and this difference was not significant between the two study groups (p=0.91). Also, the mean OLS time increased from 29.8±12.3 to 48.5±17.3 seconds (p<0.01) and from 44.4±10.4 to 80.5±14.6 seconds in the healthy controls (p<0.01) and this improvement was not significantly different between the two groups (p=0.17; Table 2, Figures 5, 6, 7).

Table 2. Changes in ABC, Functional Reach Test and One Leg Standing Test in Diabetic (n=12) and Control (n=17) Subjects

Tool	**Group**		**Mean (SE)**	**Pre-post *P* value[a]**	**Between Group *P* value[b]**
ABC	Diabetic	Pre	17.7 (3.3)	< 0.01	0.17
		Post	6.5 (1.3)		
	Control	Pre	7.5 (2.8)	< 0.01	
		Post	3.6 (1.1)		
Functional reach test	Diabetic	Pre	11.2 (0.5)	< 0.001	0.91
		Post	12.8 (0.6)		
	Control	Pre	11.7 (0.4)	< 0.01	
		Post	13.3 (0.5)		
One leg standing test	Diabetic	Pre	29.8 (12.4)	< 0.01	0.17
		Post	48.5 (17.4)		
	Control	Pre	44.4 (10.4)	< 0.01	
		Post	80.5 (14.6)		

Abbreviation: SE, standard error
a *P* value from Wilcoxon Signed Rank Test
b *P* value from Mann- Whitney U Test

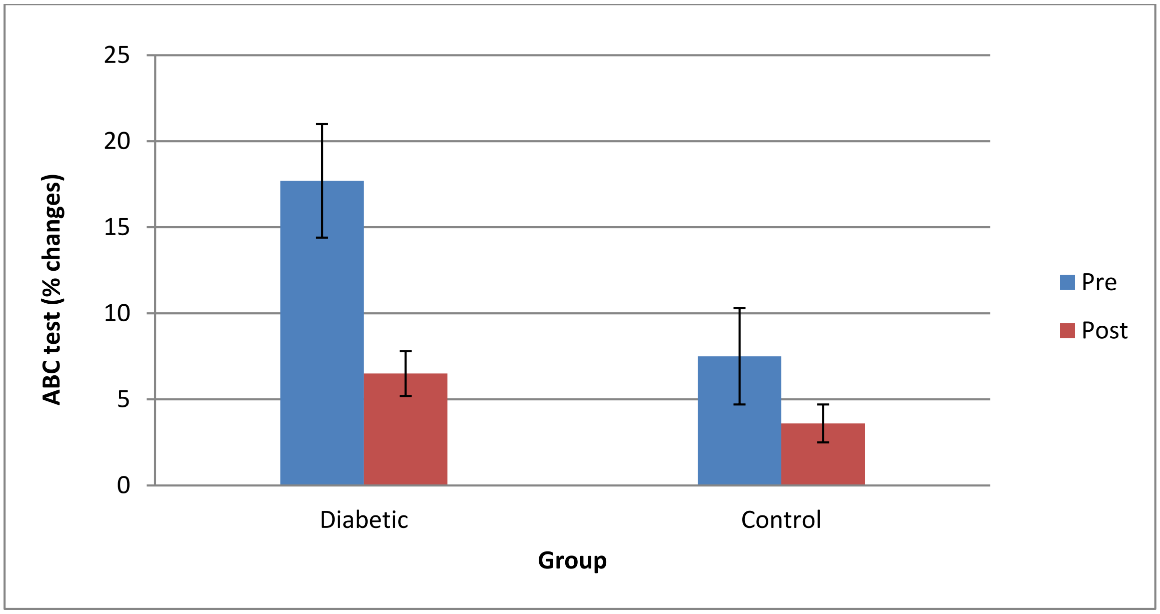

Figure 5. Mean ± SE of ABC Test Score between Two Groups Over Time
Abbreviations: SE, standard error

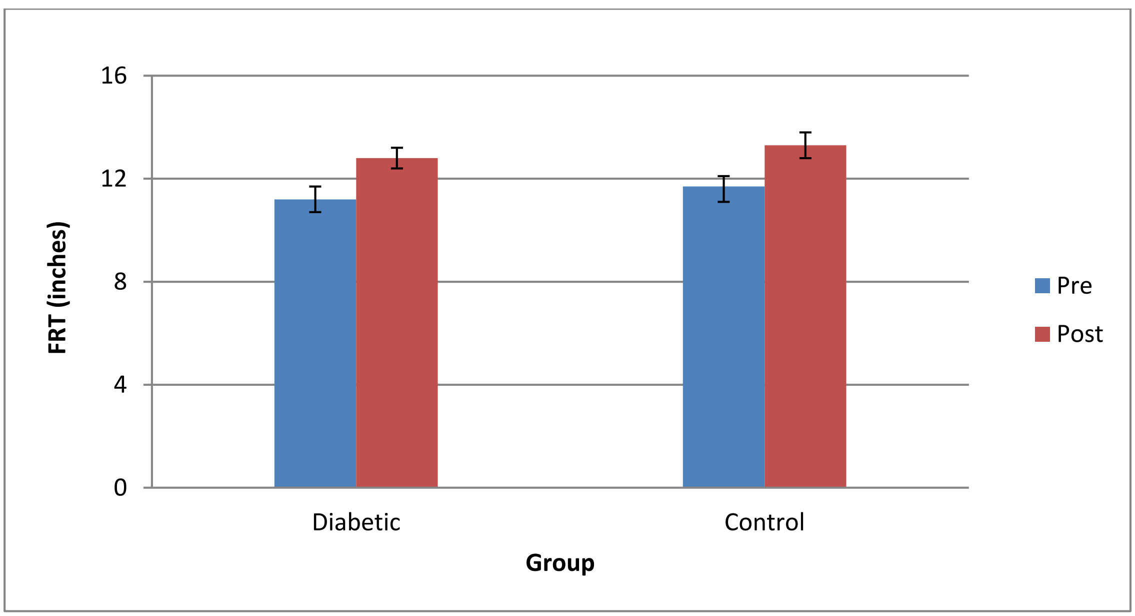

Figure 6. Mean ± SE of Functional Reach Test Score between Two Groups Over Time
Abbreviations: FRT, Functional Reach Test. SE, standard error

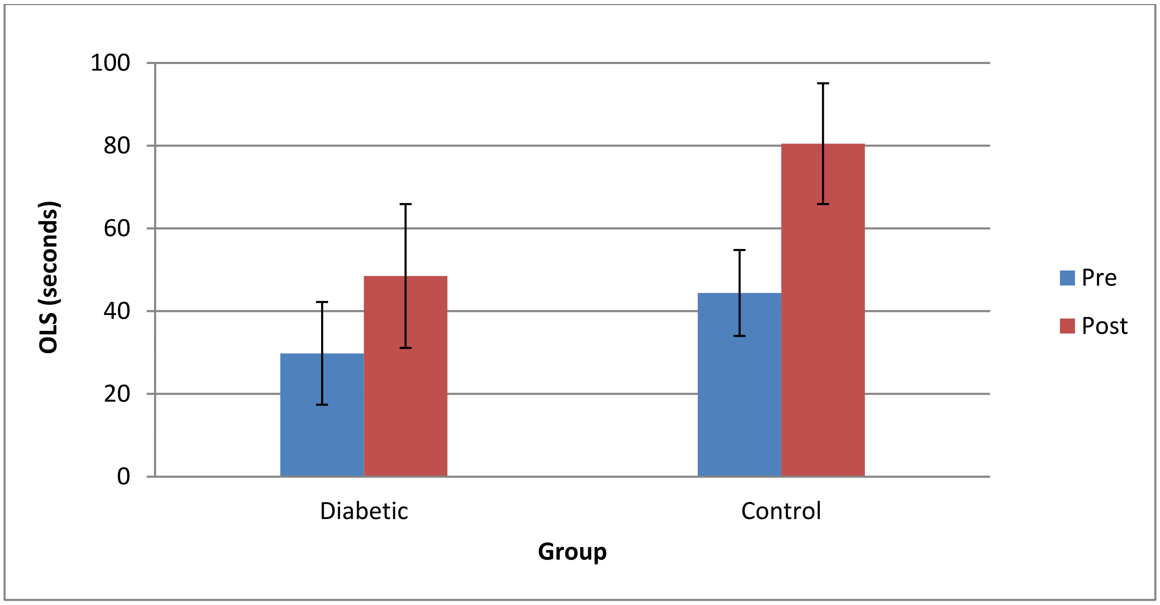

Figure 7. Mean ± SE of One Leg Standing Test Time between Two Groups Over Time
Abbreviations: OLS, One Leg Standing

In the diabetic group, there was no significant difference between HbA1C at baseline and after 8 weeks of TC training (6.8±0.8 to 7.0±1.4, p=0.50).

Both groups had balance improvements for the various tasks of balance platform; however, this improvement did not differ between groups (Table 3 and Figures 8, 9). Both groups experienced significant improvement for the following tasks in stations TEO-FIRM, FAEC-FOAM and TEC-FOAM.

Table 3. Changes in Different Stations of Balance Platform in Diabetic (n=12) and Control (n=17) Subjects

Station	Position	N. of altered factor	Sensory Factor(s)	Group		Mean (SE)	Pre-post *P* value[a]	Between Group *P* value[b]
TEO-FIRM	***Tandem standing*** Eyes open Firm surface	1	Base of Support	Diabetic	Pre	77.51 (45.48)	0.03	0.24
					Post	39.21 (22.02)		
				Control	Pre	152.70 (36.59)	0.02	
					Post	74.11 (17.71)		
FAEO-FOAM	Feet apart Eyes open ***Foam surface***	1	Surface challenges	Diabetic	Pre	125.90 (77.36)	0.56	0.29
					Post	108.10 (66.83)		
				Control	Pre	310.25 (64.99)	0.16	
					Post	154.85 (56.15)		
FAEC-FIRM	Feet apart ***Eyes closed*** Firm surface	1	Vision	Diabetic	Pre	157.86 (44.02)	0.18	0.89
					Post	101.82 (33.47)		
				Control	Pre	274.13 (36.99)	0.22	
					Post	207.83 (28.12)		
TEO-FOAM	***Tandem standing*** Eyes open ***Foam surface***	2	Base of support Surface challenges	Diabetic	Pre	159.67 (156.41)	0.04	0.26
					Post	82.91 (27.30)		
				Control	Pre	416.92 (131.41)	0.08	
					Post	122.71 (22.94)		
TEC-FIRM	***Tandem standing*** ***Eyes closed*** Firm surface	2	Base of support Vision	Diabetic	Pre	258.29 (140.27)	0.26	0.26
					Post	167.54 (35.22)		
				Control	Pre	432.15 (117.85)	0.05	
					post	137.75 (29.59)		
FAEC-FOAM	Feet apart ***Eyes closed*** *Foam surface*	2	Vision Surface challenges	Diabetic	Pre	263.56 (102.75)	< 0.001	0.10
					Post	110.79 (25.01)		
				Control	Pre	522.02 (86.33)	< 0.01	
					Post	177.07 (21.01)		
TEC-FOAM	***Tandem standing*** ***Eyes closed*** ***Foam surface***	3	Base of support vision Surface challenges	Diabetic	Pre	492.73 (179.39)	0.02	0.16
					Post	226.72 (71.07)		
				Control	Pre	799.98 (150.72)	< 0.01	
					Post	268.39 (59.71)		

Abbreviation: SE, standard errors
a *P* value from Wilcoxon Signed Rank Test
b *P* value from Mann- Whitney U Test

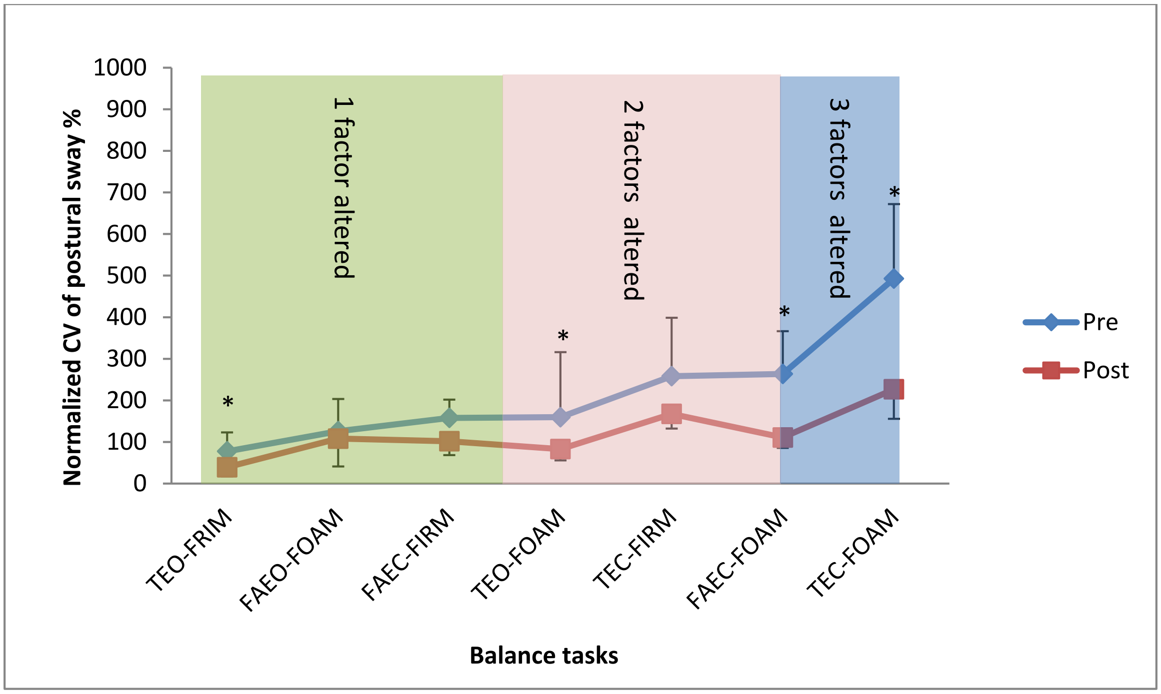

Figure 8. Mean ± SE of coefficient of variation of postural sway as a percent (normalized) of the postural sway in the reference position feet apart standing on firm surface with eyes open in diabetic group

* Significant difference between pre and post exercise

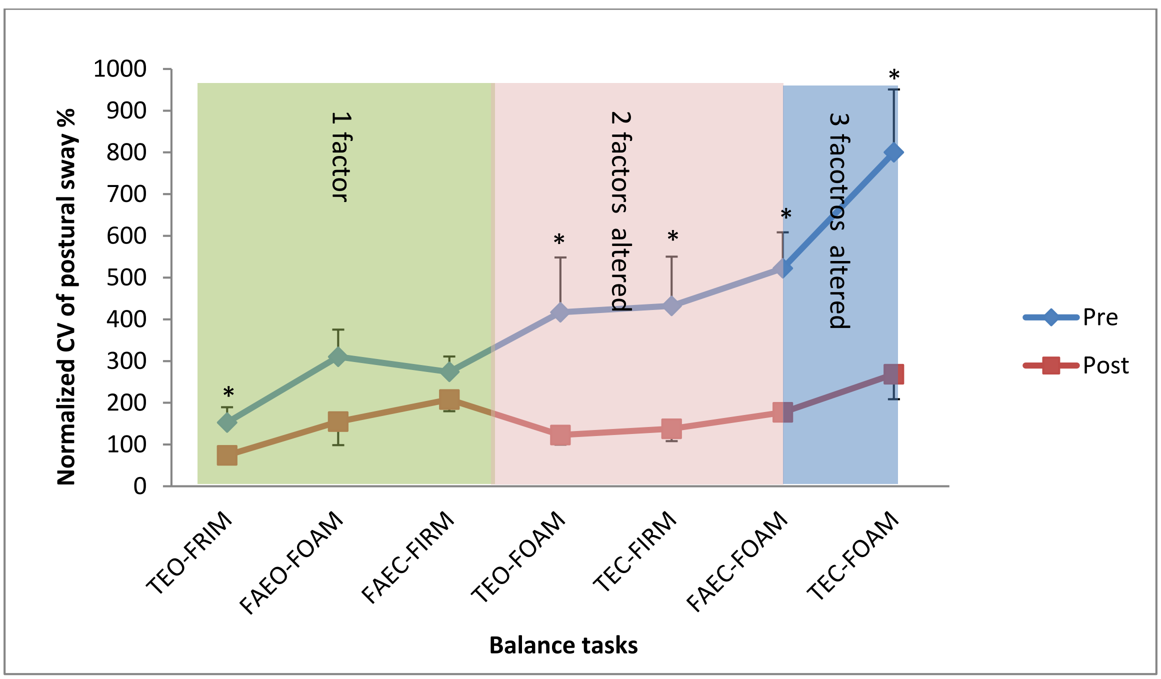

Figure 9. Mean ± SE of coefficient of variation of postural sway as a percent (normalized) of the postural sway in the reference position feet apart standing on firm surface with eyes open in control group

* Significant difference between pre and post exercise

Discussion

Fear of falling and impaired balance are two of the complications of diabetes and aging. Reflexes are generally more sluggish with older people and diabetics. Loss in balance occurs slowly over years and accelerates after the 6th decade of life[70]. Falls increase medical costs in the elderly[71].

The primary purpose of this prospective clinical study was to examine the effect of 8 weeks of TC exercise in improving balance in a diabetic group compared to age matched controls using mental imagery. To our knowledge, this was the first study using TC that focused on mental imagery to get the maximum benefit of 8 weeks of exercise.

In this study, it was hypothesized that TC exercise combined with focusing on mental imagery would improve balance control and confidence from fear of falling. Diabetes and/or aging may lead to some impairment in the sensory input in the foot, which increases the risk of falling[6-8]. Combining TC exercise and mental imagery used for applying the concept of “re-learning” enhances the somatosensory system and helps restore some functions lost due to aging and /or diabetes. The enhancement is displayed in different ways such as understanding the sequence of the movement from the instructor, doing the movement in front of mirror, feeling each sequence of movement, and doing the exercise with no shoes or socks on thick foam for a greater challenge. Together these methods help increase muscle flexibility and control balance in wider base of support.

This study had both groups achieving significant improvement in balance in 8 weeks. The improvement in both groups was similar but more beneficial to the diabetic group as diabetics had more baseline balance impairment. In other studies, it was concluded that TC improves balance. However, for those, studies the program was longer than 8 weeks [21-25,28-30,43,45,47,48] or more intense daily[40,42,72]. Here, the duration was only two times a week for 8 weeks. Using MI was able to shorten the term of TC to get the same results as in the longer studies so TC was more efficient. Practicing TC has been shown to induce changes in brain structure (brain morphometry) [73].

The *ABC* scale was calculated as the percent change, meaning a smaller percent indicates more improvement. In this study, a comparison between the two study groups at baseline indicated that the diabetic group had more balance impairment. However, both groups improved significantly, with no difference between groups. For the FRT test, the baseline measurements were similar with significant improvement in both groups. However, this change was not significantly different between groups.

For the OLS, the baseline time was less in the diabetes group compared to the control group. However, the improvement was significant in both groups. This result was consistent with the other balance outcome measures in this study that showed the diabetic group saw more improvement because their impairment was more significant at baseline.

Similarly, the results of all tasks using the balance platform improved in both groups with no significant difference between groups. This indicates that TC exercise was beneficial for both groups. The three altered sensory factors together (TEC-FOAM) showed significant improvement in both groups.

The strengths of this study include duration, intensity of the exercise, and use of mental imagery to accelerate the "re-learning" process and improve function. The findings of this study showed an improvement at 8 weeks with mild intensity TC exercise (1hour/2times/week) while most studies used similar or longer duration interventions more intense daily programs. The study had some limitations. Measurements were not taken at the mid-point (4 weeks) to check the subjects' progress. Another limitation was the number of participants who dropped out in the diabetic group due to time conflict of TC exercise was 40%. A pervious study attributed the sedentary life and bad diet to diabetes[74].

Based on this study's findings, physical therapists are encouraged to recommend TC exercise for diabetic and geriatric patients to improve balance. The results of this study suggested that teaching the patient to focus on MI theory while doing TC exercise is the best way to promote and accelerate the "re-learning" process in order to improve balance.

Conclusion

In conclusion, this clinical trial supported the effectiveness of TC exercise combined with MI in improving balance in 8 weeks for diabetic and geriatric (control) groups. TC exercise was more beneficial for the diabetic group though the rate of balance improvement was similar to the control group although the level of impairment was higher at baseline in the diabetic group, which is related to the disease pathology.

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CHAPTER THREE

EFFECTS OF TAI CHI EXERCISE ON SOLEUS H-REFLEX AND NERVE CONDUCTION VELOCITY IN PATIENTS WITH TYPE 2 DIABETES

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Abstract

Background: Diabetes is a disease that leads to damage of the peripheral nerves which may eventually cause balance instability.

Objective: To determine the effect of 8 weeks of Tai Chi (TC) training combined with mental imagery (MI) on soleus H-reflex and nerve conduction velocity (NCV) for the sural and superficial peroneal nerves in people with diabetes.

Design: Pre-test post-test in a diabetic group.

Participants: Twelve diabetic sedentary subjects with no history of TC exercise with a mean age of 63.8±8.1 years were recruited. Subjects did not have any orthopedic, neurological, cardiovascular conditions, or back pain and were not taking any medication that may affect balance. Their mean body mass index (BMI) was 27.9±5.5 kg/m^2. Subjects were included if they had a history of type 2 diabetes and a hemoglobin A1C between 6 and 10, and no foot ulcers.

Intervention: Subjects participated in a series of Yang style of Tai Chi classes with mental imagery, two sessions per week for 8 weeks. Each session was one hour long.

Outcome Measures: Soleus H-reflex, hemoglobin A1C and NCV tests for sural and superficial peroneal nerves.

Results: In the H-reflex, there was a significant increase in amplitude (μV) after completing 8 weeks of TC exercise (1226.9±320.8 vs. 1815.6±478.8, p=0.02). In the sural nerve measure, there were significant improvements in velocity (m/sec) (30.9±3.6 vs. 33.8±3.9, p=0.01), amplitude (μV) (18.2±4.1 vs. 7.6±1.2, p=0.01), and latency (ms) (3.7±0.4 vs. 3.4±0.4, p=0.01). In the superficial peroneal nerve, significant improvements were observed in velocity (m/sec) ($p=0.02$) and latency (ms) ($p=0.01$), but not in amplitude (μV) ($p>0.05$).

Conclusion: Combining TC intervention with MI theory showed an improvement in the H-reflex and NCV tests, which suggests improving balance stability.

Keywords: Tai Chi exercise, diabetes, H-reflex, and sensory nerve conduction studies.

Introduction

Diabetes mellitus (DM) is a systematic disease affecting different body systems characterized by a slow progression of symptoms which often are not discernible by the patient [1]. Sensory impairment begins in the distal lower extremities[2]. In DM-related neuropathies, both small and large fibers are affected. Small fibers affect pain and temperature sensation, while the large fibers affect proprioception and light touch[2-4]. Aging and living with diabetes over a period of years results in decreasing proprioception, which affects postural stability and protective reflexes[5,6]. This includes muscle weakness and delayed reflexes[7]. Due to postural instability, falling is a predicted result of impaired proprioception[8-10]. It is important, though difficult, to evaluate motor control. One of the ways to do this, especially with people with diabetes, is by measuring the H-reflex and nerve conduction velocities (NCV), or sensory motor testing, of the bottom of the foot. Since the largest problem with motor control is loss of sensation in the bottom of the foot, measuring H-reflex and sensory testing may show the effeteness of Tai Chi (TC) in 8 weeks. Though TC has been used in people with diabetes, motor control has not been evaluated. Some studies have shown H-reflex, NCV, and balance control improvement in people with DM and the elderly by using TC exercise; however, these studies lasted for 12 weeks, in contrast to the 8-week intervention proposed in this study [11,12].

Tai Chi has been practiced in China for centuries. In China, there is a belief that TC maintains health, improves balance and postural control. TC is a body-mind exercise in which the person uses the mind while practicing the movement[13]. Tai Chi is an amalgamation of different types of exercise, including weight shifting, correct postural mal-alignment, and slow coordinated movements with synchronized deep breathing[14,15]. This exercises involves many different elements such maintaining concentration while performing the movement, watching the instructor to learn and execute the right movement to stretch muscles while synchronizing the movement with deep breathing to improve cardiac output to provide the muscles and organs with sufficient blood flow[16,17]. Previous studies examined the effect of practicing TC for 5 years or longer on peripheral blood flow among certain elderly populations[18,19]. Researchers found an enhancement in endothelium-dependent dilation in skin vasculature and an increase in cutaneous microcirculatory function, which enhances peripheral circulation[19,20]. Some studies have shown that 12 or more weeks of TC intervention improves the H-reflex in elderly people[11,12,21].

Tai Chi (TC) differs from other types of exercise, such as running, because in Tai Chi the subject must concentrate while focusing on the whole movement as well as a complex series of movements. Concentration is an essential factor for re-learning or re-conditioning a damaged nervous system. Diabetes can cause a loss in sensation in the feet, providing false information to the brain about ground reaction forces. In TC, subjects execute movements slowly, calmly concentrating and mentally visualizing the movement, while trying to feel the movement in the feet; this enhances improvements in sensation. Previous re-learning or re-conditioning studies have showed the role of mental or motor imagery in improving function and sensation[22,23].

Motor or mental imagery (MI) is defined as “the mental representation of movement without any movement”[22]. It is a process of conceptually visualizing an action without performing the movement. The subject uses memory to think through and save the strategies of the action. During mental practice, the subject repeats the imagined movements to improve the performance of the action[22]. The combination of physical and mental practice can help to restore the lost action or function. The subject must mentally visualize the sequence of the movement while performing it. The concentration and planning involved in the movement increases the awareness of the required action[22-24]. In a transcranial magnetic stimulation (TMS) study, the motor imagery of the foot during gait led to corticospinal excitability[25]. Motor imagery enhances the plasticity process as a result of motor learning[26].

In diabetic neuropathy, nerve conduction is slower than normal due to demyelination. Also, nerve action potentials are slower due to the loss of axons[27]. The distal sensory fibers of the feet are usually the first affected, which is known as a dying-back phenomenon[28-30]. Nerve conduction velocity (NCV) studies are clinical measurements used to evaluate sensory nerve velocity conduction; in this test, both sural and superficial peroneal nerves are usually assessed for neuropathies[31]. In this study, both nerves were evaluated before and after TC exercise. The sural nerve supplies the lateral aspect of the foot, heel, and ankle in addition to the posterolateral aspect of the distal third of the leg. The superficial peroneal nerves supply sensation on the dorsum of the foot, except for the web space between the hallux and second digit. Nerve conduction velocity studies involve three specific parameters for analysis: 1) amplitude in microvolts (μV), measured from baseline to peak and which reflects the number of active nerve fibers; 2) latency in milliseconds (ms), the time it takes from the electrical stimulus to the onset of evoked response; and 3) conduction velocity in meter per second (m/s), which is measured as the distance between stimulation and the recording electrodes, divided by latency[32].

One of the tests used to measure sensory motor function is the H-reflex. This test measures sensory motor function by comparing the electrical activity of the muscle with direct stimulation of the motor nerve to reflex stimulation through spinal cord (monosynaptic). When motor nerve is stimulated, the nerve impulse goes in two directions, one impulse goes directly to the muscle causing it to contact and the other stimulate the sensory fibers from muscle spindle causing a monosynaptic reflex. If the reflex amplitude was exactly the same as the direct muscle stimulation, the ratio will be %100. Therefore, two different electrical amplitudes called M wave from the direct muscle stimulation and H-wave from monosynaptic reflex through spinal cord are measured. The normal H/M ratio is 50% in adults with no sensory impairment[26,33,34]. The variation in the H-reflex before and after the exercise intervention can be used as measure of spinal plasticity as result of motor learning[26].

During the 2015 Combined Sections Meeting (CSM) organized by the American Physical Therapy Association (APTA), physical therapists were encouraged to apply TC as a therapeutic exercise for function, rehabilitation, and wellness. Accordingly, some clinical sites have started to implement TC as a therapeutic intervention exercise[35-37]. The purpose of this study was to investigate the effect of 8 weeks of Tai Chi (TC) training combined with mental imagery (MI) on soleus H-reflex and nerve conduction velocity (NCV) tests for sural and superficial peroneal nerves in people with diabetes. It was hypothesized that combining mental imagery with Tai Chi exercise would help to improve H-reflex and sensory nerve conduction velocity in a shorter treatment time for patients with diabetes.

Methods

Study Design

The study design was a pre-test post-test design on a diabetic group. After screening for inclusion and exclusion criteria, participants were tested twice, at baseline and after the completion of a TC class for 8 weeks, two times a week for one hour, for a total 16 hours of Tai Chi exercise.

Subjects

Twelve participants, 50 to 80 years of age, with a mean age 63.8±8.1 years and a mean body mass index (BMI) of 27.9±5.5 kg/m^2 completed the study. The average duration of onset of diabetes was 10.8±5.4 years, with a mean HbA1C of 6.8±0.8 (Table 4).

This study was approved by the Institutional Review Board (IRB) at Loma Linda University (LLU) and held at the Physical Fitness Laboratory at the School of Allied Health Professions (SAHP), Department of Physical Therapy. Participants were recruited from the Drayson Center and Diabetes Treatment Center at LLU. All participants read and signed the informed consent form before beginning the study.

Table 4. Demographic Characteristics of Diabetic Participants (n=12)

Characteristic	Mean (SD)	n (%)
Age (years)	63.8 (8.1)	
Gender (Female)		8 (66.7)
Weight (Kg)	86.8 (17.2)	
Height (m)	1.8 (0.1)	
BMI (Kg/m^2)	27.9 (5.5)	
Duration of diabetes (years)	10.8 (5.4)	
A1C at baseline	6.8 (0.8)	

Abbreviations: SD, standard deviation; BMI, Body Mass Index

Participants were recruited in several ways: study flyers were placed on the main bulletin board of the School of Allied Health Professions and the main gym of the Drayson Fitness Center (APPENDIX A). Flyers were also sent via email electronically to all faculty and students in the School of Allied Health Professions. The Diabetes Treatment Center at LLU referred interested diabetic patients to the study research team if it appeared the patient matched the study criteria, providing them with a copy of the study flyer.

The following inclusion/exclusion criteria were used to determine eligibility for enrollment in study. Inclusion criteria included: 1) had not practiced TC ; 2) do not exercise more than once per week; 3) had a Body Mass Index (BMI) between 10 and35 Kg/m^2; 4) had normal or controlled blood pressure; and 5) had normal range of motion, at least 5/5 muscle power bilaterally. Participants were excluded if they: 1) take medications which can affect balance; 2) had a history of frequent falling; 3) had vision problems; and

4) had orthopedic/ neuromuscular/cardiovascular impairments that restrict exercise. A trained researcher determined eligibility for inclusion through telephone interviews to match the inclusion/ exclusion criteria.

Twenty participants diagnosed with Type 2 diabetes from 2-20 years were included in this study. Eight participants withdrew due to conflicts with the TC class schedule. The data analysis was based on the remaining 12 subjects who completed the study.

Outcomes Measures

In this study, the following outcomes measures were used before and after the intervention.

Soleus H-reflex

The H-reflex (Hoffmann reflex) test measured the monosynaptic reflex of muscles after electrical stimulation of the sensory fibers; this is one of the best tests for measuring proprioception**.** After electrical stimulation of the muscle, the signal travels through sensory fibers (Ia) to the spinal cord, through the dorsal root ganglion, then across to the anterior horn cell, which discharges down to the alpha motor axon to the muscle, with the result appearing as a muscle twitch. The test-retest reliability of H-reflex in the prone position is high (ICC ranged between .54 and .97)[38]. This test evaluates the proprioception responsible for sensing foot position. (Figure 10)

Figure10. Soleus H-reflex Testing

Nerve Conduction Velocity (NCV)

The NCV test is an electrical test used to evaluate and diagnose nerve impairment. For sensory NCV, electrical stimulation is applied to the peroneal nerve and recording from a sensory nerve. In neuropathies, nerve conduction usually is slower. Both sural and superficial peroneal nerves are commonly assessed for neuropathies[31]. (Figure 11, 12)


Figure11. Sural Nerve Testing


Figure12. Superficial Peroneal Nerve Testing

All information using the H-reflex and NCV tests was monitored and recorded on an electromyography (EMG) screen (CADWELL®, Kennewick, WA, USA). During the test, the subject lay on his or her stomach, and had three small adhesive discs placed on the muscles. The subject felt a tingling sensation.

Hemoglobin A1C

The hemoglobin A1C (HbA1C) is the most common measure of long term glycemic control[39,40]. This is a blood test which measures the average concentration of blood glucose over the last 3 months indirectly through glycated hemoglobin. Approximately 5μL of blood was obtained from a finger stick and used to measure to HbA1C with a Food Drug Administration (FDA)-approved device called the DCV Vantage Analyzer (SIEMENS®, Tarrytown, NY, USA; Figure 3). The HbA1C test is not affected by eating, thus blood samples for this test can be taken without fasting[39,40].

Figure3. HbA1C Analyzer

Procedures

An appointment was scheduled with participants who met the inclusion/exclusion criteria for baseline testing. Participants were provided with detailed information regarding the purpose of the study, procedures and tests, potential risks and scheduled time of the TC exercise. If the participant agreed to proceed, he/she signed the informed consent form as approved by the IRB (APPENDIX C) prior to testing.

A trained researcher performed all measurements. Baseline measurements were taken using the following tools: 1) soleus H-reflex, 2) nerve conduction velocity studies for sural and superficial peroneal nerves and 3) hemoglobin A1C (HbA1C). All subjects received the same intervention of TC exercise. The subject laid on his/her stomach for soleus H-reflex and NCV studies for sural and superficial peroneal nerves; skin temperature was kept between 34º-38º degree Celsius. Tests were monitored and recorded on an EMG computer (CADWELL®, Kennewick, WA, USA). During the test, the participant felt a tingling sensation. For the H-reflex test, an active adhesive electrode was placed at the junction of the soleus muscle and the gastrocnemius muscle, and a reference adhesive electrode was placed below the active electrode on the Achilles tendon. Cathodal stimulation was applied to the popliteal fossa (Figure 10). The NCV for the sural nerve was measured by placing an adhesive bar electrode with 4cm spacing between the anode and cathode; the active cathode was placed posterior to the midpoint of the lateral malleolus, and the anode (reference) was spaced 4 cm on the distal. The NCV for the superficial peroneal nerves was accomplished by placing the active electrodes over the anterior aspect of the ankle, lateral to the tendon of the extensor hallucis longus. The reference electrode was just 4 cm distally from the active electrode. The stimulation was 14cm proximal to the active electrode along the anterior crest of the tibia (Figure12). A physical therapist stayed nearby to monitor the stimuli. The entire process took approximately 20 minutes.

Subjects participated in 1 hour sessions, 2 times a week for 8 weeks. Each session consisted of 15 minutes of warm-up exercises, including stretching, loosening the muscles, and breathing exercises, and then was followed by 45 minutes of Yang style TC exercise (Figure 4).

All participants had the same TC exercise intervention. Each testing session took 30-45 minutes to complete all tests. The tests were conducted after the participant signed the consent form. Subsequently, all subjects continued 8 weeks of TC, and outcome measures were taken for the second and last time.

Figure 4. Participants during the Tai Chi Class

Data Analysis

Data were analyzed using SPSS for Windows Version 22.0. The demographic characteristics of the participants were summarized using the mean (SD) for the quantitative variables and frequency and relative frequency for categorical variables. The normality of the outcome variables at baseline and post intervention was examined using a One-sample Kolmogorov-Smirnov test. Comparisons between post and pre measures after the Tai Chi exercise were assessed using a Wilcoxon Signed rank test when the distribution of the variables was not normal. In addition, changes between post and pre measures were examined using paired t-test for approximately normal variables. The level of significance was set at $p \leq 0.05$.

Results

There was a significant increase in H-reflex amplitude (μV) after participants completed 8 weeks of Tai Chi exercise (1226.9±320.8 vs. 1815.6±478.8, p=0.02; Table 5). However, no significant changes for latency and H/M ratio were observed (p>0.05). In the sural nerve, there were significant improvements in velocity (m/sec) (30.9±3.6 vs. 33.8±3.9, p=0.01), amplitude (μV) (18.2±4.1 vs. 7.6±1.2, p=0.01), and latency (ms) (3.7±0.4 vs. 3.4±0.4, p=0.01; Table 6). In the superficial peroneal nerve, significant improvements were observed in velocity (m/sec) (28.3±4.8 vs. 32.4±5.7, p=0.02) and latency (ms) (3.2±0.5 vs. 2.8±0.5, p=0.01; Table 7). However, no significant changes in amplitude (μV) were detected in the participants (p=0.96). (Figures 13, 14&15)

Table 5. H-reflex Over Time (n=12)

	Pre	Post	*P* value[a]
	Mean (SE)	**Mean (SE)**	
Onset (latency) (ms)	0.97 (0.49)	0.64 (0.29)	0.56
H/M ratio (percent)	13.92 (8.62)	16.40 (10.00)	0.18[b]
H-reflex amplitude (μV)	1226.89 (320.78)	1815.56 (487.81)	0.02

Abbreviation: SE, standard errors
a: *P* value from paired t-test
b: *P* value from Wilcoxon Signed Rank Test

Table 6. Sural Nerve Testing Over Time (n=12)

Table 6. Sural Nerve Testing Over Time

	Pre	Post	*P* value[a]
	Mean (SE)	**Mean (SE)**	
Velocity (m/s)	30.9 (3.6)	33.8 (3.9)	0.01
Amplitude (μV)	18.2 (4.1)	7.6 (1.2)	0.01[b]
Latency/onset/ peak (ms)	3.7 (0.4)	3.4 (0.4)	0.01

Abbreviation: SE, standard errors
a: *P* value from Wilcoxon Signed Rank Test
b: *P* value from paired t-test

Table 7. Superficial Peroneal Nerve Testing Over Time (n=12)

	Pre	Post	*P* value[a]
	Mean (SE)	**Mean (SE)**	
Velocity (m/s)	28.3(4.8)	32.4 (5.7)	0.02
Amplitude(μV)	8.4(2.1)	8.3 (1.9)	0.96[b]
Latency/onset/ peak (ms)	3.2(0.5)	2.8 (0.5)	0.01

Abbreviation: SE, standard errors
a: *P* value from Wilcoxon Signed Rank Test
b: *P* value from paired t-test

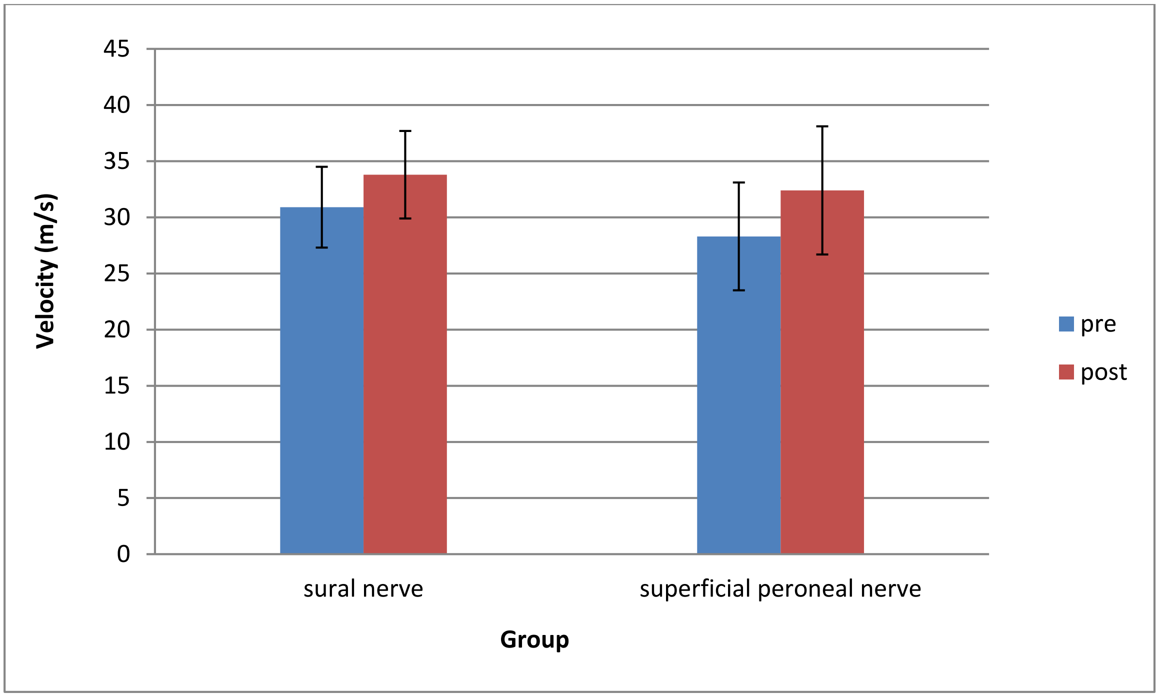

Figure 13. Mean ± SE Velocity Pre and Post Intervention in Sural and Superficial Peroneal Nerves

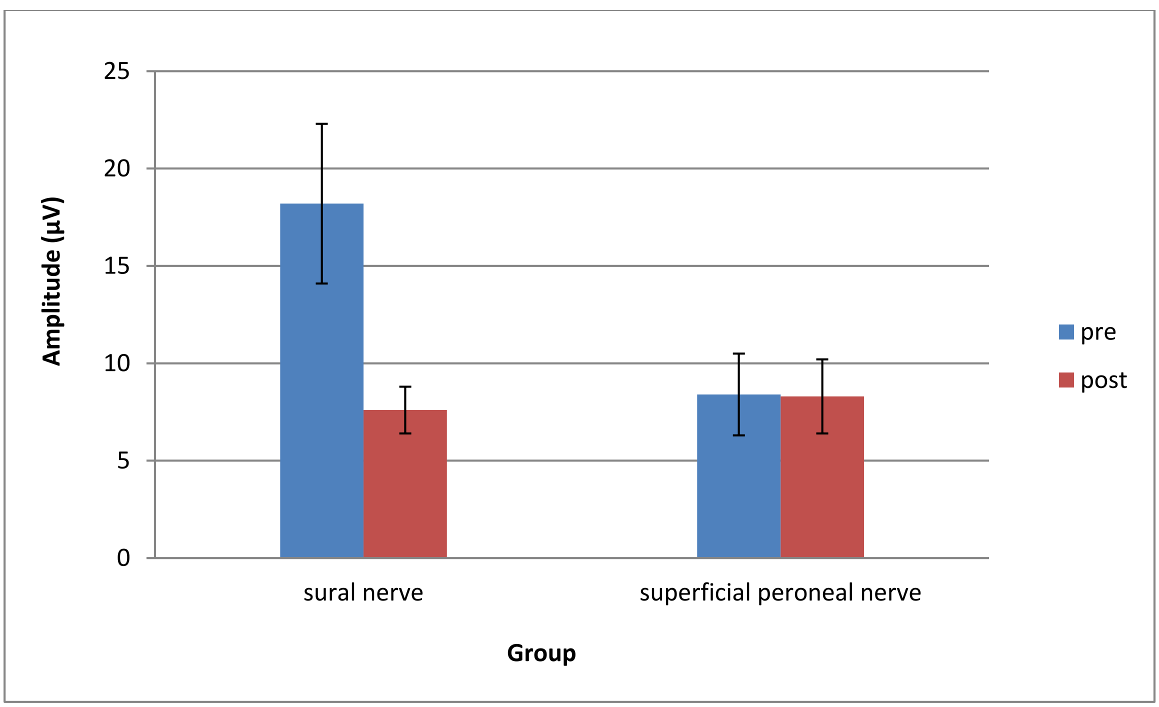

Figure 14. Mean ± SE Amplitude Pre and Post Intervention in Sural and Superficial Peroneal Nerves

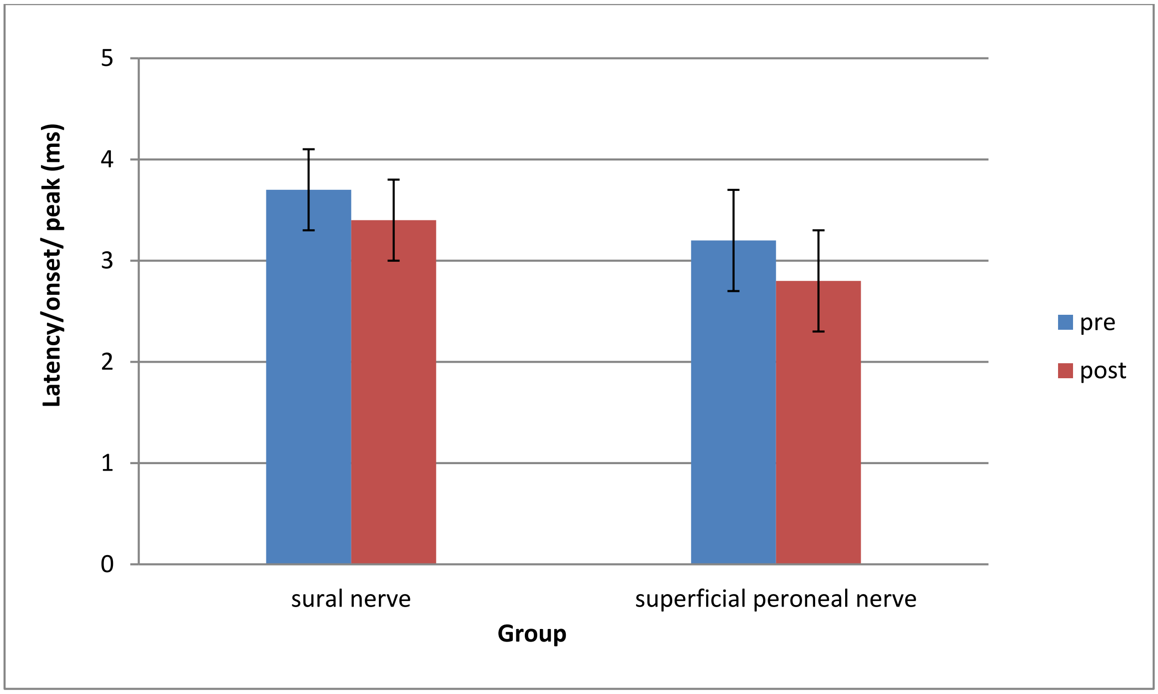

Figure 15. Mean ± SE of Latency Onset Peak between Pre and Post Intervention in Sural and Superficial Peroneal Nerves

Discussion

The prevalence of diabetes mellitus is increasing dramatically over the world[41]. One of the effects of diabetes, peripheral neuropathy, affects the peripheral nerves and circulation of the feet. It also affects somatosensory information from the ankle and feet, which are important in controlling balance[42]. Due to demyelination, the nerve conduction is slower than normal and loss of axons also slows nerve action potentials [27]. Reflexes are generally more sluggish in older people and diabetics, and while aging increases the likelihood of falling, diabetes further adds to the risk of falling[6]. However, loss in balance occurs slowly over the years and accelerates after the sixth decade of life[43].

The purpose of this prospective clinical study was to investigate the effect of 8 weeks of TC training combined with MI on soleus H-reflex and NCV tests for sural and superficial peroneal nerves in people with diabetes. To our knowledge, this was the first study using TC that focused on mental imagery strategies to get the maximum benefit of 8 weeks of training.

In this clinical trial, sensory nerve conduction velocity tests in both the sural and superficial peroneal nerves demonstrated significant improvement in velocity and latency onset after completing 8 weeks of TC intervention. In particular, the amplitude of the soleus H-reflex showed significant improvement, indicating more nerve fibers were recruited after completing the TC program. Using mental imagery during TC exercise draws on the concept of “re-learning,” which enhances the somatosensory system and helps restore some functions lost due to aging and /or diabetes. The enhancement is shown in different ways, such as understanding the sequence of the movement demonstrated by the instructor, doing the movement in front of a mirror, feeling each sequence of movement, and doing the exercise with no shoes or socks on thick foam for a greater challenge. Together these elements help increase muscle flexibility and postural stability in a wider base of support.

Exercise increases cardiac output and helps increase peripheral circulation, supplying tissues with adequate blood, which increases muscle control, thus improving postural stability. Combining TC with mental imagery theory may increase peripheral blood microcirculation, since the exercise is focused on the lower extremities. This, in turn, helps nerves to regain function due to the increased peripheral blood supply. Increasing skin temperature led to increased nerve conduction, which improved proprioception, helping the feet to recognize abnormalities on the walking surface, which further minimizes the risk of falling. Moreover, this improvement benefitted postural stability and protective reflexes. Practicing TC for years also improved peripheral microcirculation[18,19].

In previous studies, it was concluded that TC improves the H-reflex. However, in those studies, the programs lasted 12 weeks [11,12]or over a period of years[21]. Here, program was twice a week for 8 weeks, one hour per session for a total of 16 hours. Incorporating mental imagery into the program made the program more effective, enabling to achieve the same results in a shorter period of time. Practicing TC for years has been shown to induce changes in brain structure (brain morphometry) [44].

The strengths of this study include duration, intensity of the exercise, and use of mental imagery to accelerate the “re-learning” process and improve function. The findings of this study showed an improvement at 8 weeks with mild intensity TC exercise (1hour/2times/week) while most studies used similar or longer duration interventions and more intense daily programs. One limitation was the number of participants who dropped out in the diabetic group due to time conflicts (40%). A previous study hypothesized that the sedentary lifestyle and bad diet common among diabetics may be a factor in the high dropout rate[45]. Increasing peripheral circulation (microcirculation) is a possible reason for the improvement found in the H-reflex and NCV tests. Future studies should measure blood flow peripherally before and after the exercise.

Based on this study, physical therapists are encouraged to recommend TC exercise for diabetic and geriatric patients to improve balance, circulation, and function. The results of this study suggested that teaching the subject to focus on MI theory during TC exercise is the best way to improve peripheral microcirculation and accelerate the “re-learning” process to improve function in a shorter time.

Conclusion

The strategy used in this study for combining TC intervention with MI theory showed improvement in the H-reflex and NCV tests. The MI theory helped to accelerate the re-conditioning and re-learning processes. Because diabetics often impaired sensation in their feet, which increases the risk of falling, the strategy that was used in this study improved nerve conduction velocity which should reduce the chance of falling and improved balance stability as the feet became more aware of external forces on the ground.

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CHAPTER FOUR

DISCUSSION

Diabetes mellitus is a disease which causes many complications, and prevalence is increasing dramatically[2], making it a worldwide health threat. One of the effects of diabetes mellitus (DM), peripheral neuropathy, affects the peripheral nerves and circulation; it also impairs somatosensory information from the ankle and feet which are important in control balance[65]. Demyelination slows nerve conduction and the loss of axons also decreases nerve action potential [7]. Balance is affected as we age, and this is particularly true for diabetics over age 60. These losses occur slowly, with reflexes becoming more sluggish over time. [21,30,31,66]. Despite the aging increases the risk of falling, diabetes further increases the chance of falling[21]. Exercise and diet are important factors in controlling diabetes and age related impairments.

The primary purpose of this prospective clinical study was to examine the effect of 8 weeks of TC exercise and mental imagery in improving balance, balance self-confidence, H-reflex and NCV tests in a group of diabetics compared to age matched controls. To our knowledge, this was the first study using TC that focused on MI strategies. In this clinical trial, we hypothesized that TC exercise for 8 weeks combined with focusing on mental imagery would improve balance control and lessen fears about falling and balance.

The Activities-specific Balance Confidence *(*ABC*)* scale was used as the percent change variable meaning a smaller percent indicates more improvement. In this clinical trial, although the diabetic group had more balance impairment at baseline compared to the control group, both groups showed significant improvement and identical results. For the functional reach test (FRT), measurements were similar at baseline for both groups, and both groups showed significant improvement in similar amounts. For the one leg standing test (OLS), the amount of time that the diabetic group could stand at baseline was lower than in the control group; however, there was significant improvement in both groups. This result was consistent with the other balance outcome measures in this study that showed more improvement in the diabetic group since their impairment was more significant at baseline.

Similarly, both groups improved in the balance platform tasks, with no significant difference between them; this indicates that TC exercise was beneficial for both groups. The three altered sensory factor tests (TEC-FOAM), which are considered the most difficult, showed significant improvement in both groups.

The amplitude of soleus H-reflex significantly improved, which is related to more nerve fibers recruited after TC exercise. The results of the sensory nerve conduction velocity tests of the sural and superficial peroneal nerves showed significant improvement in velocity and latency onset after completing the 8 week TC intervention. Using mental imagery during TC exercise aided in “re-learning” the movements, enhancing the somatosensory system and helping restore some functions lost due to aging and /or diabetes. The improvement was demonstrated in different ways such as understanding the sequence of the movement from the instructor, doing the movement in front of the mirror, feeling each sequence of movement, and doing the exercise with no shoes or socks on thick foam to make it more challenging. Together these elements help increase muscle flexibility and postural stability in a wider base of support. Also, combining TC with mental imagery concepts may increase peripheral blood circulation warm the skin, which increases nerve conduction. This in turn improves touch sensation, or proprioception, which helps the foot recognize abnormal forces on the ground, minimizing the chance of falling. Moreover, increasing peripheral circulation helps to supply tissues with adequate blood flow, which ultimately increases muscle control and balance. Practicing TC for years has demonstrated improvement in the peripheral microcirculation[59,60].

In this study, both groups showed significant improvement in balance after the 8 week intervention. Similar improvements were noticed in both groups but since the diabetic group had more balance impairment at baseline, this group saw more benefit. Other studies have shown that TC improves balance, however, in those studies the exercise program was longer than 8 weeks [33-37,39-41,56,58,61,62] or was more intense on a daily basis[53,55,67]; in our study, participants did TC exercise twice a week for 8 weeks. Using concepts of mental imagery shortened the length of the TC program to get the same result, making the TC more effective over a shorter period. Practicing TC for years has been shown to induce changes in brain structure (brain morphometry) [68]. In previous studies, researchers found that TC improves the H-reflex; however, in those studies, the programs were 12 weeks long [51,52]or over a period of years [69]. In this study, H-reflex and NCV tests for sural and superficial peroneal nerves demonstrated improvement after 8 weeks of TC intervention using mental imagery. The use of mental imagery made the 8 week program both efficient and beneficial.

This study explored the use of TC -- both duration and intensity -- together with the use of mental imagery to accelerate the “re-learning” process and improve function. The findings of this study showed an improvement at 8 weeks with mild intensity TC exercise (1hour/2times/week), while most studies used similar or longer duration interventions or more intense daily programs. The study had some limitations. Measurements were not taken at the mid-point of the study (4 weeks) to check the subjects' progress. Also, 40% of the diabetic group dropped out due to scheduling conflicts. However,   this attrition might also be seen as reluctance to exercise on the part of sedentary participants unused to such activity[70]. Increasing peripheral circulation (microcirculation) is a possible reason for the improvement in the H-reflex and NCV tests. Future studies should measure blood flow peripherally before and after exercise.

Based on these findings of this study, physical therapists are encouraged to recommend and integrate Tai Chi in physical therapy practice as a therapeutic intervention to improve balance and general wellness among their diabetic and geriatric patients[71,72]. The results of this study suggested that teaching patients to focus on mental imagery while doing TC exercise is the best way to promote and accelerate the "re-learning" process to improve balance.

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APPENDIX A

FLYER FOR RECRUTING PARTICIPANTS

LOMA LINDA
UNIVERSITY

Research Opportunity

Diabetic and Non-Diabetic Males and Females
Between the Ages of 40-80
Needed for balance Study

Loma Linda University
School of Allied Health Professions

The Physical Therapy program is conducting a research study
Titled:

The Effects of Tai Chi Training in improving Balance in People with Diabetes

We are investigating the effects of tai chi exercise on balance and circulation. The study will be held on the LLU campus and Drayson center. You will require to have three times testing, about 60 minutes per test and attend 8 weeks tai chi exercise program, 2 times/ week for an hour.

Participant will be reimbursed

For more details and information, please contact

Abdul Alsubiheen:

Email: aalsubiheen@llu.edu or Phone: (412)805-6062

Loma Linda University
Adventist Health Sciences Center
Institutional Review Board
Approved 10/3/2012
5110209 Chair

APPENDIX B

THE ACTIVITIES-SPECIFIC BALANCE CONFIDENCE (ABC) SCALE

The Activities-specific Balance Confidence (ABC) Scale*

Instructions to Participants:
For each of the following, please indicate your level of confidence in doing the activity without losing your balance or becoming unsteady from choosing one of the percentage points on the scale form 0% to 100%. If you do not currently do the activity in question, try and imagine how confident you would be if you had to do the activity. If you normally use a walking aid to do the activity or hold onto someone, rate your confidence as it you were using these supports. If you have any questions about answering any of these items, please ask the administrator.

The Activities-specific Balance Confidence (ABC) Scale*

For each of the following activities, please indicate your level of self-confidence by choosing a corresponding number from the following rating scale:

0% 10 20 30 40 50 60 70 80 90 100%
no confidence completely confident

"How confident are you that you will not lose your balance or become unsteady when you…

1. …walk around the house? ____%
2. …walk up or down stairs? ____%
3. …bend over and pick up a slipper from the front of a closet floor ____%
4. …reach for a small can off a shelf at eye level? ____%
5. …stand on your tiptoes and reach for something above your head? ____%
6. …stand on a chair and reach for something? ____%
7. …sweep the floor? ____%
8. …walk outside the house to a car parked in the driveway? ____%
9. …get into or out of a car? ____%
10. …walk across a parking lot to the mall? ____%
11. …walk up or down a ramp? ____%
12. …walk in a crowded mall where people rapidly walk past you? ____%
13. …are bumped into by people as you walk through the mall?____%
14. … step onto or off an escalator while you are holding onto a railing? ____%
15. … step onto or off an escalator while holding onto parcels such that you cannot hold onto the railing? ____%
16. …walk outside on icy sidewalks? ____%

*Powell, LE & Myers AM. The Activities-specific Balance Confidence (ABC) Scale. *J Gerontol Med Sci* 1995; 50(1): M28-34

APPENDIX C

INFORMED CONSENT FORM

LOMA LINDA UNIVERSITY

School of Allied Health Professions

The Effect of Tai Chi Training on Improving Balance in People with Diabetes

INFORMED CONSENT

PURPOSE

You are invited to participate in a study to examine the effect of tai chi training on balance and blood circulation. We would like to see if tai chi exercise can improve foot circulation, sensation and balance. This study will include 2 groups. One group will be those with type 2 diabetes and the second group will be healthy adults. The age range of participants will be 40-80 years old. Participants must not have any history of orthopedic, neurological, or cardiovascular conditions that may affect their ability to do exercise, for example, osteoporosis, stroke and heart attack. Participants should not exercise more than 1 time per week and have not practiced tai chi in the previous 4 months. Participants should not be taking any medication that may affect their balance such as Lyrica. Their body mass index (BMI) should be in the range between 15 and 50 and blood pressure in the range between 150/90 (highest) and 90/60 (lowest). The diabetic participants should have had a diagnosis of type 2 diabetes between 2-20 years and a hemoglobin A1C level between 6 and 15.

Procedure

When you arrive for the study, we will first obtain from you the following information: gender, race, date of birth, and employment status, and then pre-study screening will be performed on all potential research participants to determine that you meet the criteria for this research study.

If you decide to participate, your name, address, telephone number, date of birth, height and weight will be recorded. You will be required to fill out one page questionnaire to assess your confidence (Activities-Specific Balance Confidence Scale). You will be placed into the diabetic or non-diabetic group. Each group will perform the same tai chi exercises which will take 1 hour, 2 times a week for 8 weeks.

_____INITIAL
_____DATE

Loma Linda University
Adventist Health Sciences Center
Institutional Review Board
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#5110209 Chair R L Rigsby

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A Seventh-day Adventist Institution
DEPARTMENT OF PHYSICAL THERAPY | Nichol Hall, Loma Linda, California 92350
(909) 558-4632 · (800) 422-4558 · fax (909) 558-0459 · www.llu.edu/llu/sahp/pt

The Effect of Tai Chi Training on Improving Balance in People with Diabetes

Next, we will measure a reflex on your leg using a device called an electromyograph (EMG). This test will help to evaluate your ability to sense your foot position and we will measure how well your reflex works. This will be done by putting a couple of small adhesive discs over the back of the knee and another couple over the calf. Then, small electric currents will go through the back of the knee causing small shocks and may make you feel uncomfortable while recording your muscle activity. During the test, you will lie on your stomach and will feel a tingling sensation. A physical therapist will always be very close by as a precaution, to watch the stimulus. The entire process will take approximately 20 minutes.

The second test will be a balance test. This test will be conducted to measure body sway for 2 minutes from a standing position on a balance platform. This platform will be connected to a device that monitors and records your sway. We will put a belt around your waist as a safety measure. A physical therapist will always be within an arm's reach in case you become unsteady. The measure will be taken 3 times 1) standing over the platform, 2) standing over foam, 3) standing with one foot in front of the other. Each position will be measured with your eyes open and your eyes closed.

After these tests, we will measure your blood pressure. Then, we will draw a blood sample to measure the hemoglobin A1C. Approximately 1/2000 of a teaspoon blood (from finger stick) will be obtained to measure the average level of glucose in your blood over the last three months. Then, we will measure your circulation in your leg. In this test, a sensor will be attached close to the ankle joint and a blood pressure cuff will applied and pumped to 200 mm Hg (*millimeters of mercury*) for four minutes; then, we will release it to see the change in your circulation.

Next, a test will be performed to assess your standing balance. This test is called the one-leg standing test. We will assess your ability to maintain your position for a specific time, under 3 different positions for each leg. First, with eyes open then with eyes closed. You will be asked to complete each position 3 times.

Then, we will check how far you can reach. In this test, a yardstick will be placed on the wall at shoulder level. You will reach forward as far as possible without taking a step forward. We will measure the distance that you can reach in four trials.

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The Effect of Tai Chi Training on Improving Balance in People with Diabetes

In the last test, you will sit in a standard armchair, then stand up and walk a distance of 9.8 feet, then turn and walk back to a chair, and then sit down. We will measure how long this task takes. You will be asked to repeat this task three times.

Finally, you will be asked to walk at your normal speed for a distance of 32.8 feet, and we will measure the time in seconds.

After you complete the various tests, you will start a class of tai chi administered by a certified instructor. The class will be one hour, two times a week for eight weeks. After completing four and eight weeks of tai chi, you will be asked to complete the tests that were just described. These appointments will be made for you when you begin the tai chi class.

There will be three appointments for testing and each one will take no longer than 2 hours. It will take placed in Nichol Hall Room A640 at Loma Linda University. The tai chi class will be one hour, two times/week for eight weeks. The class will be held at Drayson Center, Loma Linda University, 25040 Stewart St., Loma Linda, CA.

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#5110209 **Chair** R L Rugsleymd

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Risks

You may lose your balance while performing tests. However, a physical therapist will be close by to you to keep you from falling. You may have skin irritation or feel discomfort on the leg where the adhesive discs are placed. Participation in this study puts you at minimum risk. This means no more risk than you might encounter in daily life.

Benefits

Although you might get benefit from tai chi as an exercise, there may be no benefit to you personally. The expected benefit of this study is to provide better understanding of the role of tai chi in improving foot sensation and circulation. It may be one of the best exercises for improving peripheral sensation and circulation.

Participant's Rights

Participation in this study is voluntary. You may leave the study at any time. Your decision whether or not to participate or stop at any time will NOT affect your present or future relationship with those conducting the study at Loma Linda University Department of Physical Therapy and will not involve any penalty or loss of benefits to which you are otherwise entitled.

Confidentiality

All records will be confidential. The obtained data will be saved to a secure storage location. In any publication, you will not be identified by name; however, an ID number may be used to describe the results of this study.

Additional Costs/ Reimbursement

There is no cost to you for your participation in this study beyond the time involved to participate. You will receive monetary compensation of $80 for participation at the end of the study.

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The Effect of Tai Chi Training on Improving Balance in People with Diabetes

IMPARTIAL THIRD PARTY CONTACT

If you wish to contact an impartial third party not associated with this study regarding any question or complaint you may have about the study, you may contact the Office of Patient Relations, Loma Linda University Medical Center, Loma Linda, CA 92354, phone (909) 558-4674, e-mail patientrelations@llu.edu for information and assistance.

INFORMED CONSENT STATEMENT

I have read the contents of the consent form and have listened to the verbal explanation given by the investigators. My questions concerning this study have been answered to my satisfaction. I hereby give voluntary consent to participate in this study. I have been given a copy of this consent form. Signing this consent document does not waive my rights nor does it release the investigators, institution, or sponsors from their responsibilities. I may call and leave a voice message for Dr. Jerrold Petrofsky during routine office hours at this number (909) 558 4300 ext. 82186 or e-mail him at jpetrofsky@llu.edu, if I have additional questions and concerns. I have been given a copy of this consent form.

SIGNATURES

______________________ ______________________

Signature of Subject **Date**

I have reviewed the contents and this consent form with the person signing above. I have explained potential risks and benefits of this study.

______________________ ______________________

Investigator **Date**

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