EFFECTS OF BALANCE TRAINING PROGRAM ON ANKLE PROPRIOCEPTION, BALANCE PERFORMANCE AND FEAR OF FALLING IN THE ELDERLY WITH DIABETIC PERIPHERAL NEUROPATHY

A THESIS

BY

RAPEEPUN THUNGTAK

Presented in Partial Fulfillment of the Requirements for the

Master of Science in Physical Therapy

at Srinakharinwirot University

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AN ABSTRACT

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Rapeepun Thungtak. (2013). *Effects of balance training program on ankle proprioception, balance performance and fear of falling in the elderly with diabetic peripheral neuropathy.* Master thesis, M.Sc. (Physical Therapy). Bangkok: Graduate School, Srinakharinwirot University. Advisor Committee: Asst. Prof. Dr. Saitida Lapanantasin.

The objective of this study is to investigate the effects of a group exercise program for balance training on ankle proprioception, balance performance, and fear of falling in elderly with diabetic peripheral neuropathy. Twenty-seven elderly women with diabetic peripheral neuropathy volunteered for this study. They were randomly assigned in two groups: (1) a balance training group, average age 68.38 ± 3.99 years (n=13) and (2) a control group, average age 69.35 ± 3.97 years (n=14). The balance training group received a designed group exercise program for balance training while the control group received an individual exercise with resistance bands. The elderly enrolled in the exercise program of their assigned group for four weeks (50 minutes/day, three days/week). Ankle proprioception measured by ankle repositioning test, balance performances measured by Modified Clinical Test of Sensory Interaction on Balance (mCTSIB), Berg Balance Scale (BBS), and Timed Up and Go test (TUG), and fear of falling measured by Thai Geriatric Fear of Falling Questionnaire of the elderly were performed before and after training during week 4. After four weeks of training, the balance training group showed significant increases in the ankle proprioception, balance performances, and reduce fear of falling as compared to pre-training. Compared with the control group, it also demonstrated a significantly higher ankle proprioception, balance performance, and reduced fear of falling. On the other hand, the control group showed no statistically significant pre- and post- training difference in all parameters. It can thus be concluded that the group exercise program for balance training developed for this study can improve the ankle proprioception, balance performance, and reduce fear of falling of elderly with diabetic peripheral neuropathy within four weeks of training. This balance training program can therefore be further applied to promote health among elderly with diabetic peripheral neuropathy in the Thai community in aspects of improving their ankle proprioception and balance performance, and also reducing fear of falling.

ผลของโปรแกรมการฝึกการทรงตัวต่อการรับความรู้สึกของข้อเท้า ประสิทธิภาพการทรงตัวและภาวะกลัวการล้มในผู้สูงอายุที่มีเส้นประสาทส่วนปลายเสื่อมจากเบาหวาน

บทคัดย่อ

โดย

ระพีพรรณ เทือกทักษ์

เสนอต่อบัณฑิตวิทยาลัย มหาวิทยาลัยศรีนครินทรวิโรฒ เพื่อเป็นส่วนหนึ่งของการศึกษาตาม

หลักสูตรปริญญาวิทยาศาสตรมหาบัณฑิต สาขาวิชากายภาพบำบัด

ตุลาคม 2556

ระพีพรรณ เทือกทักษ์. (2556). ผลของโปรแกรมการฝึกการทรงตัวต่อการรับความรู้สึกของข้อเท้า ประสิทธิภาพการทรงตัว และภาวะกลัวการล้มในผู้สูงอายุที่มีเส้นประสาทส่วนปลายเสื่อมจากเบาหวาน. ปริญญานิพนธ์ วท.ม. (กายภาพบำบัด) กรุงเทพฯ: บัณฑิตวิทยาลัย มหาวิทยาลัยศรีนครินทรวิโรฒ. คณะกรรมการควบคุม: ผศ.ดร.สายธิดา ลาภอนันตสิน.

การศึกษานี้มีวัตถุประสงค์เพื่อศึกษาผลของโปรแกรมการฝึกการทรงตัวแบบกลุ่มต่อการรับความรู้สึกของข้อเท้า ประสิทธิภาพการทรงตัว และภาวะกลัวการล้มของผู้สูงอายุที่มีเส้นประสาทส่วนปลายเสื่อมจากเบาหวาน ผู้เข้าร่วมการวิจัยเป็นผู้สูงอายุหญิงที่มีเส้นประสาทส่วนปลายเสื่อมจากเบาหวาน จำนวน 27 คน สุ่มแบ่งเป็น 2 กลุ่ม ได้แก่ กลุ่มที่ได้รับโปรแกรมการฝึกการทรงตัวแบบกลุ่ม อายุเฉลี่ย 68.38 ± 3.99 ปี จำนวน 13 คน และกลุ่มควบคุมที่ได้รับการออกกำลังกายด้วยยางยืด อายุเฉลี่ย 69.35 ± 3.97 ปี จำนวน 14 คน ทั้งสองกลุ่มได้รับการออกกำลังกายตามโปรแกรมของแต่ละกลุ่ม 50 นาที/วัน จำนวน 3 วัน/สัปดาห์ เป็นระยะเวลา 4 สัปดาห์ และได้รับการประเมินการรับความรู้สึกของข้อเท้าโดยการประเมินความสามารถการรับรู้ตำแหน่งของข้อเท้า การประเมินประสิทธิภาพการทรงตัวด้วย Modified Clinical Test of Sensory Interaction on Balance (mCTSIB), Berg Balance Scale (BBS) และ Timed Up and Go test(TUG) และการประเมินภาวะกลัวการล้มด้วยแบบประเมินภาวะกลัวการล้มในผู้สูงอายุไทยก่อนการฝึกและหลังการฝึกในสัปดาห์ที่ 4 ผลการวิจัยพบว่า ภายหลังการออกกำลังกายเป็นระยะเวลา 4 สัปดาห์ กลุ่มที่ได้รับโปรแกรมการฝึกการทรงตัวแบบกลุ่มมีการเพิ่มขึ้นของการรับความรู้สึกของข้อเท้า ประสิทธิภาพการทรงตัว และลดภาวะกลัวการล้มอย่างมีนัยสำคัญทางสถิติเมื่อเปรียบเทียบกับก่อนได้รับการฝึก และมีการรับความรู้สึกของข้อเท้า และประสิทธิภาพการทรงตัวสูงกว่าตลอดจนภาวะกลัวการล้มต่ำกว่ากลุ่มควบคุมอย่างมีนัยสำคัญทางสถิติร่วมด้วย ในขณะที่กลุ่มควบคุมไม่มีความแตกต่างของการรับความรู้สึกของข้อเท้า ประสิทธิภาพการทรงตัวและภาวะกลัวการล้มระหว่างก่อนและหลังได้รับการออกกำลังกายอย่างมีนัยสำคัญทางสถิติ จึงสรุปได้ว่าโปรแกรมการออกกำลังกายแบบกลุ่มเพื่อฝึกการทรงตัวของงานวิจัยนี้สามารถเพิ่มการรับความรู้สึกของข้อเท้า ประสิทธิภาพการทรงตัว และลดภาวะกลัวการล้มของผู้สูงอายุที่มีเส้นประสาทส่วนปลายเสื่อมจากเบาหวานในการฝึกเพียง 4 สัปดาห์ ดังนั้น โปรแกรมนี้สามารถนำไปประยุกต์ใช้เพื่อเพิ่มการรับ

ความรู้สึกของข้อเท้า ประสิทธิภาพการทรงตัวและลดภาวะกลัวการล้มในการส่งเสริมสุขภาพสำหรับผู้สูงอายุที่มีภาวะเส้นประสาทส่วนปลายเสื่อมจากเบาหวานในชุมชนของประเทศไทยต่อไปได้

The thesis titled

"Effects of Balance Training Program on Ankle Proprioception, Balance Performance and Fear of Falling in The Elderly with Diabetic Peripheral Neuropathy"

by

Rapeepun Thungtak

has been approved by the Graduate School as partial fulfillment of the requirements for the Master of Science Program in Physical Therapy of Srinakharinwirot University.

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Rapeepun Thungtak

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CHAPTER 1

INTRODUCTION

Background

Diabetes mellitus (DM) or diabetes is a metabolic disease characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both (1). Number of people with DM in the world is increasing, including in Thailand. Nowadays, type 2 DM has been estimated to affect more than 100 million people worldwide and the prevalence is predicted to increase to 300 million by 2025 (2). The increase in diabetes prevalence in Thailand can be revealed by the 3rd National Health Examination Survey (NHES) in 2007 (3) and the 4th NHES in 2009 which showed the prevalence in Thai adults rising from 6.7% to 7.5% of the population (4).

Individual persons who have got diabetic symptoms longer than ten years almost always have associated peripheral neuropathy (5) which is the most common complication that affects a large population with type 2 diabetes as well (6). Moreover, the survey study on DM management and complication status in primary care setting in Thailand found that the prevalence of late complication with peripheral neuropathy occurred mostly around 34% of diabetes (7).

The cause of diabetic peripheral neuropathy is associated with microvascular damage. The diabetic nerve and blood vessel changes are due to chronic hyperglycemic condition associated with inflammatory/immune processes. The types of nerves that can be affected are either large or small sensory fibers (8). The large fiber disease causes impaired proprioception, pressure and light touch sensation, while the small fiber disease impairs pain and temperature sensation. Both of the large and small fiber diseases are commonly presented as peripheral neuropathic complications in most diabetic cases (9). As proprioception decreases, the ability to coordinating basic protective reflexes and joint movement as well as complex balance and postural control also decreases (10, 11). Therefore, postural instability in diabetic neuropathy patient was often due to a lack of somatosensory feedback from, particularly, proprioception of the lower limbs (12).

Patients with diabetic neuropathy showed a postural instability that confirmed by an increases in area of center of pressure (CoP) sway, sway velocity of CoP, CoP trace length, ankle rotation, root mean square values of the CoP–CoM variable [the scalar distance at a given time between CoP and center of motion (CoM)], and values of CoPnet, which is the weighted sum of the time-varying position of the CoP from two force plates (13). According to postural instability in diabetic neuropathy, it will affect balance performance, especially in the elderly, which is an important cause of increasing falls risk and leading to decrease in quality of life (14) and developing fear of falling (15).

Most of the previous studies examined the effects of exercise programs improving glycemic control, insulin sensitivity, and other risk factors (16-18). However, there are very few studies that conducted on improving balance and reducing fear of falling in patients with diabetic peripheral neuropathy (19-21). Those studies found that individuals with diabetic peripheral neuropathy improved in balance (19-21) and reduced fear of falling (20) after training. However, most of those studies used equipments or devices for training which may be not feasible for home-based or community-based exercise.

Other than physical factors, it was found that older adults with diminished physical and functional abilities who also expressed a fear of falling were less likely to participating in social activities (22). The fear of falling among older people can influence on socialization stage of them (23). Falls history appears an important contributor to fear of falling. Moreover, the fear of falling appears more impact on functional activities and social support. This indicates that both physiological (strength and proprioception) and cognitive behavioral factors (fear of falls) should be considered when treating the elderly with diabetic patients (24).

Previous study recommend that group exercise has good effects on elderly persons in term of care prevention that can maintain function in daily life either physical or mental activities (25). The study suggested that weight or balance training as a group exercise improved the quality of an older adults' life by helping them to lessen the fear of falling. After 8 weeks, most of the participants indicated that they were very happy to meet and to do exercise or socialization regularly and wanted the study to continue (26).

Hence, group exercise program to improve balance and stimulate proprioception is important for elderly patients with diabetic peripheral neuropathy because it can also promote social participation and cognitive-behavior. Furthermore, there are only a few studies about the interaction of proprioception and balance in people with diabetes (21). In Thailand, there were previous studies related to an exercise program for balance training to improve balance performance in the elderly (27, 28). However, there is no study related to balance training program in elderly with diabetic peripheral neuropathy in Thai community.

Therefore, this study is interested in developing a balance training program as a group exercise for the elderly, who got diabetic peripheral neuropathy, in the community and investigating the training effects of the program on balance performance, ankle proprioception and fear of falling in the elderly with diabetic peripheral neuropathy. The hypothesis of this study is that the developed program can improve ankle proprioception, balance performance and reduce fear of falling in elderly with diabetic peripheral neuropathy who received the training.

Research Question

Does the developed balance training program of this study improve ankle proprioception, balance performance, and decrease fear of falling in elderly with diabetic peripheral neuropathy?

Objectives

General Objective

To investigate effects of the developed balance training program on ankle proprioception, balance performance and fear of falling in older individuals with diabetic neuropathy.

1. Specific Objectives

1. To compare balance performance, ability to recognize the ankle position and expression to fear of falling between groups of older individuals with diabetic peripheral neuropathy who receive and do not receive the balance training program before training and the 4th week after training.

2. To compare balance performance, ability to recognize the ankle position and expression to fear of falling between before training and the 4th week after training within each groups of older individuals with diabetic peripheral neuropathy who receive and do not receive the balance training program.

Hypothesis

1. The developed balance training program can increase balance performance and the ability to recognize ankle position (proprioception) in older individuals with diabetic peripheral neuropathy after training at the 4th week.

2. The developed balance training program can reduce fear of falling in older individuals with diabetic peripheral neuropathy after training at the 4thweek.

Expected Benefits &Application

1. The program of balance training in this study can be applied as a recommendation for improving ankle proprioception, balance performance and reducing fear of falling in elderly with diabetic peripheral neuropathy.

2. This study can encourage healthcare provider and elderly people in community to concern on an importance of training or exercise without requiring expensive equipment.

3. The results of this study can used as basic informations for other further studies related to proprioceptive and balance training.

Definition of Terms

1. Diabetes mellitus is a metabolic disease characterized by hyperglycemia resulting from defects in insulin secretion, insulin action, or both.

2. Peripheral neuropathy is a term for damage to nerves of the peripheral nervous system.

3. Balance is an ability to maintain the center of gravity of a body within the base of support with minimal postural sway.

4. Fear of falling is an anxiety symptom related to walking or a fear of falling in varying degrees of extreme, and is typical in most humans and mammals.

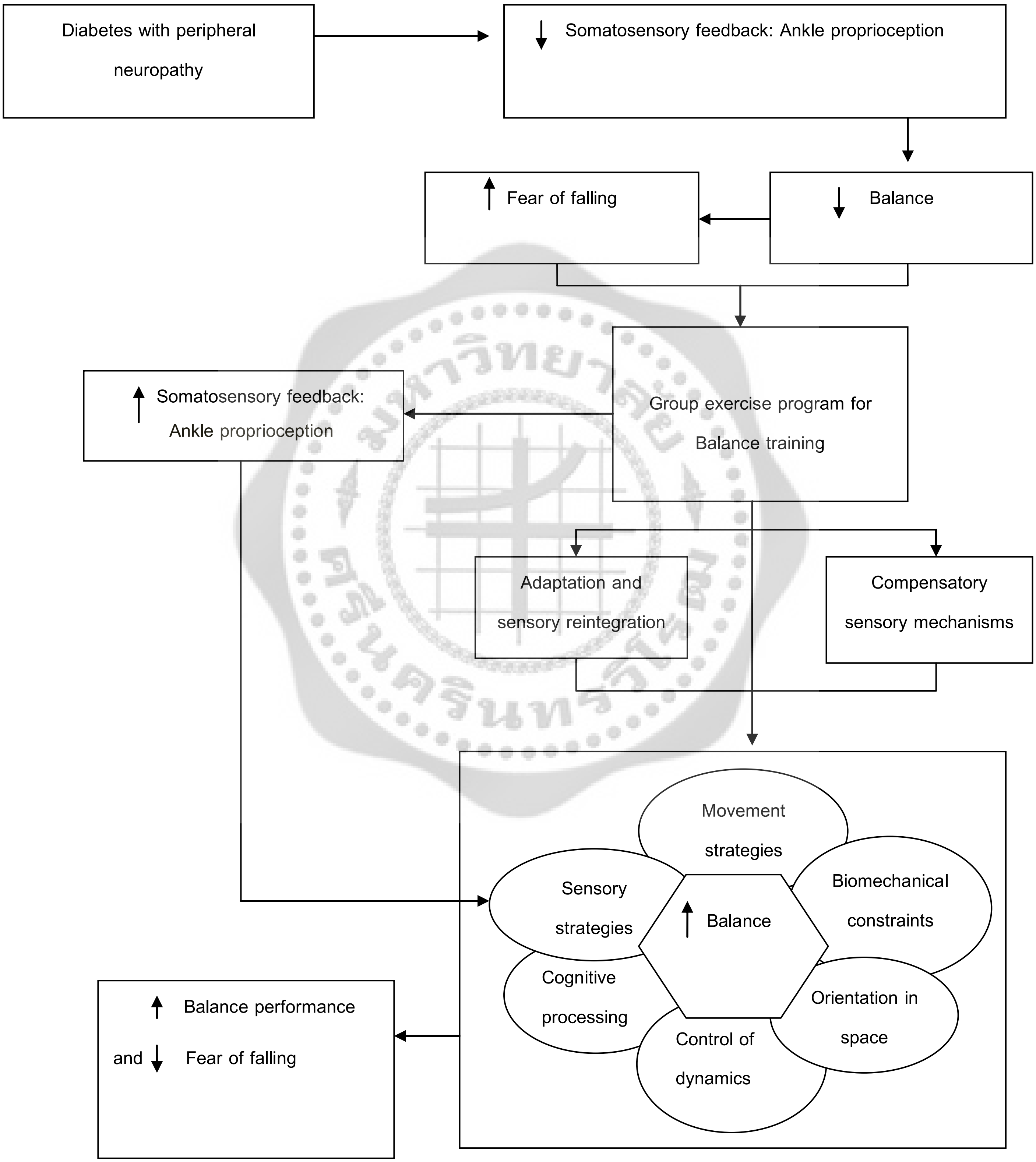
5. Proprioception is the sense of the relative position of neighbouring parts of the body and strength of effort being employed in movement.

6. Limits of stability are the areas over which an individual can move their center of mass (CoM) and maintain equilibrium without changing the base of support.

Keywords

Diabetic peripheral neuropathy, Balance, Proprioception, Fear of falling, Elderly

Conceptual Framework



CHAPTER 2

THE LITERATURES REVIEW

The review of literatures is divided into 21 parts as follows.

1. Pathophysiology of Diabetes Mellitus

2. Prevalence of Diabetes

3. Complications of Diabetes

4. Prevalence of Late Complication

5. Pathogenic Mechanisms for Microvascular Disease in Diabetes

6. Diabetic Peripheral Neuropathy

7. Peripheral Nerve Regeneration in Diabetes Mellitus

8. Drug Therapy for Glycemic Control in Older Patients with Diabetes

9. Aerobic Exercise

10. Exercise Training for Glycemic Control and Prevention of Complication in Patients with Diabetes

11. Exercise Training on Cutaneous Blood Flow and Nerve Function in Diabetes with Peripheral Neuropathy

12. Cause of Falling in Elderly Patient with Diabetes

13. Balance Impairment in Diabetes with Peripheral Neuropathy

14. Adaptation and Sensory Reintegration/ Compensatory Sensory Mechanisms

15. Postural Control

16. Exercise to Prevent Falls in Older Adults

17. Clinical Assessment of Diabetic Peripheral Neuropathy

18. Balance Assessment of Older Community Dwelling Adults

19. Proprioceptive Test

20. Fear of Falling Measurement Tools

21. Related Studies

1. Pathophysiology of Diabetes Mellitus

Diabetes mellitus, or Diabetes, is a group of chronic metabolic conditions characterized by hyperglycemia resulting from a relative or absolute lack of insulin action, or from resistance to insulin action, or both (1). The chronic hyperglycemia is usually associated with a long-term damage of multiple organs such as the retina, renal glomerulus, and peripheral nerve (1). The dysfunction and failure of these common affected structures result in long-term complications of diabetes as retinopathy, nephropathy, peripheral neuropathy and autonomic neuropathy (1).

From American Diabetes Association in 2012, diabetes mellitus is classified in to four clinical classes as follows:

1.1) Type 1 diabetes, previously called insulin dependent diabetes or juvenile-onset diabetes, is resulted from beta-cell destruction in the pancreas, and is characterized by a complete lack of insulin production. Type 1 diabetes accounts for 5% to 10% of all cases with diabetes (1).

1.2) Type 2 diabetes, referred to as non–insulin dependent diabetes or adult-onset diabetes, is resulted from an abnormal increase in resistance to the action of insulin and the body cannot produce enough insulin to overcome the resistance (1). Type 2 diabetes accounts for 90% to 95% of all diagnosed diabetes cases. The risk of developing of type 2 diabetes associates with genetic and increases with age, obesity, and also lack of physical activity (1).

1.3) Gestational diabetes is a condition of glucose intolerance that affects some women during pregnancy (1).

1.4) Other specific types of diabetes is a group of other types of diabetes caused by specific genetic defects of beta-cell function or insulin action, diseases of the pancreas, or drugs or chemicals (1).

2. Prevalence of Diabetes

Type 2 diabetes mellitus (Type 2 DM) has been estimated to affect more than 100 million people worldwide and the prevalence is predicted to increase to 300 million by 2025 (2). Including in Thailand, the number of patients with diabetes mellitus is also increasing. The increase in diabetes prevalence in Thailand can be revealed by the 3rd National Health Examination Survey (NHES) in 2007 (3) and the 4th NHES in 2009 which showed the DM prevalence in Thai adult rising from 6.7% to 7.5% of the population (4). Therefore, the study related to management and prevention of complications associated with diabetes is an important topic that should be concerned.

3. Complications of Diabetes

Many different organ systems in the body can be affected by diabetes and can becomes serious complications with advancing time of chronic hyperglycemia. Complications from diabetes can be classified as microvascular and macrovascular complications which resulting in organ and tissue damage (29).

Microvascular complications involve small vessels, while macrovascular complications involve large vessels. Microvascular complications include nervous system damage (neuropathy), renal system damage (nephropathy) and eye damage (retinopathy). Macrovascular complications include cardiovascular disease, cerebrovascular disease and peripheral vascular disease (29).

3.1 Microvascular Complications of Diabetes

The following reviews are related to a common microvascular complications that usually found associated with chronic diabetes.

3.1.1 Diabetic retinopathy

Diabetic retinopathy (DR) is a microvascular complication affecting the peripheral retina, the macula, or both which causes of visual disability and blindness in people with diabetes. A poor glycemic control appears to be the factor inducing development and progression of DR in people with diabetes because hyperglycemic condition will cause of an impairment of retinal blood flow, an increased inflammatory cell adhesion to retinal blood vessels, and a capillary blockage that lead to hypoxia and damage of the retina (29).

3.1.2 Diabetic neuropathy

Diabetic peripheral neuropathy (DPN) is a common complication estimated to affect 50% of individuals with diabetes. The primary risk factor for DPN is a poor hyperglycemia, while the other independent risk factors are age, duration of disease, cigarette smoking, hypertension, dyslipidemia, and elevated triglycerides. The risk factors result in thickening of basement membrane of blood vessel, pericyte loss, loss of microfilaments, and decreased capillary blood flow to nerve fibers, which leading to decreased nerve perfusion and endoneural hypoxia (29).

3.1.3 Diabetic nephropathy

Diabetic nephropathy is defined as persistent proteinuria in patients without urinary tract infection or other diseases causing the proteinuria. The thickening of glomerular basement membranes and glomerular hyperfiltration are the pathologic characteristics found in diabetic nephropathy. These pathological changes lead to mesangial (central part of the renal glomerulus) extracellular matrix expansion and further increases in urinary albumin excretion and progressing to glomerular and tubular sclerosis and renal failure which is a cause of end-stage renal disease (29).

3.2 Macrovascular complications of diabetes

3.2.1 Cerebrovascular disease (CVD)

Hyperglycemic condition in diabetes is one of risk factors of stroke and people with diabetes who having a stroke usually show more severe neurological deficits and disability. Since diabetes affects the cerebrovascular circulation by increasing the risk of intracranial and extracranial atherosclerosis which finally leading to the presence of CVD (29).

3.2.2 Peripheral artery disease

Peripheral artery disease (PAD) is characterized by the intermittent pain, ache, or discomfort of lower extremity that may occur during exercise or walking but resolves with rest that called intermittent claudication symptoms. For the severe PAD, the symptoms also show even at rest. The pain at rest is caused by ischemia of the lower extremity, indicating inadequate blood flow to the affected lower extremity. The ischemia of the lower extremity from PAD is a major risk factor for lower-extremity amputation in patient with diabetes (29).

4. Prevalence of Late Complication

The survey study on diabetes management and complication status in primary care setting in Thailand found that the prevalence of late complication with peripheral neuropathy was quite high which occurred around 34% of diabetes (7) as shown in Table 1.

Table 1 The prevalence of late complication in primary care setting in Thailand (7)

Complications	Prevalence of late complications
Peripheral neuropathy	34.0%
Proteinuria	17.0%
Retinopathy	13.6%
Healed foot ulcer	6.9%
Stroke	1.9%
Acute foot ulcer/gangrene	1.2%
Myocardial infarction	0.7%
End stage renal failure	0.1%

5. Pathogenic Mechanisms for Microvascular Disease in Diabetes

The pathogenic mechanism of microvascular disease is a chemical reaction between by-products of sugars and proteins which causes of irreversible cross-linked protein derivatives called advanced glycosylated end products (AGEs) (29). These derivatives can effect on surrounding tissues, including thickening of collagen and endothelium that lead to endothelial cell dysfunction (29). While, the other mechanisms involved in microvascular disease are the protein kinase C (PKC) pathway (a family of multifunctional enzymes involved in signal transduction and gene expression of growth factors and inflammatory signals that may increase vascular permeability) and the polyol pathway (the enzymes aldose reductase and sorbitol dehydrogenase, which catalyze reactions that can lead to sorbitol accumulation-associated osmotic and oxidative stress damage to the endothelium) (29).

6. Diabetic Peripheral Neuropathy

"Diabetic peripheral neuropathy (DPN) is defined as the presence of symptoms and/or signs in the peripheral nerves, mostly affecting the lower extremities, resulting from diabetes without other causes of neuropathy (30)". DPN is usually found in people with long-termed diabetes in the prevalence around 50%.

The metabolic effects of chronic hyperglycemia and the consequences of ischemia on the peripheral nerves lead to neuro-axonal dysfunction and damage (30). The pathophysiology of DPN from hyperglycemic effects are including of an increase in oxidative stress yielding advanced glycosylated end products (AGEs), a polyol accumulation causing impaired (Na+/K+)-ATPase activity, homocysteinemia and decrease in nitric oxide leading to impaired endothelial function (31). These effects result in nerve sodium accumulation, impaired axonal transport and structural damage to the nerves (30).

DPN can be classified into 3 major groups by the nature of symptoms, clinical course and pattern of neurological involvement as follows; 1) focal neuropathies, 2) generalized symmetrical polyneuropathy , and 3) radiculo-plexus neuropathies (30).

6.1 Focal neuropathies can occur in early or later course of diabetes. It may involve either cranial nerve (CN), commonly in CNIII, CNIV, CNVI and CNVII, or peripheral nerves of limbs. The mechanism of focal neuropathy in people with diabetes is evoked by repeated microtrauma, ischemia, and inflammatory process (30).

6.2 Generalized symmetrical polyneuropathy can be subdivided into 3 forms; 1) chronic sensorimotor polyneuropathy, which is the most common form of DPN that involves either small nerve fibers, large nerve fibers or mixed, 2) acute sensory neuropathy which is a rarely form of DPN that shows the acute severe pain associated with sudden weight loss, depression and erectile dysfunction, and 3) peripheral autonomic neuropathy which involves a decrease in or absence of sympathetic tone innervations of the peripheral vasculatures and/or sweat glands (30).

6.3 Radiculo-plexus neuropathies are developed by the same mechanisms as focal neuropathy and may also occur in early and later course of diabetes, but affect the roots of nerve plexus such as lumbosacral plexus. Therefore, the neuropathic symptoms of multifocal neuropathies are widespread or radiated along a group of peripheral nerves originated from the involved nerve roots unlike specific focal neuropathy (30).

7. Peripheral Nerve Regeneration in Diabetes Mellitus

Diabetes mellitus is usually associated with both large and small vessel vascular changes which caused impaired peripheral nerve regeneration and increased risk for diabetic complications such as peripheral neuropathy, nephropathy and retinopathy (32).

Ebenezer and colleagues in 2011 examined blood vessel, Schwann cell and axonal regeneration using validated axotomy models and compared patterns and the relationship of regeneration among these different structures in diabetes mellitus with neuropathy. The studied observed and quantified regenerative and collateral axonal sprouting rates, blood vessel growth rate and Schwann cell density by using established stereology techniques. The study found that rates of collateral ($P=0.0001$), dermal axonal regenerative sprouting ($P=0.02$), Schwann cell migration ($P<0.05$) and blood vessel growth ($P=0.002$) were slower in diabetes mellitus with neuropathy. The studied recommend that regenerative deficits are a common in diabetes mellitus which may development of neuropathy, and suggested that enhancement of blood vessel growth might facilitate axonal regeneration (32).

Bradley and colleagues in 1995 assessed myelinated nerve fiber regeneration in diabetic sensory polyneuropathy in sural nerve biopsy specimens. The study found that regenerative clusters initially developed within abnormally persistent Schwann cell basal laminal tubes which reduce in total myelinated fiber density. The study recommended that reduction in the number of regenerating fibers with declining total fiber density indicating that axonal regeneration failure with advancing neuropathy related to a lack of nerve growth factor (NGF) receptor production by Schwann cells. The production of (NGF and NGF receptors by denervated Schwann cells is important for axonal regeneration in diabetic sensory polyneuropathy (33).

Therefore, the studies confirmed that regenerative deficits are a common occurrence in diabetes mellitus which may develop neuropathy. The studies recommended that production of nerve growth factor (NGF) and NGF receptors by denervated Schwann cells might facilitate axonal regeneration in diabetic sensory polyneuropathy.

8. Drug Therapy for Glycemic Control in Older Patients with Diabetes

8.1 Alpha-Glucosidase Inhibitors

Alpha-glucosidase inhibitors delay glucose absorption in small intestine by blocking the enzyme alpha-glucosidase in the brush border of the small intestine. Thus it can reduce the meal-related blood glucose increases (34). The available commercial alpha-glucosidase inhibitors drugs include of Acarbose, Voglibose and Miglitol (35). Acarbose should be taken before carbohydrate containing meals and should not be used when meals are missed. It does not cause weight gain or hypoglycaemia. Acarbose is contraindicated in patients with hepatic or renal impairment, inflammatory bowel disease, or a history of bowel obstruction. While, its side-effects include of bloating, flatulence, abdominal cramps, and diarrhea, which limits their clinical use (34). Voglibose is the newest of the alpha-glucosidase inhibitors drugs that has been shown significantly improving glucose tolerance, in terms of delayed disease progression and the high number of patients who achieved normoglycemia (35).

8.2 Sulfonylureas

Sulphonylureas actions are mainly by stimulating insulin release from the beta-cells of a pancreas and also decreasing insulin resistance in peripheral target tissues such as muscle and fat (34). Although, these actions are normally well tolerated because they stimulate endogenous insulin secretion (35), hypoglycemia is still the most common side effect found (34). Glyburide and Glipizide are trade name of sulphonylureas drugs. The Glyburide is associated with higher rates of hypoglycemia compared to Glipizide. There are many risk factors for hypoglycemia when using sulphonylueas including of age-related impaired renal function, simultaneous use of insulin or insulin sensitizers, age greater than 60 years, current hospital discharge, alcohol abuse, caloric restriction, multiple medications or medications that potentiate sulfonylurea actions (35).

8.3 Meglitinides

The glinides, repaglinide, and nateglinide, are commercial meglitinides. Meglitinides functions as secretagogues that stimulate the release of insulin from the beta-cells by the pancreas (34). Meglitinides shows a rapid onset and a short duration of action (4-6 hrs). Thus it causes lower risk of hypoglycemia. Meglitinides are given before meals for postprandial blood glucose control (35). The glinides has a faster onset and shorter duration of action than the sulphonylureas and thus it associated with a reduced risk of hypoglycaemia. Therefore, meglitinides can be used in patients with impaired renal function, lessen weight gain, and are metabolized and excreted by the liver (34).

8.4 Biguanides

An example of biguanides is metformin. The metformin is the most commonly used in overweight DM patients. It suppresses hepatic glucose production, increases insulin sensitivity, and decreases the absorption of glucose from the gastrointestinal tract (35). Therefore, a potential concern with metformin is lactic acidosis which should be used with caution in elderly diabetic individuals with renal impairment (34). The metformin have a low incidence of hypoglycemia compared to sulfonylureas (35) when used as monotherapy. Since, it does not affect insulin secretion. However, It can be associated with hypoglycaemia when used in combination with sulphonylureas or insulin (34).

8.5 Dipeptidyl-Peptidase IV Inhibitors

Dipeptidyl-peptidase IV inhibitors (DPP-4 inhibitors) can increase active levels of hormones improving islet function and glycemic control in type 2 DM. DPP-4 inhibitors are a new class of anti-diabetogenic drugs (35). It is effective in controlling hyperglycaemia, reducing glycosylated haemoglobin (HbA1c), improving pancreatic beta-cell function. DPP-4 inhibitors can be used as monotherapy or in combination with other agents (34). The DPP-4 inhibitors have low risk of producing hypoglycemia and weight gain (35). Whereas, an inhibition of DPP-4 activity by the DPP-4 inhibitors may cause several adverse effects such as increased blood pressure, neurogenic inflammation, and immunological reactions (34).

8.6 Incretins/GLP-1 mimetics

Incretins/GLP-1 mimetics actions by stimulating insulin production from pancreatic beta-cells and also decreasing glucagon secretion resulted from slowing gastric emptying, and suppressing appetite. Incretins/GLP-1 mimetics infusion will increase insulin release and reduce fasting blood glucose concentrations in patients with longstanding type 2 DM. The side-effects of incretins/GLP-1 mimetics is including of nausea and less commonly vomiting or diarrhea, particularly when starting therapy. While, using a sustained release formulation of Incretins/GLP-1 mimetics can improve glycaemic control and reduce in body weight, without increase in risk of hypoglycaemia (34).

8.7 Thiazolidinediones

Thiazolidinediones (TZDs) can improve insulin sensitivity by increasing the efficiency of glucose transporters. Therefore, TZDs can reduce both fasting and postprandial glucose concentrations leading to lowering HbA1C by 1–2%. TZDs do not cause hypoglycaemia when used as a single agent but can do so when used in combination with other agents. TZDs have also been associated with an increase in myocardial infarction (MI) incidence and thus worsening of heart failure (34).

8.8 Insulin

Individuals with type 2 DM and progressive beta-cell failure may need insulin therapy as the disease progresses (34). Insulin can be used alone or combined with oral hypoglycemic agents (35). The long acting forms of insulin are less likely to cause hypoglycemia when compared to the short acting forms (35). Furthermore, insulin use can improve insulin resistance and may have cardiovascular benefits (34).

8.9 Insulin analogues

Insulin analogue therapy is limited in its ability to mimic normal physiological insulin secretion. Traditional intermediate and long acting insulins (NPH insulin or neutral protamine Hagedorn, lente insulin, and ultralente insulin) are limited by inconsistent absorption (35)

Therefore, the information related to drugs treatment for glycemic control in individual patients with diabetes should be known as a basic data for giving an advice to the patients and keeping awareness of complications/side effects from the drug use such as hypoglycemia that may occur during the patients enroll the exercise programs.

9. Aerobic Exercise

Aerobic exercise aims principally to improve cardiorespiratory function (36). The features of an aerobic exercise include of the mode, duration, intensity and frequency (37). The modes of aerobic exercise may be a high or a low impact exercises. Some sport activities present aerobic training if continuous movement are involved (36). The best duration of an aerobic exercise session is the continuous range of 30 to 60 minutes. Intensity of aerobic exercise should be at least 50% of an individual's maximal oxygen uptake (50% of VO_{2max}) (37). The frequency of an aerobic exercise has been approved in at least three sessions a week (37).

Maximal oxygen uptake (VO_{2max}) is dependent upon many factors, including natural physical endowment, activity status, age, and gender, but it is the best index of exercise capacity and maximal cardiovascular function (37). Aerobic training can increase maximal oxygen uptake by up to 25%. The degree of increase depends upon the initial level of fitness and age as well as the intensity, frequency, and duration of training (37). The percentage of maximal oxygen uptake, which requires laboratory measurements, can be practically approximated by heart rate or by level of perceived exertion during exercise (37) because there is a well-established relationship between percentage maximal oxygen uptake (VO_{2max}) and percentage maximum heart rate (HR_{max}) and also level of perceived exertion (38).

The aerobic exercise can be performed as being short-term (5-10 minute), light (30-49% of VO_{2max}) to moderate (50-74% of VO_{2max}) submaximal exercise and long- term (longer than 30 minute), moderate to heavy submaximal (60-85% of VO_2max) exercise (39). The comfortable and effective exercise intensity is suggested at 70% of HR_{max} as the threshold for aerobic improvement (38). However, the exercise at a lower intensity of 60% to 65% HR_{max} for 45 minutes also proves as aerobic benefits (38).

In addition to oxygen uptake and heart rate indicators of exercise intensity, the rating of perceived exertion (RPE) (Appendix G) also can be used as an indicator. RPE is a psychophysiologic approach, the perceived feelings relative to exertion level during exercise are rated on a numerical scale called the Borg scale (38). The adjusting RPE during exercise is an effective way to recommend exercise on the basis of an individual's perception (38). For example, an RPE of 13 or 14 (exercise that feels "somewhat hard"; coincides with about 70% HR_{max} during cycle ergometer and treadmill exercise) (38).

10. Exercise Training for Glycemic Control and Prevention of Complication in Patients with Diabetes

Colberg and colleagues in 2010 suggested that the exercise plays a major role in the prevention of insulin resistance and complication in type 2 diabetes. Both aerobic training and resistance training improve insulin action and can assist with management of blood glucose levels, lipids, blood pressure, cardiovascular risk, mortality, and quality of life (40).

The systematic review by Umpierre and colleagues in 2011 recommended that aerobic, resistance, and combined training are associated with hemoglobin A1c (HbA1c) decreases. The study demonstrated that an exercise of more than 150 minutes per week is associated with greater declines in HbA1c than that of 150 minutes or less per week in patients with type 2 diabetes (16). A combination of aerobic and resistance exercise training may be more effective in improving blood glucose control than either alone (40). The effects of a single bout of aerobic exercise on insulin action vary with duration, intensity, and subsequent diet (41).

Bacchi and colleagues in 2012 evaluated the effects on blood glucose of a single bout of aerobic exercise or resistance exercise in a group of type 2 diabetic patients enrolled in a regular training program. Glucose concentrations were measured by continuous glucose monitoring system for 48 hours, comprising a day with an exercise session and the following non-exercise day. The study found that aerobic and the resistance training induced similar long-term improvements in HbA1c levels, there were different behaviors between the groups in blood glucose readings during and for several hours after a single exercise session. Moreover, the study found the significant reduction in glucose concentrations during the aerobic exercise but not during the resistance exercise. This study suggested that aerobic exercise and resistance exercise training have similar long-term metabolic effects in diabetic subjects. However, the acute effects of single bouts of these exercise types be different, with a possible increase in late onset hypoglycemia risk after aerobic exercise (42).

Aerobic exercise should be performed at least three times per week with no more than two consecutive days between bouts of activity because of the transient nature of exercise-induced improvements in insulin action which may risk to hypoglycemia (41). Aerobic exercise should be at least at moderate intensity, approximately 40%–60% of VO_{2max}, and additional benefits may be gained from vigorous exercise (> 60% of VO_{2max}). For most people with type 2 DM, brisk walking is a moderate-intensity exercise (41).

Resistance exercise should be undertaken at least twice weekly on nonconsecutive days but more ideally three times a week as part of a physical activity program for individuals with type 2 DM, along with regular aerobic activities (41). Training should be moderate (50% of 1-repetition maximum, or 1-RM) or vigorous (75%–80% of 1-RM) for optimal gains in strength and insulin action. Each training session should minimally include 5–10 exercises involving the major muscle groups (in the upper body, lower body, and core). The exercise for each major muscle groups should be done with the resistance that causing only closed to fatigue symptoms by completed 10-15 repetitions at the beginning and then progress by gradually increase the weight or resistance that can be lifted completely in 8-10 repetitions. Resistance machines and free weights (e.g., dumbbells and barbells) can result in fairly equivalent gains in strength and mass of targeted muscles (41).

Although moderate aerobic exercise improves blood glucose and insulin action acutely, the risk of exercise-induced hypoglycemia is minimal without use of exogenous insulin or insulin secretagogues (40). Glucose monitoring can be performed before and after physical activity to assess its unique effect. The American Diabetes Association recommends that carbohydrate must be ingested before any physical activity if the pre-exercise blood glucose level of patients is less than 100 $mgIdL^{-1}$ (5.5 $mmolIL^{-1}$). Insulin users should likely consume up to 15 g of carbohydrate before exercise for an initial blood glucose level of 100 $mgIdL^{-1}$ or lower (41). While, persons with type 2 diabetes who do not using insulin or insulin secretagogues are unlikely to experience hypoglycemia related to physical activity. Users of insulin and insulin secretagogues are advised to supplement with carbohydrate as needed to prevent hypoglycemia during and after exercise with type 2 diabetes.

Before undertaking exercise more intense than brisk walking, sedentary persons with type 2 diabetes will likely benefit from an evaluation by a physician (40). The goal is to more effectively target individuals at higher risk for underlying cardiovascular disease (CVD). In general, electrocardiography (ECG) stress testing may be indicated for individuals matching one or more of these criteria (e.g., Age > 40 years, with or without CVD risk factors other than diabetes; Age > 30 years and Type 1 or 2 diabetes of > 10 years in duration, hypertension, cigarette smoking, dyslipidemia, proliferative or preproliferative retinopathy, nephropathy including microalbuminuria). While, any of the following, regardless of age, such as a known or suspected coronary artery disease, cerebrovascular disease, and/or peripheral artery disease; autonomic neuropathy; advanced nephropathy with renal failure, should be recommended for ECG stress test as well before undertaking exercise more intense than brisk walking (41). Moreover, individuals with angina classified as moderate or high risk should likely begin exercise in a supervised cardiac rehabilitation program (40).

Physical activity is advised for anyone with peripheral artery disease (40). Mild to moderate exercise may help prevent the onset of peripheral neuropathy (41). Individuals with peripheral neuropathy and without acute ulceration can participate in moderate weight-bearing exercise, for example, a moderate walking likely does not increase risk of foot ulcers or re-ulceration with peripheral neuropathy (40). In contrast, anyone with a foot injury or open sore or ulcer should be restricted to only a non-weight bearing physical activity (41). Additionally, an education for a comprehensive foot care including daily inspection of feet and use of proper footwear is suggested for prevention and early detection of sores or ulcers in diabetes (40).

Furthermore, a moderate-intensity aerobic training can improve autonomic function in individuals with and without cardiovascular autonomic neuropathy (41). Individuals with cardiac autonomic neuropathy should be screened and received physician approval and possibly exercise stress test prior to exercise initiation. Exercise intensity is best prescribed using the heart rate reserve method with direct measurement of maximal heart rate (40).

Cautiously, the careful screening and physician approval are suggested in diabetic individuals with proliferative or preproliferative retinopathy or macular degeneration, before initiating an exercise program (41). The exercise for individuals with uncontrolled proliferative retinopathy should avoid activities that greatly increase intraocular pressure and hemorrhage risk (40).

Diabetic nephropathy is a major risk factor for death in those with diabetes and it approximately develops in 30% of individuals with diabetes. Before begin a physical activity in individuals with diabetic nephropathy, it should be carefully screened, had physician approval, and possibly undergone stress testing to detect coronary artery disease and abnormal heart rate and blood pressure responses. However, both aerobic and resistance training can improve physical function and quality of life in individuals with kidney disease. Especially, the resistance exercise training is effective in improving muscle function and activities of daily living, which are normally severely affected by later-stage kidney disease (41).

The previous studies revealed that either aerobic or resistance training can improve insulin action and blood glucose control. Therefore, those trainings can be able to prevent complications from hyperglycemic condition in diabetes and leading to a better quality of life in patients with diabetes.

11. Exercise Training on Cutaneous Blood Flow and Nerve Function in Diabetes with Peripheral Neuropathy

Diabetes is correlated with both microvascular and macrovascular diseases affecting several organs. While, diabetic microvascular diseases involving small vessels, such as capillaries. Especially, characteristic of peripheral neuropathy include axonal thickening with progression to axonal loss, basement membrane thickening, loss of microfilaments in pericyte (ie, cytoskeletal filaments comprising actin and myosin), and decreased capillary blood flow to C fibers, leading to decreased nerve perfusion and endoneurial hypoxia (29).

Heidarianpour and colleagues in 2007 evaluated the effects of exercise training on endothelial dysfunction and insulin signaling of cutaneous microvascular in streptozotocin-induced diabetic rats. The study found the significant increases cutaneous blood flow in diabetic groups. This study suggested that chronic exercise improved endothelium-dependent dilatation in diabetic rats (43).

Heidarianpour in 2010 evaluated the effects of exercise training on characterize cutaneous microvascular responses by Laser Doppler flowmetry in streptozotocin-induced diabetic rats. The study found the significant increases acetylcholine (Ach) induced cutaneous perfusion. This study suggested that beneficial effect of regular exercise on cutaneous microvascular endothelium-dependent dilatation in diabetic rats after training (44).

Kluding and colleagues in 2012 evaluated the effects of the exercise on nerve function in people with diabetic peripheral neuropathy (DPN). The study found the significant reductions in pain, neuropathic symptoms and increased intraepidermal nerve fiber branching from a proximal skin biopsy in people with diabetic peripheral neuropathy after training (45).

From the previous studies, exercise training should increase cutaneous blood flow and nerve function in diabetic peripheral neuropathy after training by cutaneous microvascular endothelium-dependent dilatation and intraepidermal nerve fiber branching.

12. Cause of Falling in Elderly Patient with Diabetes

Older adults with type 2 diabetes have an increased risk of falls. The risk factors for falls in diabetes-related complications are such as peripheral neuropathy, reduced vision, renal dysfunction, impaired balance, strength and gait. Additionally, DM with insulin therapy demonstrated an association with increase in falls due to more severe of disease and hypoglycemic episodes (46).

Schwartz and colleagues in 2002 studied the risk factors of falling in older women with diabetes. The study found that falls risk factors tended to be the most common among individuals using insulin. Side-effects of insulin treatment, such as episodes of dizziness or fainting, may lead to an increased risk of falls. Effect of poor static and dynamic balance is a factor in the causal pathway between diabetes and increased risk of falling which postural instability was only increased in individuals with diabetes who also had peripheral neuropathy. Other factors that association between falls risk were history of coronary heart disease, arthritis, depression, poor vision, and use of medications for sleeplessness or anxiety (47).

Volpato and colleagues in 2005 studied the risk factors for falling in older women with diabetes. The study found that risk factors for falls included of cardiovascular conditions, peripheral nerve dysfunction, visual impairment, elevated body mass index (BMI), lower Mini-Mental State Examination (MMSE) score, and more depressive symptoms. Moreover, the diabetes women having poorer lower-extremity function and activities of daily living (ADL) disability and using insulin therapy also showed the highest risk of falling (48).

Quandt and colleagues in 2006 studied the risk factors of falls among the older with diabetes. The study found that falling in diabetic elderly usually related to the presence of health characteristics, including slow foot healing, tingling and numbness in the feet, arthritis, eye problems, and stroke. Moreover, falling was also associated with a greater number of chronic conditions, long duration of diabetes, poorer physical functioning, limited lower limb mobility, lower mental and physical scores and more prescription medications (49).

Schwartz and colleagues in 2008 studied the risk factors for falling among the older women with diabetes. There are a lot of factors were found to be associated with falls. Those factors were loss of light touch discrimination, low peroneal nerve response amplitude at the popliteal fossa, loss peripheral nerve function, visual acuity, decreasing glomerular filtration rate (GFR < 60 mL/min/1.73 m^2), change diastolic blood pressure (DBP), grip strength, knee extensor strength, and standing balance (46).

Therefore, the previous studies related to falls risk in older women with diabetic demonstrated that management of older women with diabetes, beside the medication treatment, should also be considered in fall prevention. Thus, developing an effective program for improving balance and somatic sensation, especially proprioception of ankles, in elderly women with diabetic peripheral neuropathy is the focus of this research.

13. Balance Impairment in Diabetes with Peripheral Neuropathy

There are many studies presented an impaired postural stability founded in diabetes with peripheral neuropathy. For example, the study using a posturography to detect postural sway in diabetic patients showed that type 2 diabetic patients with neuropathy had a larger area of postural sway and a higher speed of postural sway per second than patients without neuropathy (50).

Another study using the Interactive Balance System (Tetrax, Ramat Gan, Israel) assess an interaction of vertical pressure fluctuations on four independent platforms found that, in a position with closed eyes, diabetic patients with severe and moderate neuropathy were significantly less stable than normal subjects and diabetic patient without neuropathy (51).

Emam and colleagues in 2009 used a computerized dynamic posturography in type 2 diabetic patients with neuropathy to examine postural equilibrium. The study found that the composite equilibrium score, sensory organisation test 1, 2 and 3 conditions were significantly lowered in neuropathic when compared to non-neuropathic patients, and no significant difference could be found between the two groups in dynamic conditions. This study reflects that the impairment of postural stability in type 2 diabetes patients with peripheral neuropathy due to an impairment of the somatosensory system (10).

Turcot and colleagues in 2009 used an accelerometric-based method to measure accelerations at lumbar and ankle levels in diabetic patients and compared with control subjects. The study found that diabetic patients with peripheral neuropathy showed a higher-range and root mean squared acceleration values compared with diabetic patients without peripheral neuropathy. Significant differences between groups were detected for anterior posterior range of lumbar acceleration, which was significantly higher for diabetic patients with peripheral neuropathy compared with those of other groups. Significant higher values for diabetic patients with peripheral neuropathy were also detected for anterior posterior range and root mean square of ankle accelerations when compared with control subjects (52).

All the studies that mentioned above confirm that diabetic patients with peripheral neuropathy have impaired static and dynamic balances and the balance impairment is related with the underlying impaired somatosensory of the lower leg (10). Moreover, previouse study found that the body sway in patients with diabetic peripheral neuropathy was associated with somatosensory deficits in position, vibration, and tactile sensation (13).

The tactile system is associated with sensations of touch and pressure and vibration which the involved receptors are Merkel’s cells, Pacinian corpuscles, Meissner’s corpuscles, and Ruffini endings. The proprioceptive system is associated to joint position sense, and joint motion sense (kinesthesia). The receptors providing the central nervous system with proprioceptive information are muscle spindles, joint afferents, and Golgi tendon organs (53).

The lower leg proprioceptive feedback is a critical component for human automatic balance correcting responses. When both tactile and proprioceptive information are not conducted to the central nervous system in patient with diabetic neuropathy, impairment in control of static and dynamic balance may occur and may lead to an increased risk of falling (53).

14. Adaptation and Sensory Reintegration/ Compensatory Sensory Mechanisms

Control of upright standing relies on the integration of sensory inputs from vestibular, visual, and proprioception. To maintain postural stability in human, the information from several sensory channels will be compromised by reweighting them, for instance, in older that lose vestibular, visual, or proprioceptive function will reweight or compensate by using the information from the remaining inputs. In daily living, the ability to quickly reweight sensory information in response to sudden changes in the environment is also frequently challenged. For example, when a bus is stopping or when moving from a bright to a dark environment (54).

The normal postural control to maintain orientation and stability in various tasks and environmental changes needs sensorimotor adaptation that means the modifications of how we sense and move. Many previous study have emphasized an importance of adaptation between sensory and movement strategy, for example: execution of the ankle strategy adapting for maintain stability depends on somatosensory inputs that reporting body's position related to surface of support, whereas hip strategy execution relies on sensation from vestibular inputs (55).

The adaptation is an essential aspect of normal postural control due to the experience and learning of individuals. The learning process can facilitate an increase in synaptic activity of neuron in the brain which called plasticity. The plasticity can result in either short term functional change or long term, structural change, and then if there is a long-term structural change, this will become a behavioral skill (55).

Therefore, adaptation is an important aspect of normal postural control and is significantly dependent on experience and learning that can be resulted from training effects. Thus, the balance training in older people should facilitate sensorimotor adaptation by using the sensory-reintegration and movement strategy to induce plasticity of the brain which leading to improvement of postural control skill.

15. Postural Control

Postural control systems contain a complex organization that controls the orientation and the equilibrium of the body during upright stance position (56). Postural orientation involves the active control of body alignment and tone with respect to gravity, support surface, visual environment and internal references (57). Postural equilibrium involves the coordination of sensorimotor strategies to stabilize the body's centre of mass (CoM) during both self-initiated and externally triggered disturbances in postural stability (57).

Understanding and properly performing stability and balance training in patients need absolute knowledge of the sources of patients' postural problems (56). A summary of six important resources for postural control is biomechanical constraints, movement strategies, sensory strategies, orientation in space, control of dynamics, and cognitive processing (57).

Biomechanical constraints are important factors that affect balance. They are related to the size and quality of the base of support, that are the feet. Therefore, the quality of the base of support which affecting balance of individual person includes of size, strength, range of motion, pain or control of their feet (57).

Movement strategies are ankle strategy, hip strategy, and stepping strategy. These strategies can be used to return the body to equilibrium in a stance position which two strategies (ankle and hip strategies) keep the feet in place and the other strategy (stepping strategy) changes the base of support through the individual stepping or reaching. The ankle strategy is the body moves at the ankle as a flexible inverted pendulum to maintain balance for small amounts of sway when standing on a firm surface. The hip strategy is the body exerts torque at the hips to quickly move the body CoM, is used when persons stand on a narrow or a compliant surface (57).

Sensory strategies are an integration of sensory information from somatosensory, visual and vestibular to interpret complex sensory environments. While subjects change the sensory environment, they need to re-weight their relative dependence on each of the senses. During standing on a firm base of support, healthy persons rely on integrated information from somatosensory (70%), vision (10%) and vestibular (20%). While standing on an unstable surface, they increase sensory weighting to vestibular and visual information as decreasing their dependence on surface somatosensory inputs for postural orientation. So, the ability to re-weight sensory information with respect to the sensory context for maintaining stability is very important when an individual moves from one sensory context to another. Therefore, persons with somatosensory loss from neuropathy will be limited in their ability to re-weight postural sensory dependence which will impair their postural control responses and risk to fall in particular sensory contexts (57).

Orientation in space is the ability to orient the body parts with respect to gravity, support surface, visual surround and internal references. Therefore, the environmental context, task and a health nervous system are critical components affecting the control of body orientation or postural adjustment (57).

Control of dynamics is the control of balance during gait and while changing from one posture to another that requires complex control of a moving body CoM (57).

Cognitive processing: Postural control also needs cognitive function of the brain. The control of posture at the same time with another cognitive processing will, thus, share available cognitive resources in the brain. So, the postural control performance will be disturbed by a secondary cognitive task. Accordingly, individuals who have limited cognitive processing resources due to neurological impairments may risk to fall or show a longer reaction time if he/she do a difficult complex tasks or dual task because of insufficiency of cognitive processing for control posture while splitting some cognitive processing resource to a secondary cognitive task (57).

Therefore, the exercise program to improve balance performance for persons with diabetic peripheral neuropathy who have balance impairments should rely on principal of the six important resources for postural control.

16. Exercise to Prevent Falls in Older Adults

From the systematic review by Sherrington and colleagues in 2011 recommended that prevention of falls and mobility-related disability among older people can be prevented with appropriately designed intervention programs. Both home-based and group-based programs can prevent falls. Furthermore, the designed group-based interventions can also prevent falls and promote psychosocial in elderly, while home-based programs is also important if older people are reluctant to or unable to attend group exercise classes (58).

Additionally, this systematic review suggested that exercises should aim to challenge balance in three ways as follows;

1. Reducing the base of support (e.g. standing with both legs close together, standing with one foot directly in front of the other, i.e. a tandem stance position and, if possible, standing on one leg) (58).

2. Movement of the centre of gravity-control of the body's position while standing (e.g. reaching safely, transferring the body weight from one leg to the other, stepping up onto a block) (58).

3. Reducing the need for upper limb support when exercises in standing. If this is not possible the aim should be to decrease reliance on the arms (e.g. hold onto a bar with one hand instead of both hands, rest one finger on a table rather than the whole hand) (58).

Therefore, exercise for balance training should target both the general elderly in community and those at high risk for falls. The balance training exercise can be introduced as a group or home-based setting. Also, strength and a walking training may be included in balance training program but for the high risk individuals should not be prescribed a rapid walking in the program.

17. Clinical Assessment of Diabetic Peripheral Neuropathy

Diabetic sensorimotor polyneuropathy (DSPN) is the most common form of chronic complication associated with diabetes mellitus. The diagnosis of diabetic peripheral neuropathy is an assessment on neurological signs and symptoms of both feet. The Michigan Neuropathy Screening Instrument questionnaire (MNSIq) and Physical Assessment is a screening instrument with numerous composite scores which most frequently used to evaluate neuropathy (59). The Michigan Neuropathy Screening Instrument is a simple tool to assess symptoms in diabetic peripheral neuropathy. The questionnaire composes of 15 questions related to a history of neuropathic signs and symptoms of the patients with diabetes (Table 2). A positive response on 4 or more questions correlates with the presence of peripheral neuropathy (60).

The physical assessment in the Michigan Neuropathy Screening Instrument consists of foot inspection, vibration sensation test, muscle stretch reflexes and monofilament testing. The foot inspection is an observational assessment of both feet to identify of dry skin, callous formation, fissures, frank ulceration and deformities. The deformity feet include flat feet, hammer toes, overlapping toes, halux valgus, joint subluxation, prominent metatarsal heads, medial convexity (Charcot foot) and amputation. The vibration sensation is tested bilaterally using a 128 Hz tuning fork placed over the dorsum of the great toe on the bony prominence of the DIP joint. The ankle reflexes are examined by using an appropriate reflex hammer. The monofilament testing is evaluated by using a 10 grams monofilament pressing on the dorsum of the great toe midway between the nail fold and the DIP joint until the filament is slightly bended (60).

In addition, the clinical measurement of glycosylated hemoglobin (HbA1c) levels and the duration of diabetes correlated with diabetes complications risks of peripheral neuropathy are also recorded (59).

Table 2 The questions in Michigan Neuropathy Screenings Instrument Questionnaire (60)

	Michigan Neuropathy Screening Instrument questionnaire
1.	Are you legs and/or feet numb?
2.	Do you ever have any burning pain in your legs and/or feet?
3.	Are your feet too sensitive to touch?
4.	Do you get muscle cramps in your legs and/or feet?
5.	Do you ever have any prickling feelings in your legs or feet?
6.	Does it hurt when the bed covers touch your skin?
7.	When you get into the tub or shower, are you able to tell the hot water from the cold water?
8.	Have you ever had an open sore on your foot?
9.	Has your doctor ever told you that you have diabetic neuropathy?
10.	Do you feel weak all over most of the time?
11.	Are your symptoms worse at night?
12.	Do your legs hurt when you walk?
13.	Are you able to sense your feet when you walk?
14.	Is the skin on your feet so dry that it cracks open?
15.	Have you ever had an amputation?

18. Balance Assessment of Older Community Dwelling Adults

Various approaches to measure balance have been developed including questionnaires, laboratory measures and functional balance test. Questionnaires, such as the Rivermead Mobility Index and the Activities Specific Balance Scale, provide only self-report information regarding functional status. Laboratory measures, such as computerized force platforms, provide the most accurate data of postural sway. Anyway, the laboratory measures are complex equipment and high cost (61).

For functional balance tests, there are many functional balance tools such as Berg Balance Scale (BBS), Timed Up and Go Test (TUG), Functional Reach Test (FRT), Tinetti Performance Orientated Mobility Assessment (POMA), balance subscale, Balance Screening Tool (BST), Multi-Directional Reach Test (MDRT), Lateral Reach Test (LRT), Step Tests, Fullerton Advanced Balance Scale (FAB), Sensory Orientated Mobility Assessment Instrument (SOMA) and Clinical Test of Sensory Interaction and Balance (CTSIB). These functional balance tools are practical assessments that can be used in a variety of settings because of their low cost, less complex equipment and time efficiency (61).

The Berg Balance Scale and the Timed Up and Go Test have been confirmed a high intrarater and interrater reliability in older community dwelling adults (61). And also, the Clinical Test of Sensory Interaction and Balance (CTSIB) have been confirmed a good test-retest reliability in older community dwelling adults (61). Moreover, BBS is easy to administer and does not require special equipment (62), and the TUG Test is a test that can be done quickly, low cost and easy to estimate the effect of balance training program to prevent fall (61). While, the CTSIB can evaluate the reliance on the different sensory systems in maintaining balance (61). Therefore, this study will use BBS, TUG and CTSIB as the tools for measuring balance performance in the elderly with diabetic peripheral neuropathy.

18.1 Berg Balance Scale

The Berg Balance Scale (BBS) was developed as a performance-oriented measure of balance for people with balance impairment by assessing the performance of functional tasks. The BBS consists of 14 functional items that are scored on a scale of 0 to 4 (as shown in Appendix B). A score of 0 is unable to do the task and a score of 4 is able to complete the task on the criterion that has been assigned. The items include of mobility tasks (e.g., transfers, standing unsupported, sit-to-stand) and difficult tasks (e.g., tandem standing, turning 360°, single-leg stance) (63). It takes approximately 15 minutes to complete an assessment of BBS and requires a step, two chairs, a stopwatch, a 40 cm ruler and minimal space (64). The maximum total score for assessment is 56. A score below 45 indicate impairment, with an increased fall risk. Reliability and validity of the BBS were assessed in community dwelling older adults (62, 65). It was found that inter-rater reliability of BBS was good to excellent (ICC=0.88-0.98). While, Intra-rater reliability demonstrated greater variability (ICC=0.68-0.99) (62).

18.2 Timed Up and Go Test

The Timed Up and Go (TUG) test is a test of balance that is commonly used to examine functional mobility in community-dwelling in older adults (66). This test measures the time taken by an individual to stand up from a standard armchair (approximate seat height of 46 cm), walk a distance of 3 m, turn, walk back to the chair, and sit down. The subject wears his or her regular footwear and uses his or her customary walking aid (cane, walker, etc.) but no physical assistance is given. Time taken to complete the test is strongly correlated to level of functional mobility (67). The TUG takes approximately 1-2 minutes to complete and requires only a chair and stopwatch (64). The TUG scores as shown in table 3. The TUG showed an excellent inter-rater reliability (ICC=0.98-0.99) (66, 67) and also excellent intra-rater reliability (ICC=0.97-0.98) (63, 67).

Table 3 Timed Up & Go Test Scores (63)

Age (y)	Gender	Mean (seconds)	Normal Range (seconds)
60-69	Male	8	7-8
60-69	Female	8	7-9
70-79	Male	9	7-11
70-79	Female	9	8-10
80-89	Male	10	9-11
80-89	Female	11	9-12

18.3 Clinical Test of Sensory Interaction and Balance

Shumway-Cook and Horak in 1986 designed the clinical assessment of the influence of sensory interaction on standing postural stability in the patient with neurologic problems (e.g., peripheral neuropathy, vestibular disorders, and stroke) (68). The Clinical Test of Sensory Interaction and Balance is a timed test that was developed for testing the influence of systematically sensory inputs, as visual, vestibular and somatosensory, on standing balance (69). The patient have to maintain standing balance under six different intersensory conditions that either eliminate input or produce inaccurate visual and surface orientation inputs (68). The test uses combinations of three visual and two support-surface conditions (68).This test is easily to address, inexpensive and requires minimal equipment (69).

The surface conditions consist of flat surface and a firm surface (40.64 x 40.64 x 7.62 cm piece of medium-density Sunmate foam) (69) to confirm an accurate orientation information from the somatosensory system. During stance on a foam surface, the foam surface will reduce the accuracy of the orientation information from ankles (68), then changes in ankle position may no longer correlate with movement of the center of gravity. Therefore, patients may rely on information from ankle proprioceptors less than the information from sensory receptors in the head and neck to control body sway (70).

The visual conditions include of a blindfold and a visual-conflict dome. The blindfold is for eliminating visual input and a visual-conflict dome is for producing inaccurate visual input. The dome was constructed from a paper lantern and a dental headband (Figure 1) by Shumway-Cook and Horak (68). When wearing the visual-conflict dome, the subjects will be instructed to keep their eyes open and looking forward. The dome will be moved in synchrony with head movement and therefore "neutralized vision (or reduced the sense of vision as a reference for body sway. The effect of the dome on visual inputs has been referred to as "visual stabilization," because the visual field moves in proportion to body sway (70).

The Clinical Test of Sensory Interaction and Balance includes of six test conditions (Figure 2). The first three conditions require the patient to quiet standing on the floor with looking straight ahead (condition 1), to quiet standing on the floor with eyes closed (condition 2), and to quiet standing on the floor wearing the conflict dome (condition 3). The second three conditions are managed by instructing the patient to quiet standing on the foam with eyes open (condition 4), with eyes closed (condition 5) and with wearing the conflict dome (condition 6) (69). The CTSIB demonstrated a good test-retest reliability (r=0.75) in older community dwelling adults (70).

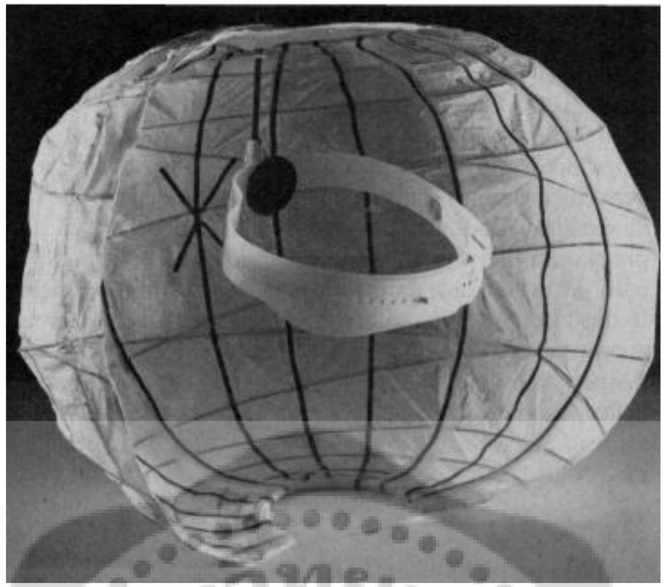


Figure 1 Visual-conflict dome to produce inaccurate visual orientation inputs during balance testing (68)

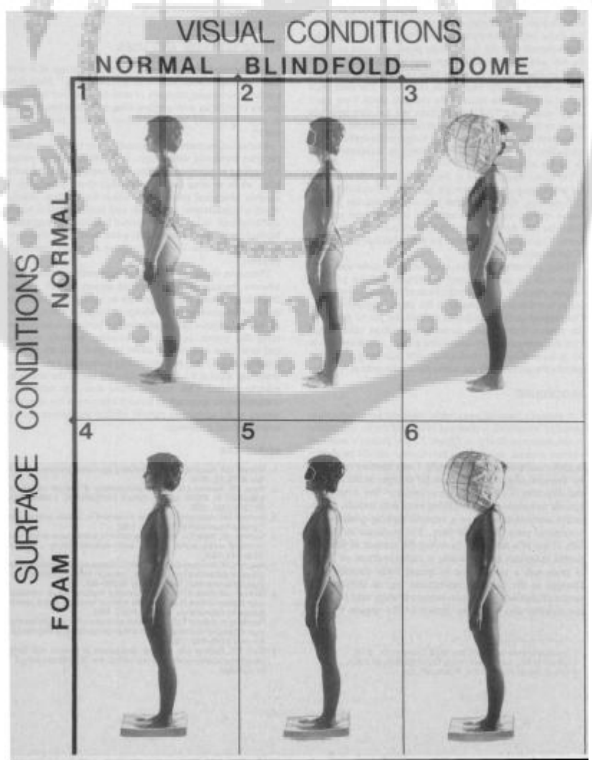


Figure 2 Sequence of six conditions for testing the influence of sensory interaction on balance (68)

19. Proprioceptive Test

19.1 Qualitative testing of proprioception

19.1.1 Contra-lateral limb matching test In this test, the subject is shown the directions into which his or her limb is going to be moved. Then the subject is asked to memorize the directions of movement of the moving limb thereafter do the same movement on his opposite side on contra-lateral limb within 5 seconds (71).

19.1.2 Distal joint positional sense test The subject is asked to identify the position of the finger or toe (whether up, middle, or down) with closed eyes. Then, he or she is asked to tell the right answer within 5 seconds. This test is done for all MCP and MTP joints (71).

19.1.3 Perceived Synergy Sense Test Perceived Synergy Sense Test is meant to determine the position of upper limb and lower limb (one extremity at a time) in the form of any synergy pattern. The subject was asked to assume the position, just demonstrated to him and asked him to do the position on the both sides and both limbs. If the subject was unable to duplicate the test position, the experimenter passively placed the subject's extremity into the test position and asked the subject to maintain this position. If the subject was able to assume the test position, the experimenter then asked him to hold the shoulder/hip component of the position for 5 seconds while attempting to reciprocate the most distal component of that position (71).

19.2 Quantitative testing of proprioception

19.2.1 Foot Placement Sense Test The subject is instructed to walk on 12 feet long paper with comfortable foot step. He is told to memorize the placing of his each foot step. Then with eyes fixed to a point in front or not looking down, he is told to walk on the same paper roll as before for once. Then the error is recorded by comparing between the taken target footprint and subject original foot placement with visual fixation after walking. The average of the error is taken and grading is done as according to the performance of the test (71).

19.2.2 Objective Positional Sense Test The subject is asked to move his testing limb to the predetermined target angle/position and let him feel that angle/position for 5 sec. Then the limb is taken to the starting position passively, the subject is then asked to move the limb to that target position actively from the starting position. The angular difference between the target angle and patient's perceived angle is measured. The angular error in each plane of a joint is recorded and taken as the actual angular error in one particular plane of a joint (71).

19.2.3 Motion tracking sense test This is an instrument designed to quantitatively measure the proprioceptive error in an individual. This instrument is made up of wood and has a slider to point out the reading on the scale and protractor fixed on the instrument. The subject is seated in front of a table on which the instrument is kept. The Subject is asked to slide the pointer in the instrument to a predetermined number on the scale over the instrument with opened eyes and maintain for 5 seconds there, so that the subject could memorize the position. Then with vision block the subject is asked to reposition in the target position. The distance and angular error between the target angle/distance and subject's perceived angle/distance respectively is recorded (71).

19.2.4 Modified Romberg test In this test the subject is asked to close his eyes and stand on one leg for one minute and the number of times the subject lost balance in one minute is recorded (71).

19.2.5 Timed Unilateral Stance Performance test Subject is asked to stand comfortably and fix his eyes further to a point. Thereafter the subject is asked to stand on the right and left foot separately as long as possible without losing balance or fall. The time duration he could stand without losing balance is recorded (71).

20. Fear of Falling Measurement Tools

Fear of falling in the elderly occurs in 12% to 65% of who live independently in the community and do not have a history of falling. The fear of falling of the elderly is a condition of worry about falling that ultimately limits the performance of daily activities and loss of confidence in his or her balance abilities which caused by change in physical, psychological, and functional (72). The tools that measure fear of falling are such as, Thai Geriatric Fear of Falling Questionnaire, Falls Efficacy Scale (FES) and Activities-Specific Balance Confidence Scale (ABC)

20.1 Thai Geriatric Fear of Falling Questionnaire

The Thai Geriatric Fear of Falling Questionnaire is an instrument developed to assess the fear of falling in Thai community dwelling elders. The Thai Geriatric Fear of Falling Questionnaire (Appendix C) consists of 34 items with a 6 point Likert scale. These 34 items are grouped into 3 major domains as the physical and functioning domain (15 items), the environmental domain (8 items), and the psychosocial domain (11 items). The questionnaire shows a high internal consistency (r = 0.965) and test-retest reliability (r = 0.874). The convergent validity tested with Modified Thai Fall Efficacy Scale (MTFES) is high (r = -0.910). The cut-off score is 66 (73).

20.2 Falls Efficacy Scale

The Falls Efficacy Scale (FES) is a tool for assessment fear of falling that contributing to functional decline in older adults. The scale measures fear of falling by looking at fall-related self-efficacy or a person's self-confidence in his or her ability to avoid falling during performing everyday activities (e.g., cleaning house, getting dressed, and simple shopping). The FES consists of 10 questions each question is rated on a scale of 1 to 10. Therefore, the summation of total scores from 10 questions is between 0 and 100. The FES shows good test-retest reliability (Pearson's correlation 0.71) (74).

20.3 Activities-Specific Balance Confidence Scale

The Activities-Specific Balance Confidence Scale (ABC) uses the same idea of fall related self-efficacy as the FES but it is proper for older adults with higher functioning. The ABC scale composes of 16-item questionnaire that asks the subject to rate his or her balance confidence on a visual analog scale (0–100) while zero represents no confidence and 100 indicates complete confidence in performing the activity (75).

21. Related Studies

The literature-reviews found significantly impairment of balance in diabetes with peripheral neuropathy which may lead to an increase in risk of fall. There are very few studies that have been conducted on improving balance in patients with diabetic peripheral neuropathy.

Richardson et al in 2001 studied the effect of a specific exercise regimen on clinical measures of postural stability and confidence in a population with peripheral neuropathy (PN). The exercise intervention aimed to increase rapidly available distal strength and balance. The exercise interventions performed daily on a firm surface for 3 weeks included bipedal toe raises and heel raises, bipedal inversion and eversion, unipedal toe raises and heel raises, unipedal inversion and eversion, wall slides and unipedal balance for time. The study found that an exercise improved balance performance in older persons with mild to moderate PN (19).

Song et al in 2011 studied the effects of an exercise program on balance in older adults with diabetic neuropathy. The exercise was conducted twice a week for 8 weeks. Balance exercises consisted of three parts. The first and second part consisted of eyes opened and eyes closed, such as heel and toe raises, one-leg stance for each limb respectively. The second part subjects were paired for their safety and they performed it in turns. The third part included three activities to challenge and increase their balance. In the first activity, the subjects stood in a circle on foam and passed doughnuts from themselves to the next subject in the circle. The second activity was performed in pairs comprised of catching and throwing a ball while standing on the foam. The third activity was performed in a similar way but on a trampoline instead of on foam to challenge balance strategies. The size of the ball, the number of repetitions, and the distance between subjects were increased progressively as the patients' balance responses improved. The studied found that postural sway significantly decreased ($P<0.05$), the one-leg stance test significantly increased ($P<0.05$), and dynamic balance from the Berg Balance Scale, Functional Reach Test, Timed Up and Go test, and 10-m walking time improved significantly after balance exercise ($P<0.05$) (21).

Allet et al in 2010 studied the effect of a specific training program on gait and balance of diabetic patients. The intervention consisted of physiotherapeutic group training including gait and balance exercises with function orientated strengthening (twice weekly over 12 weeks). Balance and walking tasks included of stance on heel/toes, tandem stance, one leg stance, different kinds of walking alternated with functional strength and endurance exercises and progressively increased, e.g. changing from stable to unstable surfaces (wobble board), increasing step height. Sessions were completed with interactive games (e.g. badminton, obstacle race in teams) and a short feedback session with suggestions for individual home exercises. The study found that the training program increased habitual walking speed by 0.149 m/s (0.54 km/h; $p<0.001$) compared with the control group. The dynamic balance test (time to walk over a beam), the performance-oriented mobility assessment test (total score and sub-scores), the Biodex sway index recorded at level 6, the Falls Efficacy Scale International (FES-I) score, the hip and ankle plantar flexor strength, and hip flexions mobility. After 6 months, the differences in all these variables remained significant ($p<0.0026$) except for the Biodex sway index ($p=0.005$) and ankle plantar flexor strength ($p=0.217$). A specific gait and balance training program based on a circuit approach including gait and balance exercises combined with function-orientated strengthening can improve gait speed and balance, and increase both muscle strength and joint mobility of diabetic patients with a vibration perception threshold ≤ 4 (20).

Salsabili et al in 2011 studied the balance training in diabetes with peripheral neuropathy. The task trainings conducted standing balance trainings by using the Biodex stability system (BSS) for 10 sessions in 3 weeks, every session lasting 30 minutes with a 1-day interval and the same standing method and feet placement of the familiarization trial. Trainings consisted of two limits of stability, three weights shifting with visual-external biofeedback practices, and one standing practice with covered biofeedback. All trainings progressed from easy to difficult, with the stability level decreasing through sessions. The study found that diabetes with peripheral neuropathy improved their BSS assessment scores and force platform evaluations with open eyes in the mediolateral sway direction (56).

Anyway, most of those studies used equipments or devices for training which may be not feasible for home-based or community-based exercise. Moreover, in Thailand there were only previous studies related to an exercise program for balance training to improve balance performance in healthy elderly (27, 28), but there were no studies related to effects of balance training program in elderly diabetic with peripheral neuropathy in Thai community.

Kuptniratsaikul and colleagues in 2011 studied the effectiveness of simply-performed balancing exercises in elderly patients with history of frequent falls. Simple balancing exercise was performed at home every day and was recorded in the booklet. The study found that performing simply-designed balancing exercises, at least 3 days per week can increase balancing abilities, and decrease fall rates in the elderly with a history of previous falls (27) .

Lapanantasin et al in 2010 studied the effectiveness of a developed group exercise program for feasible community-use on balance performances of elderly women. The study found that group exercise enrolled in a 4 week-training program at 3 days per week can improve balance performances in elderly (28).

Falls history appears an important contributor to fear of falling, whereas the impact of this fear on activities appears more on a function of social support. The fear of falling among older people can be an adverse effects on the socialization stage (23). A group exercise showed a good benefit on elderly persons in term of care prevention that can maintain function in daily life either physical or mental activities (25).

Previous study suggested that balance training group improved the quality of an older adult's life by helping them to reduce the fear of falling. After 8 weeks, participants were very happy to be involved in the study although they were not certain about what training would have done for them. Most of the participants indicated that they were happy to meet and to do exercise or socialisation regularly and wanted the study to be continued (26)

From the previous study, it was found that patients with diabetic neuropathy who demonstrated a reduction of somatosensation were also showed significantly increased passive joint motion perception threshold when compared to the healthy subjects (11). As proprioception decreases, the ability to coordinating basic protective reflexes and joint movement as well as complex balance and postural control also decreases (10, 11).

Another, study by Westlak et al in 2007 about the effects of balance exercises on ankle proprioception in older adults found that the balance exercise group showed post intervention improvements in velocity discrimination sense in ankle movement, but not improved in joint position sense (JPS), that measured by passive joint position reproduction (76).

Furthermore, there are only a few studies about the interaction of proprioception and balance in people with diabetes (21). Therefore, this study is interested in assessing the effects of a group exercise program for balance training on balance performance, ankle proprioception and fear of falling in the elderly with diabetic peripheral neuropathy.

CHAPTER 3

METHODOLOGY

1. Research design

This study is a randomized controlled trial with two arms (a balance training group and a control group). It was conducted at the Thasala Hospital in Nakhon Sri Thammarat, Thailand. Data were collected from February 2013 to May 2013.

2. Subjects

The inclusion criteria of subjects were as follows:

1. Be an older woman 60 to 79 years of age with type 2 diabetes mellitus
2. Having score of the Michigan Neuropathy Screening Instrument higher than 3 out of 13 in the questionnaire section, and also higher than 2 out of 10 for physical assessment section (60, 77)
3. Having score between 46 to 52 (out of a total of 56 points) on the BBS (78-80)
4. Be able to walk 10 metres without assistive devices or the assistance
5. If there was any plantar ulceration, it should be healed for at least six months (41)
6. No partial or total foot amputation
7. Never receiving or receiving a balance training less than 2 hours a week for a 6-months period prior attending this study (58)

The exclusion criteria of subject were the persons who having the history or clinical evidence on physical examination of the following:

1. Significant central nervous system dysfunction (such as hemiparesis, parkinson's disease, and cerebellar ataxia)
2. Vestibular dysfunction
3. Lower extremity arthritis or pain that limited exercise (such as severe osteoarthritis, fracture or malformation of lower extremity)
4. Severe cardiovascular diseases that limited or contradicted the exercise (such as myocardial infarction or heart failure)
5. Angina or angina-equivalent symptoms (such as nausea, diaphoresis, and shortness of breath with exercise)
6. An uncontrolled proliferative retinopathy (such as neovascularization and accompanying hemorrhages) (81)
7. An end–stage renal disease (GFR < 15 mL/min/1.73 m^2) (82)

3. Sample size calculation

The sample size of this study was calculated based on the 2 x 2 repeated measures ANOVA design with an expected statistical power of 0.80 (alpha error probability of 0.05) and effect size of 0.3 by using G* Power program 3.1.5 as shown in Figure 3. The determined sample size for this study from calculation is needed totally 18 subjects. Anyway, a 50% drop-out rate should be concerned. Therefore this study aims to recruit 28 patients in total (14 patients/ group).

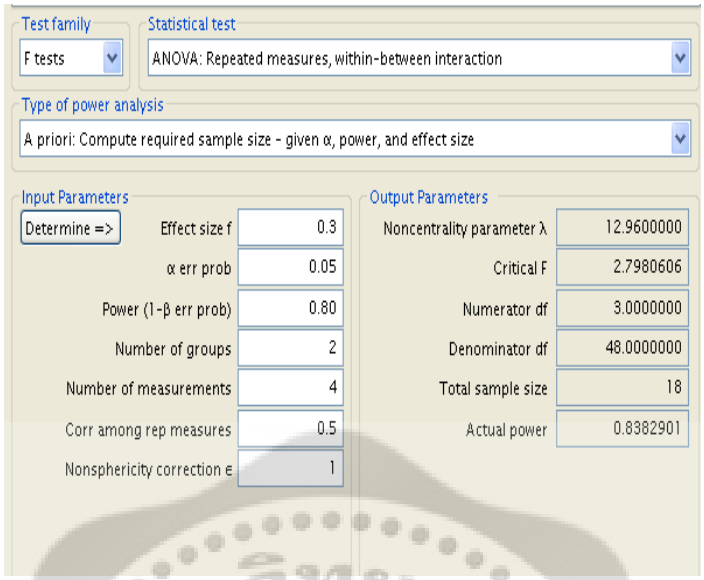


Figure 3 The sample size from calculation by using G* power program 3.1.5.

4. Outcome measures

This study investigated the effects of balance training in patients with diabetic peripheral neuropathy on their balance performances, ankle proprioception and fear of falling. The assessments (physical measurements or questionnaire data) were performed by a physical therapist whom was blinded to a group allocation (intervention vs. control) of the patients.

The outcomes measured of this study included balance performances, ankle proprioception and fear of falling that were collected at the baseline and then after 4 weeks of participation. Balance performances were evaluated either static, dynamic or functional mobility balances that represented by a modified clinical test of sensory interaction and balance (mCTISB), Berg balance scale (BBS), and timed up and go test (TUG). The ankle proprioception was evaluated by measurement of an absolute angular error of joint reposition with the electrogoniometer (Biometrics SG 110®). For an outcome of the fear of falling, subject's worry of falling when thinking of performing different activities, was assessed with Thai Geriatric Fear of Falling Questionnaire (Appendix C).

Modified Clinical Test of Sensory Interaction on Balance

Static balance of the participants in this study was evaluated by the Modified Clinical Test of Sensory interaction on balance (mCTSIB) (Appendix F). The mCTSIB protocol consists of four separate conditions, of increasing difficulty, performed with the subject in a quiet upright stance. The four sensory conditions were 1) firm surface with eyes open, 2) firm surface with eyes closed, 3) foam surface with eyes open and 4) foam surface with eyes closed as shown in Figure 4. This test is designed to assess how well an older adult is using sensory inputs when one or more sensory systems are compromised. In condition one, all sensory systems (i.e., vision, somatosensory, and vestibular) are available for maintaining balance. In condition two, vision has been removed and the older adult must rely on the somatosensory and vestibular systems to balance. In condition three, the somatosensory system has been compromised and the older adults must use vision and the vestibular system to balance. In condition four, vision has been removed and the somatosensory system has been compromised. The older adults must not rely primarily on the vestibular inputs to balance. Begin timing each trial using a stopwatch, with a ten-second rest between each trial. Each condition is last 30 seconds and be repeated 3 times. The trial is overed when the participant 1) opens eyes in eyes closed condition, 2) raises arm from the side of the body or (3) loses balance and requires manual assistance to prevent a fall. Then, a represent outcome of each condition was the average value of the 3 repetitions. The combination of these sub-test conditions can infer to the presence of sensory dysfunction that affecting postural control ability of the participants (68, 83).

Figure 4 The four sensory conditions of modified clinical test of sensory interaction on balance

Berg Balance Scale

Dynamic and static balances in functional mobility of the participants in this study were assessed by Berg Balance Scale (BBS). Since, the BBS was developed to measure balance among older people with balance impairment by assessing the performance of functional tasks. The BBS consists of 14 task-assessments (Appendix B). Each task was scored on a 5-point scale (0–4) ranking according to the quality of the performance or the time taken to complete the task. The maximum total score for this assessment was 56. A score below 45 indicates balance impairment with an increased risk of falls (84). The tests showed high intra-rater reliability (ICC = 0.99) and inter-rater reliability (ICC = 0.98), (*P*<.001). Therefore, for assessing balance, this test had the high reliability and internal validity (62, 84). Consequently, it was a valid instrument used for evaluation of the effectiveness of interventions and for quantitative descriptions of functional balance in clinical practice and research.

Timed Up and Go test

The Timed Up and Go test (TUG) was an evaluation of functional mobility balance that is commonly used to examining the functional mobility balance in community-dwelling frail older adults. This test demonstrated good intra-rater and inter-rater reliability (r=0.99 and 0.98, respectively). So, this study used TUG to test a functional mobility balance of the participants. This test was measured, in seconds, the time taken by an individual to stand up from a standard armchair (approximate seat height of 46 cm), walk a distance of 3 meters, turn, walk back to the chair, and sit down as shown in Figure 5. Three trials was performed and the average to be a representative value for each participants. The participants were allowed to wear individual regular footwear during testing. The previous study showed that time taken to complete the test was strongly correlated to level of functional mobility (67).

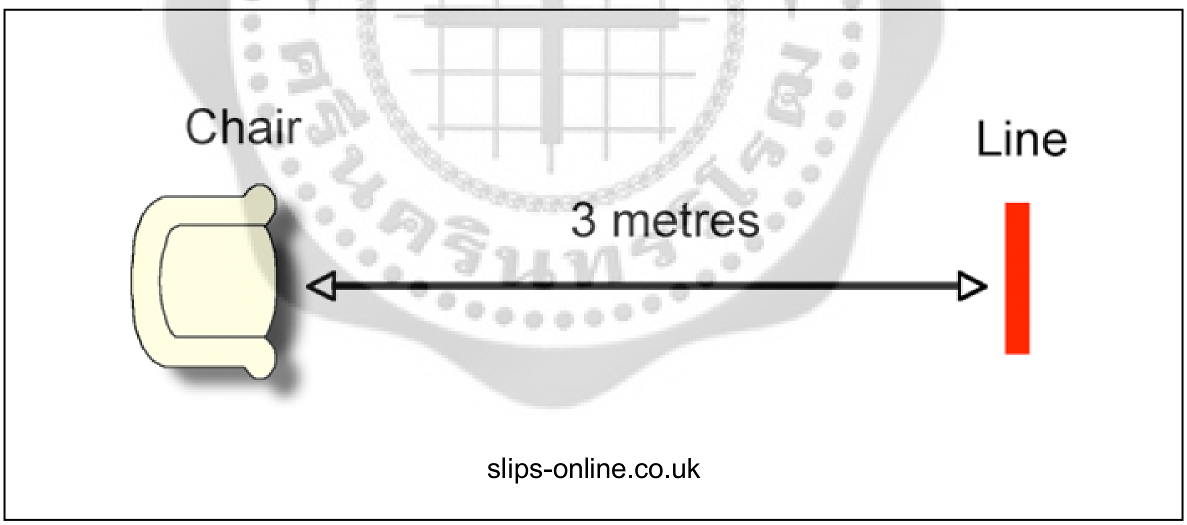


Figure 5 The time up and go test

Ankle Repositioning Errors

Ankle repositioning errors was one of the most common tests to assess ankle proprioception. The ankle proprioception was represented as an ability to recognize the position of the ankle by measuring the degree of angular deviation of the return to its original assessed position with the electrogoniometer (85).

This study assessed ankle proprioception by active repositioning of the ankle movement under a non-weight-bearing condition with using an electrogoniometer (Biometrics SG 110®) to measure (Figure 6). The ankle repositioning error outcome of this study was an absolute value of the angular difference between the randomized target position and the patient's reproduced position, ignoring the direction of the error.

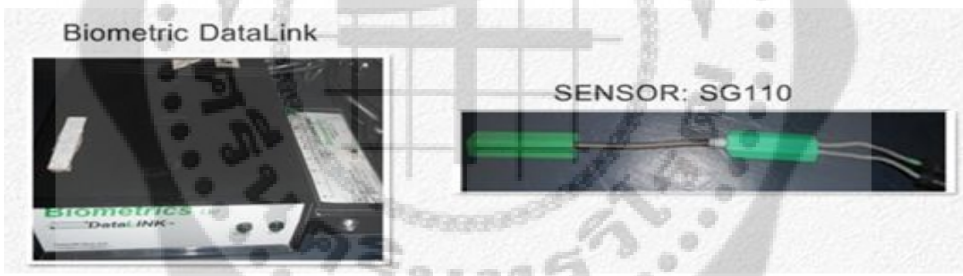


Figure 6 Electrogoniometer (SG 110, Biometrics) Gwent, NP11 7HZ, UK

Electrogoniometers were used to measure lower extremity angular displacements in gait (running, cutting, stairs, etc) in healthy subjects and subjects with various lower extremity changes (anterior cruciate ligament deficiency and reconstruction, spasticity, joint replacement, etc) while performing mid-range sagittal plane movements (86). In addition, an electrogoniometer has a good promise in reliability and validity in the measurement of dance movements, when compared to 3D motion analysis. The test found that it had a high intra-rater reliability (r=0.98), criterion and concurrent validity (r=0.95 and 0.94, respectively) (86). Therefore, this study was used electrogoniometer, Biometrics SG 110®, to assess ankle proprioception of the participants by measuring an absolute angular error of ankle repositioning test.

Electrogoniometer consisted of two potentiometers or strain gauge sensors placed between two plastic end-blocks. The customary biaxial electrogoniometer sensor for the ankle was attaching of the distal end-block of the SG110 (SG110, Biometrics, Gwent, UK) to the back of the heel and the proximal end-block to the posterior of the leg (85, 86) as shown in Figure 7.

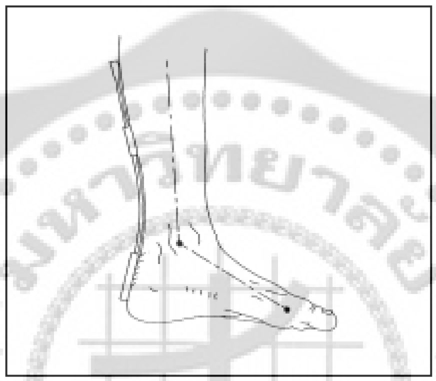


Figure 7 Placement of electrogoniometer for measuring ankle proprioception (85)

Biaxial electrogoniometer was used for recording doriflexion/plantarflexion angle in the sagittal plane and inversion/eversion angle in the frontal plane of the right ankle in a sitting position (85). The participant was asked to actively move his testing ankle to the predetermined target angle/position and let her feel that angle for 5 sec. Then the ankle was taken to the starting position. After that, the participant was asked to move her ankle to that target position again actively from the starting position. Ankle joint position was measured by electrogoniometer in degrees, with the resolution of 10^{-2}. The ankle repositioning error of this study was calculated as the absolute difference between the target and perceived angles, ignoring the direction of the error (71). Each plane of an ankle motion (doriflexion/plantarflexion and inversion/eversion) was tested 3 times and then the representative outcome in one particular plane of an ankle joint was an average absolute angular error of the 3 repetitions.

Thai Geriatric Fear of Falling Questionnaire

The "Thai Geriatric Fear of Falling Questionnaire" (Appendix C) composed of thirty-four questions related to the feeling of fear or worry during performing physical function, and also in the environmental and psychosocial situations that are risky to fall. Thai Geriatric Fear of Falling Questionnaire showed good promise in reliability and validity in the measurement with Thai elderly over sixty years old, when compared to Thai Falls Efficacy Scale and Thai Geriatric Depression Scale (TGDS). The test demonstrates a high intra-rater reliability (r=0.891), and good convergent validity (r = -0.91). Therefore, this study used this questionnaire for measuring the fear of falling in DPN subjects as a quantitative outcome (73).

5. Materials and research tools

The materials used in this study included of the followings.

1. Electrogoniometer (SG 110, Biometrics) Gwent, NP11 7HZ, UK
2. Semmes-Weinstein monofilament size 10 grams (Humeric Monofilament)
3. Tuning fork 128 Hz
4. Jerk hammer
5. Stopwatch (ALBA Stopwatch)
6. Measuring tape
7. Two Standard Chairs (one with arm rests, one without)
8. Step
9. Foam Pad
10. Derma Temp Infrared Skin Thermometer (EXERGEN, USA)

11. Accu-Chek Diabetic Monitor System (ACCU-CHEK Performa)

12. Polar RS800CX Heart Rate Monitor Watch (POLAR)

13. Balls

14. Resistance Bands

15. Pillows

16. BORG Rate of Perceived Exertion Scale (87)

17. Global Physical Activity Questionnaire (88, 89)

18. Thai Geriatric Fear of Falling Questionnaire (73)

19. Michigan Neuropathy Screening Instrument (60)

20. Berg Balance Scale (62)

6. Intervention

Exercise intensity

The intensity of group exercise program for balance training in this study was mild to moderate intensity corresponding approximately to 40%–70% of maximum heart rate (41). The heart rate of the participant was monitored using a Polar heart rate monitor (Figure 8) set to record heart rate every 10 minutes throughout the exercise and two minutes post-exercise. The average of all exercise heart rates obtained during the exercise program was calculated to estimate the average exercise intensity for each participant. Additionally, the exhaustion of participant during exercise was detected by the rating of perceived exertion, the Borg scale (87). The rating of perceived exertion (Appendix G) was noticed approximately every 10 minutes throughout the exercise session (at the same instance as heart rate) and averaged for each participant.

Figure 8 Polar RS800CX Heart Rate Monitor Watch (Polar Standard Set)

The group exercise program for balance training

The group exercise program for balance training in this study was designed based on exercise interventions of previous studies that were shown to improve balance (21, 28). The exercise program for balance training of this study was conducted for 50 minutes/day, three days a week, for 4 weeks. The training program was accompanied in group (five to eight participants) in order to promote long-term participation (90). The training program was directed by a physical therapist and one trained assistance for safety reasons.

The designed group exercise program comprised of 3 sessions as following; 1) 10 minutes for warm-up, 2) 30 minutes for balance training, and 3) 10 minutes for cool-down. A warm-up was first performed to increase flexibility of trunk and lower limb muscles by stretching as shown in Figure 9. Then balance training which including of passing ball to each other in various directions by hands and foot, and alternated tip-toe and heel standing was performed as shown in Figure 10-15. After the balance training, cool down was performed by stretching same as warm-up activities as shown in Figure 9.

The balance training session consisted of three parts. The first part was reducing the base of support included standing on heels and toes, tandem standing and standing on one leg. The second part was initiation of weight shift by anterior-posterior and left-right ball passing (facilitated reaching and weight shift). The third part was ball games multiple tasks. The weight and size of the ball, the number of repetitions, the distance for ball passing between subjects, the change in a surface of the base of support by standing on pillow, the decrease in visual cue by eye closed, and the cognitive dual task (80) while throwing and catching the ball were added progressively each week. The details of variety tasks in the program are shown in the following table 4-6.

Table 4 Exercise program for balance training in summary

Sessions in the program	**Included tasks**
Warm up (10 min)	Stretching of trunk and lower limb muscles
Balance training (30 min)	1. Standing exercise on stable surface - Alternated heel and toe rises - One-leg stance for each limb - Tandem stance - Passing ball to each other by hand and foot to facilitate weight shift and reaching in a stability limit (anterior-posterior and left-right ball passing) 2. Standing exercise on a pillow - Alternated heel and toe rises - One-leg stance for each limb - Tandem stance - Passing ball to each other by hand and foot to facilitate weight shift and reaching in a stability limit (anterior-posterior and left-right ball passing) 3. Ball games multiple tasks
Cool-down (10 min)	Stretching of trunk and lower limb muscles same as the warm up session

Table 5 Tasks in balance training session of the program

Balance training tasks	Progressing the challenge	Resources for postural control
1. Alternated heel and toe rises in standing	- Decrease visual cue (eye closed) - Number of repetitions - Standing on pillow	- Biomechanical constraints: Lower limb strengthening - Movement strategies: Ankle strategy training - Sensory strategies: Somatosensory stimulation
2. Standing on one leg	- Decrease visual cue (eye closed) - Standing on pillow	- Biomechanical constraints: Lower limb strengthening - Orientation in space: Anticipatory postural adjustment - Sensory strategies: Somatosensory stimulation
3. Tandem standing	- Standing on pillow	- Orientation in space: Anticipatory postural adjustment - Sensory strategies: Somatosensory stimulation
4. Ball passing (facilitated reaching and weight shift)	- Increasing the weight and size of objects - Increasing the distance between subjects - Standing on pillow	- Control of dynamics: Challenging limits of stability - Sensory strategies: Somatosensory and Vestibular stimulation - Biomechanical constraints: Lower limb strengthening - Orientation in space: Anticipatory postural adjustment - Movement strategies: Ankle strategy and Hip strategy training
5. Ball games (throwing and catching ball)	- Progress to a smaller or a heavier balls or 2 or 3 balls at once - Add a cognitive dual task while throwing and catching the ball	- Orientation in space: Anticipatory postural adjustment - Movement strategies: Ankle strategy training, Hip strategy and Stepping strategy - Cognitive processing

Table 6 Group exercise program for balance training in 4 weeks

Week 1	Week 2	Week 3	Week 4
1. Alternated heel and toe rises in standing (two sets of 10 repetitions,), with hand support, if necessary	- Same as week 1, but progressing the challenge by eye closed for one set, and by stance on pillow for the other set	- Same as week 2, but progressing the challenge by increased repetitions of heel and toe rises (two sets of 15 repetitions)	- Same as week 3, but progressing the challenge by increased repetitions of heel and toe rises (two sets of 20 repetitions)
2. Standing and passing ball forward to each other by hand	- Same as week 1, but progressing the challenge by increasing the distance between subjects for reaching	- Same as week 2, but progressing the challenge by standing on pillow	- Same as week 3, but Progressing the challenge by increasing the weight and size of a ball
3. Standing and passing ball sideway (left and right) to each other by hands	- Same as week 1, but progressing the challenge by increasing the distance between subjects	- Same as week 2, but progressing the challenge by standing on pillow	- Same as week 3, but progressing the challenge by increasing the weight and size of a ball
4. Tandem standing and passing ball overhead (forward and backward) to each other by hands	- Same as week 1, but progressing the challenge by increasing the distance between subjects	- Same as week 2, but progressing the challenge by standing on pillow	- Same as week 3, but progressing the challenge by increasing the weight and size of ball
5. Standing on one leg on stable surface (with hand support, if necessary)	- Same as week 1, but Progressing the challenge by eye closed	- Same as week 1, but Progressing the challenge by passing ball sideway (left and right) to each other by foot,	- Same as week 3, but progressing the challenge by standing on pillow
6. Ball games (throwing and catching ball)	- Same as week 1, but progressing the challenge by add a cognitive dual task while throwing and catching the ball	- Same as week 2, but progress to improve a precision or an anticipatory postural adjustment by using a smaller or a heavier ball	- Same as week 3, but progress to increase in a frequency of throwing and catching ball by using 2 or 3 balls at once

Figure 9 Stretching of trunk and lower limb muscles in balance training group

Figure 10 Alternated heel and toe rises in standing on a floor and on a pillow

Figure 11 Standing and passing ball forward to each other by hand

Figure 12 Standing and passing ball sideway (left and right) to each other by hands

Figure 13 Tandem standing and passing ball overhead (forward and backward) to each other by hands

Figure 14 Standing on one leg (by using one foot to rolling or passing a ball)

Figure 15 Ball games (throwing and catching ball)

Control group

The control group did not receive any balance exercise, but received upper limb exercise of 150 minutes per week for glycemic control in patients with diabetes (16). The training was conducted for 50 minutes/day, three days a week for 4 week. The subjects were instructed to start with a 10 minute warm-up, and then 30 minutes of exercise, and ended with cool-down for 10 minutes.

Warm-up was firstly performed to increase flexibility of upper limb muscles by stretching in sitting position (Figure 17). Resistance bands (Figure 16) was used for the training (91). The upper limb exercise was a workout of upper body and extremities, in sitting position (Figure 18). The intensity of exercise was mild to moderate (40% to 70% of maximum heart rate) for optimal gains in insulin action and glycemic control (41). After the exercise, cool down was performed by stretching same as warm-up activities.

Fiqure 16 Resistance Bands

Figure 17 Stretching of upper limb muscles in control group

Figure 18 Exercise program for control group (upper limb exercise)

Health education for diabetes

Both groups were received a routine instruction about how to prevent complications in patients with diabetic neuropathy which approved by institutional ethics committee. Health educational session was given to the participants once a week for 4 week with each session lasting 30 minutes. Health education for diabetes was conducted by a professional health nurse and another individual specialized health profession (physical therapist, nutritionist and pharmacist). The goals of this comprehensive and systematically given diabetes education were to create awareness among the older individuals with diabetes how to manage the disease and to find the ways to prevent its complication. The content of this education consisted of 4 parts. The first part focused on definition, disease process and complication of diabetes. The second part was to suggest diet plan. The third part educated about the importance of exercise therapy in management for diabetes. The fourth part was to educate participants about foot care on complication of diabetes.

7. Data collection

Subjects with type 2 diabetes diagnosed by physicians from diabetes clinic at Thasala Hospital in Nakhon Sri Thammarat were recruited to the study. Peripheral neuropathy was evaluated and screened with the criteria of Michigan Neuropathy Screening Instrument (MNSI) by a physical therapist. Subjects who volunteer were interviewed for inclusion and exclusion criteria and sign an inform consent. Then, subjects were randomly divided into two groups as a balance training group and a control group.

Before enroll the program, demographics, balance performance, ankle proprioception and fear of falling were assessed by physical therapist. All participants were collected the baseline information related to health characteristics, including age, body height, body weight, HbA1c within three month prior enrollment to this study, prescribed medications, marital status, education, ethnicity, duration of diabetes mellitus and comorbid illnesses. Body mass index was measured as weight in kilograms per a squared height in meters. Moreover, the participants were asked about history of falls that occurred during the six months before enrollment.

The participants' physical activity levels over the previous seven days were assessed using the Global Physical Activity Questionnaire (GPAQ) as presented in Appendix D for activities at work, travel to and from places, and recreational activities (88, 89).

Peripheral neuropathy was evaluated and screened with the criteria of Michigan Neuropathy Screening Instrument (MNSI) by a physical therapist. The Michigan Neuropathy Screening Instrument questionnaire and physical assessment (Appendix E) was used to characterize the signs and symptoms of peripheral neuropathy and to monitor the peripheral neuropathic status (60, 77). The questionnaire composes of 15 questions related to a history of neuropathic signs and symptoms of the patients with diabetes. A positive response on score higher than 3 out of 13 correlates with the presence of peripheral neuropathy (60). While, the physical assessment in the Michigan Neuropathy Screening Instrument consists of foot inspection, vibration sensation test, muscle stretch reflexes and monofilament testing. The foot inspection is an observational assessment of both feet to identify of dry skin, callous formation, fissures, ulceration and deformities. The deformities of feet include of flat feet, hammer toes, overlapping toes, halux valgus, joint subluxation, prominent metatarsal heads, medial convexity (Charcot foot) and amputation. The vibration sensation is a test using a 128 Hz tuning fork placed over the dorsum of the great toe on the bony prominence of the DIP joint. The ankle reflex is an examination of reflex by using an appropriate reflex hammer. The monofilament testing is an evaluation of a pressure sense by using a 10 grams monofilament pressing on a dorsum of the great toe midway between the nail fold and the DIP joint until the filament is slightly bended. A positive response on score higher than 2 out of 10 for physical assessment correlates with the presence of peripheral neuropathy (60).

All participants in both groups were received a 30 minutes of health education for diabetes. Health education for diabetes was conducted by a professional health nurse and another individual specialized health profession. The participants in a balance training group received the designed group exercise program for balance training of this study (3 days/week, 50 minutes/day), whereas the control group received the upper limb exercise (3 days/week, 50 minutes/day).

Either balance training or upper limb exercise was managed by physical therapist for 4 weeks. Capillary glucose of each subject was checked. If pre-exercise glucose level is 100 mg/dL or lower, subject will be ingested with an added glucose (15-20 g) before attending the exercise for prevention of hypoglycemia (92).

Before enrollment and after 4 weeks enrollment of the study, balance performances, ankle proprioception and fear of falling of each participant was assessed by another physical therapist that was blinded from group random sampling and exercise interventions. During the study, some subjects who participated less than 80% of all exercises was excluded.

8. Data Analysis

All data outcomes of this study were analyzed in the following sequences:

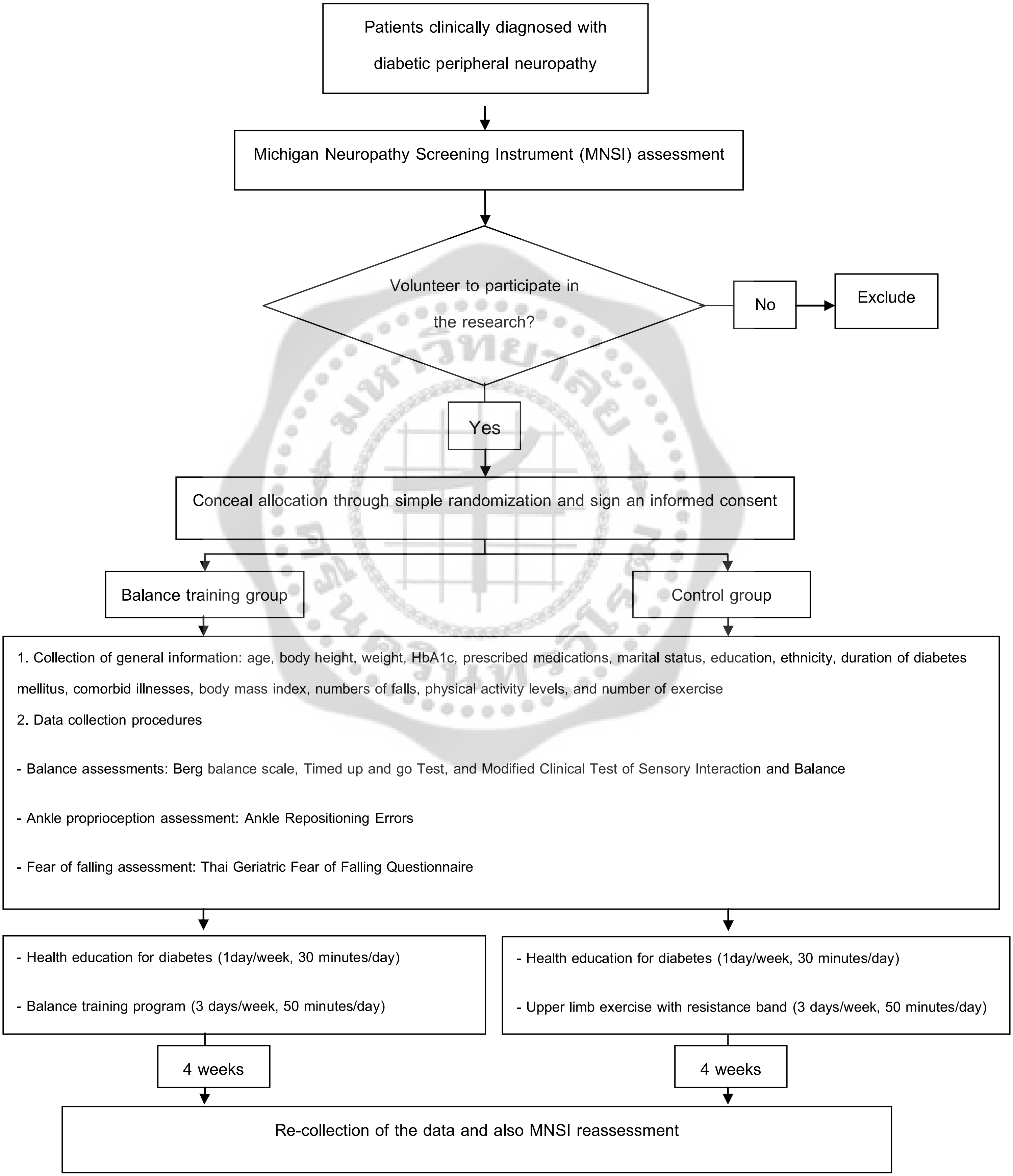
1. The normal distribution of data was analyzed by Kolmogorov-Smirnov test.

2. Two-way ANOVA mixed model was used to analyze the training effect, time effect, and training x time interaction effect. The level of significance is $p \leq 0.05$.

9. Ethical Considerations

This research protocol was approved by the research and ethical committee of the Thasala Hospital, Nakhon Sri Thammarat, Thailand. (นศ 0032.301(09)/1051)

FLOW CHART OF PROCEDURE



CHAPTER 4

RESULTS

This study aimed to investigate effects of the developed balance training program on balance performance, ankle proprioception and fear of falling in the elderly with diabetic peripheral neuropathy. The results of this study are presented as the following.

There were 45 older women volunteered to this study, but only 28 volunteers met the inclusion criteria. The twenty eight volunteers were randomly assigned to the balance training group (n=14) and the control group (n=14). By the end of the 4-week interventions, 27 participants remained in the study. One participant who dropped out from this study was in a balance training group. She dropped out because of an illness.

Baseline Characteristics of Subjects

Table 7 shows the baseline characteristics of the elderly women in the balance training and the control groups. The elderly with diabetic peripheral neuropathy of both groups were equivalent in terms of age, height, weight, body mass index, HbA1c level, years since diabetes diagnosis, history of falling in 6 months, Michigan Neuropathy Screening Instrument (MNSI) questionnaire score, MNSI physical assessment score, and physical activity levels. There was no statistical difference of the baseline characteristics between the balance training and control groups.

Table 7 Characteristics of elderly in balance training and control groups at baseline

Characteristics	Balance training group (n= 13)	Control group (n= 14)	*p*-Value*
Age (years)	68.38 ± 3.99	69.35 ± 3.97	0.923
Weight (kg)	63.38 ± 9.22	63.50 ± 9.64	0.488
Height (cm)	157.07 ± 5.37	154.85 ± 4.81	0.502
Body mass index (kg/m^2)	25.66 ± 3.41	26.73 ± 3.75	0.514
HbA1c level (%)	7.16 ± 1.48	7.25 ± 1.21	0.562
Year s since diabetes diagnosis	10.07 ± 7.00	10.92 ± 6.86	0.811
MNSI questionnaire (score)	6.30 ± 1.88	6.42 ± 1.45	0.496
MNSI physical assessment (score)	3.61 ± 0.79	3.64 ± 1.06	0.139
Fall in 6 months (n)[a]			
No fall (%)	84.62	85.71	
≥ 1 fall (%)	15.38	14.29	
Physical Activity Levels[b]			
Low (%)	38.5	42.9	
Moderate (%)	46.2	42.9	
High (%)	15.4	14.3	

Data are shown as mean ± SD values of the group, except the fall in 6 months and physical activity level.

[a] A fall was defined as an unexpected event in which the participant comes to rest on the ground, floor or lower level (93).

[b] Physical activity level classified by Global Physical Activity Questionnaire (GPAQ)

*p-value from Independent-samples *t* test

Balance performance, ankle proprioception and fear of falling outcome measures

Table 8 shows mean ± SD for the balance performance, ankle proprioception and fear of falling measured at the baseline and at the 4th week after training of the balance training and control groups.

Table 8 Means and standard deviations for balance performances, ankle proprioception, and fear of falling measured at baseline and at the 4th weeks after training in the balance training and control groups

	Baseline		4th Week	
	Balance training group (n=13)	**Control group (n=14)**	**Balance training group (n=13)**	**Control group (n=14)**
Balance Performances				
- mCTSIB (s)				
firm surface with eyes open	30.00 ± 0.00	30.00 ± 0.00	30.00±0.00	30.00±0.00
firm surface with eyes closed	29.65 ± 1.24	28.40 ± 4.27	30±0.00	28.43±4.73
foam surface with eyes open	7.74 ± 4.99	8.95 ± 4.49	22.76±5.50	8.99±4.64
foam surface with eyes closed	2.67 ± 1.57	2.96 ± 1.64	10.71±7.56	2.30±1.64
Total	70.07 ± 6.87	70.31 ± 6.82	93.47±12.19	69.73±7.51
- Berg Balance Scale (score)	48.77 ± 2.35	48.36 ± 2.13	53.31±1.54	48.36±2.27
- Timed “Up & Go” test score (s)	11.85 ± 1.26	11.52 ± 1.54	9.22±0.98	11.70±1.23
Ankle Proprioception[a]				
- Dorsiflexion (˚)	4.36 ± 2.54	4.51 ± 2.21	1.44±0.97	4.44±2.31
- Plantarflexion (˚)	2.52 ± 1.85	2.52 ± 2.12	0.82±0.56	2.28±1.83
- Eversion (˚)	2.90 ± 1.45	3.13 ± 1.35	0.80±0.51	3.42±1.05
- Inversion (˚)	2.81 ± 1.16	2.96 ± 1.03	1.23±1.06	3.25±0.84
Fear of Falling				
- Thai Geriatric Fear of Falling Questionnaire (score)				
Functional domain	26.38±17.58	25.79±16.54	13.00±10.63	27.79±16.95
Environmental domain	23.62±9.58	22.00±8.77	11.23±5.86	19.21±8.71
Psychosocial domain	12.15±8.84	12.21±9.07	6.00±5.80	13.14±8.61
Total	62.15 ± 29.96	60.00 ± 24.91	30.23±19.38	60.14±24.23

Data are mean ± SD

[a]reposition angular error of right ankle joint movement

mCTSIB = Modified Clinical Test of Sensory Interaction on Balance

From two-way ANOVA analysis, there were statistically significant effects of the training, time, and training x time interaction on the balance performances, ankle proprioception and fear of falling parameters as shown in table 9.

Table 9 The two-way ANOVA analysis of the effects of training, time, and training x time interaction on outcome measures

Outcome Measures	**Analysis of Variance**	**SS**	**df**	**MS**	**F**	**p**
mCTSIB (s)	Training effect	1861.383	1	1808.018	24.480	0.001**
	Time effect	1755.610	1	1755.610	23.771	0.001**
	Training x time interaction	1938.836	1	1938.836	26.251	0.001**
Berg Balance Scale (score)	Training effect	96.925	1	96.925	21.879	0.001**
	Time effect	69.422	1	69.422	15.670	0.001**
	Training x time interaction	69.422	1	69.422	15.670	0.001**
Timed “Up & Go” test score (s)	Training effect	15.488	1	15.488	9.450	0.003**
	Time effect	20.284	1	20.284	12.376	0.001**
	Training x time interaction	26.756	1	26.756	16.325	0.001**
Ankle Proprioception (˚)						
Dorsiflexion	Training effect	33.194	1	33.194	7.468	0.009**
	Time effect	30.268	1	30.268	6.810	0.012*
	Training x time interaction	27.423	1	27.423	6.170	0.016*
Plantarflexion	Training effect	7.064	1	7.064	2.412	0.127
	Time effect	12.958	1	12.958	4.426	0.040*
	Training x time interaction	7.390	1	7.390	2.524	0.118
Eversion	Training effect	27.465	1	27.465	20.518	0.001**
	Time effect	11.122	1	11.122	8.309	0.006**
	Training x time interaction	19.220	1	19.220	14.359	0.001**
Inversion	Training effect	15.954	1	15.954	14.988	0.001**
	Time effect	5.511	1	5.511	5.177	0.027*
	Training x time interaction	11.715	1	11.715	11.006	0.002**
Thai Geriatric Fear of Falling Questionnaire (score)	Training effect	2596.938	1	2596.938	4.190	0.046*
	Time effect	3404.015	1	3404.015	5.492	0.023*
	Training x time interaction	3465.496	1	3465.496	5.591	0.022*

* Significant difference at $p < 0.05$ ** Significant difference at $p < 0.01$

mCTSIB = Modified Clinical Test of Sensory Interaction on Balance

The results of each outcome were found as follows.

1. Balance Performances

This study evaluated balance performances of the elderly by using Modified Clinical Test of Sensory interaction on Balance, Berg Balance Scale, and Timed Up and Go test.

1.1 Modified Clinical Test of Sensory interaction on Balance (mCTSIB)

Pre-training, there was no significant difference in a total time for balance maintaining in four conditions of mCTSIB between a balance training group and a control group.

Post-training, the balance training group demonstrated a significant longer total time for balance maintaining in four conditions of mCTSIB compared to pre-training (*P*=0.001) and also statistically significant longer than that of the control group either pre- or post-training (*P*=0.001) as shown in Figure 19. Whereas, the control group showed no statistically significant difference in the total time of mCTSIB between pre- and post -training.

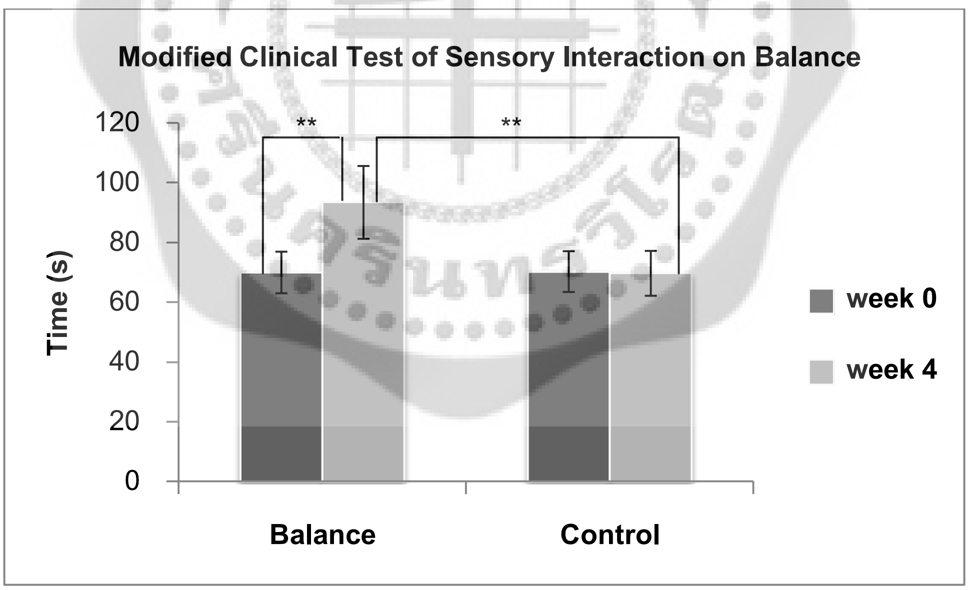


Figure 19 Comparison of the total time used in four conditions of Modified Clinical Test of Sensory Interaction on Balance (mCTSIB) between balance training group and control group either before training (week 0) or week 4 after training.

** Statically significant difference at p=0.001

Moreover, it was found that the significant time increase in mCTSIB post-training of the balance training group were specific in two conditions, foam surface with eyes open and foam surface with eyes closed. Whereas, the other two conditions, firm surface with eyes open and firm surface with eyes closed, showed no statistically significant difference in the mCTSIB between pre- and post –training, as shown in Figure 20.

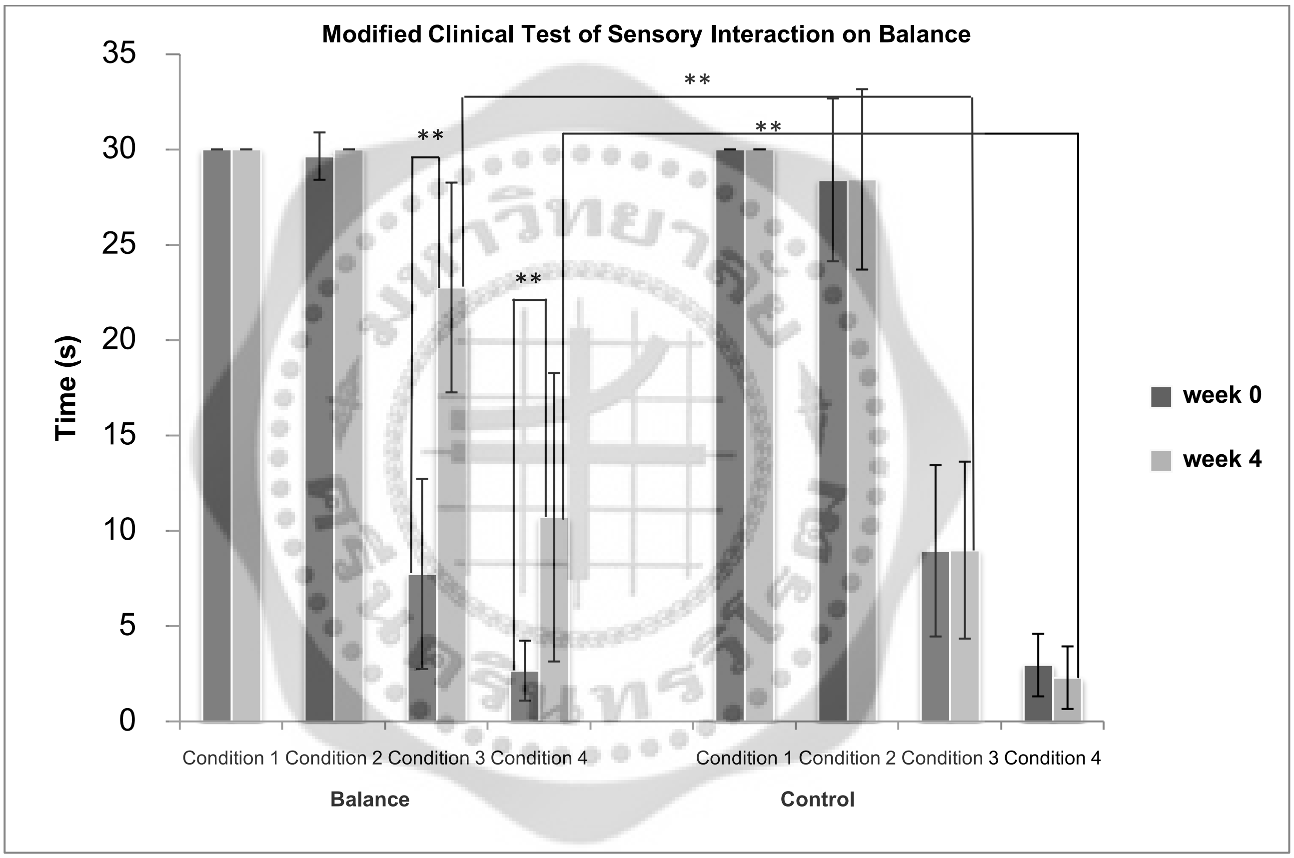


Figure 20 Comparison of the time used in each condition of Modified Clinical Test of Sensory Interaction on Balance (mCTSIB) between balance training group and control group either before training (week 0) or week 4 after training.

Note:** Statically significant difference at p=0.001

Note: condition 1 = firm surface with eyes open, condition 2 = firm surface with eyes closed, condition 3 = foam surface with eyes open, condition 4 = foam surface with eyes closed

1.2 Berg Balance Scale (BBS)

Pre-training, there was no significant difference in BBS between a control group and a balance training group. The week 4 after training, only the balance training group demonstrated a significantly increased BBS compared to the before training (p=0.001) and to the control group (*P*=0.001) as shown in Figure 21.

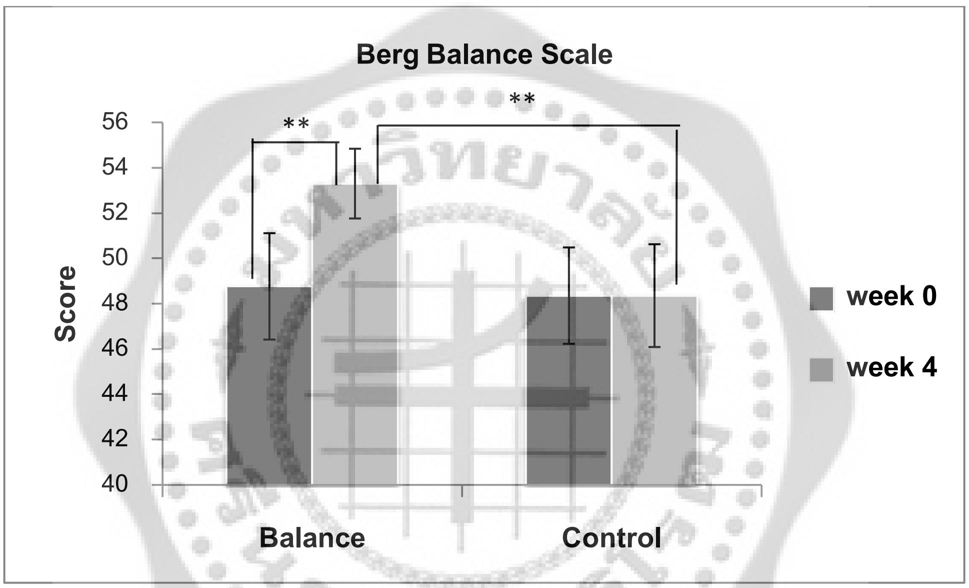


Figure 21 Comparison of the Berg Balance Scale between balance training group and control group either before training (week 0) or week 4 after training.

** Statically significant difference at p=0.001

Table 10 shows mean ± SD for the score of each activity of Berg Balance Scale that was measured at the baseline and at the 4th week after training of the balance training and control groups.

Table 10 Means and standard deviations for the score of each activity of Berg Balance Scale measured at baseline and at the 4th weeks after training in the balance training and control groups

	Baseline		4th Week	
	Balance training group (n=13)	Control group (n=14)	Balance training group (n=13)	Control group (n=14)
Berg Balance Scale (score)				
1. Sitting to standing	3.69 ± 0.48	3.57 ± 0.51	3.92 ± 0.27	3.64 ± 0.49
2. Standing unsupported	4.00 ± 0.00	4.00 ± 0.00	4 ± 0.00	4.00 ± 0.00
3. Sitting with back unsupported	4.00 ± 0.00	4.00 ± 0.00	4.00 ± 0.00	4.00 ± 0.00
4. Standing to sitting	4.00 ± 0.00	4.00 ± 4.00	4.00 ± 0.00	4.00 ± 0.00
5. Transfers	4.00 ± 0.00	4.00 ± 0.00	4.00 ± 0.00	3.92 ± 0.26
6. Standing unsupported with eyes closed	4.00 ± 0.00	4.00 ± 0.00	4.00± 0.00	4.00 ± 0.00
7. Unsupported with feet together	3.57 ± 0.51	3.50 ± 0.52	4.00 ± 0.00	3.50 ± 0.51
8. Reaching forward	2.84 ± 0.37	2.78 ± 0.42	3.84 ± 0.37	2.85 ± 0.53
9. Pick up object from floor	4.00 ± 0.00	4.00 ± 0.00	4.00 ± 0.00	4.00 ± 0.00
10. Turning to look behind	3.84 ± 0.37	3.92 ± 0.26	4.00 ± 0.00	4.00 ± 0.00
11. Turn 360 degrees	3.69 ± 0.48	3.57 ± 0.51	3.92 ± 0.27	3.57 ± 0.51
12. Placing alternate foot on step	4.00 ± 0.00	4.00 ± 0.00	4.00 ± 0.00	4.00 ± 0.00
13. Standing unsupported one foot in front	1.69 ± 0.85	1.64 ± 0.74	3.00 ± 0.70	1.57 ± 0.64
14. Standing on one leg	1.38 ± 0.65	1.21 ± 0.42	2.61 ± 0.86	1.14 ± 0.36

From two-way ANOVA analysis for each activity of BBS, there were statistically significan effects of training, time, and training x time interaction on the only three activities of Berg balance Scale (reaching forward with outstretched arm while standing, standing unsupported one foot in front, and standing on one leg) as shown in table 11

Table 11 The two-way ANOVA analysis of the effects of training, time, and training x time interaction on each activity of Berg balance Scale.

Berg Balance Scale (score)	**Analysis of Variance**	**SS**	**df**	**MS**	**F**	**p**
Activity						
1. Sitting to standing	Training effect	0.542	1	0.542	2.623	0.112
	Time effect	0.308	1	0.308	1.489	0.228
	Training x time interaction	0.086	1	0.086	0.414	0.523
2. Standing unsupported	Training effect	0.000	1	0.000	.	.
	Time effect	0.000	1	0.000	.	.
	Training x time interaction	0.000	1	0.000	.	.
3. Sitting with back unsupported but feet supported on floor	Training effect	0.000	1	0.000	.	.
	Time effect	0.000	1	0.000	.	.
	Training x time interaction	0.000	1	0.000	.	.
4. Standing to sitting	Training effect	0.000	1	0.000		
	Time effect	0.000	1	0.000	.	.
	Training x time interaction	0.000	1	0.000	.	.
5. Transfers	Training effect	0.017	1	0.017	0.926	0.341
	Time effect	0.017	1	0.017	0.926	0.341
	Training x time interaction	0.017	1	0.017	0.926	0.341
6. Standing unsupported with eyes closed	Training effect	0.000	1	0.000	.	.
	Time effect	0.000	1	0.000	.	.
	Training x time interaction	0.000	1	0.000	.	.
7. Unsupported with feet together	Training effect	1.143	1	1.143	5.699	0.021*
	Time effect	0.643	1	0.643	3.205	0.079
	Training x time interaction	0.643	1	0.643	3.205	0.079

Table 11 (Continue)

Berg Balance Scale (score)	Analysis of Variance	SS	df	MS	F	p
8. Reaching forward with outstretched arm while standing	Training effect	3.712	1	3.712	19.627	0.001***
	Time effect	3.869	1	3.869	20.458	0.001***
	Training x time interaction	2.906	1	2.906	15.366	0.001***
9. Pick up object from floor from a standing position	Training effect	0.000	1	0.000	.	.
	Time effect	0.000	1	0.000	.	.
	Training x time interaction	0.000	1	0.000	.	.
10. Turning to look behind over left and right shoulders while standing	Training effect	0.023	1	0.023	0.437	0.512
	Time effect	0.171	1	0.171	3.263	0.077
	Training x time interaction	0.023	1	0.023	0.437	0.512
11. Turn 360 degrees	Training effect	0.753		0.753	3.567	0.065
	Time effect	0.179	1	0.179	0.851	0.361
	Training x time interaction	0.179	1	0.179	0.851	0.361
12. Placing alternate foot on step or stool while standing unsupported	Training effect	0.000	1	0.000	.	.
	Time effect	0.000	1	0.000	.	.
	Training x time interaction	0.000	1	0.000	.	.
13. Standing unsupported one foot in front	Training effect	7.363	1	7.363	13.430	0.001***
	Time effect	5.151	1	5.151	9.396	0.004**
	Training x time interaction	6.410	1	6.410	11.693	0.001***
14. Standing on one leg	Training effect	9.097	1	9.097	24.956	0.001***
	Time effect	4.530	1	4.530	12.428	0.001***
	Training x time interaction	5.715	1	5.715	15.679	0.001***

Note: * Significant difference at $p \leq 0.05$, ** Significant difference at $p \leq 0.01$,

*** Significant difference at $p \leq 0.001$

This study found that the significant increase in BBS post-training of the balance training group were specific in three activities; 1) reaching forward with outstretched arm while standing, 2) standing unsupported one foot in front, and 3) standing on one leg. Whereas, the other activities showed no statistically significant difference in the BBS between pre- and post – training, as shown in Figure 22-23. For a comparison of score of BBS between the two groups, it revealed a significant increase in the post-training score of a balance training group when compared with either the pre- or post- training score of the control group and specifically in the four activities; 1) unsupported with feet together 2) reaching forward with outstretched arm while standing 3) standing unsupported one foot in front 4) standing on one leg as well.

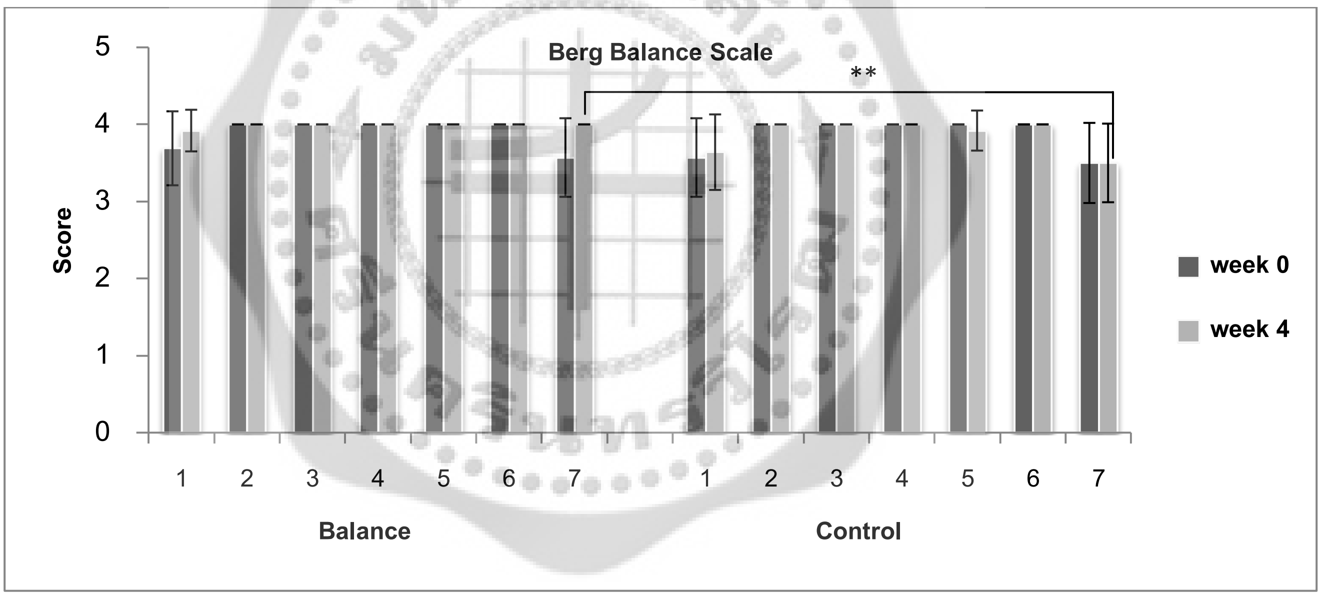


Figure 22 Comparison of the score for each activity of Berg Balance Scale between balance training group and control group either before training (week 0) or week 4 after training.

Note: ** Statically significant difference at p=0.05

Note: 1 = Sitting to standing, 2 = Standing unsupported, 3 = Sitting with back unsupported but feet supported on floor or on a stool, 4 = Standing to sitting, 5 = Transfers, 6 = Standing unsupported with eyes closed, 7 = Unsupported with feet together

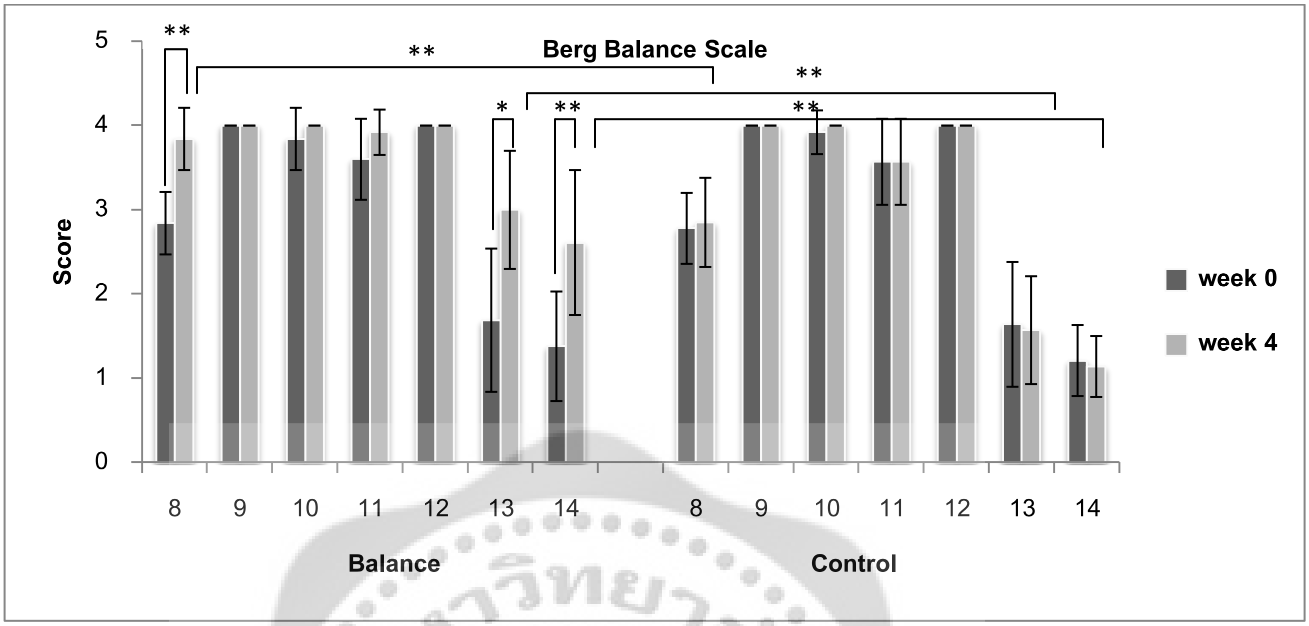


Figure 23 Comparison of the score for each activity of Berg Balance Scale between balance training group and control group either before training (week 0) or week 4 after training

Note: ** Statically significant difference at p=0.001, * Statically significant difference at p=0.01

8 = Reaching forward with outstretched arm while standing, 9 = Pick up object from floor from a standing position, 10 = Turning to look behind over left and right shoulders while standing, 11 = Turn 360 degrees, 12 = Placing alternate foot on step or stool while standing unsupported, 13 = Standing unsupported one foot in front, 14 = Standing on one leg

1.3 Timed Up and Go test (TUG)

Pre-training, there was no significant difference in TUG between the balance training and control groups. The control group demonstrated no statistical change in TUG between pre- and the 4th week post-training. While, post-training, the balance training group showed a significant decrease in time taken of TUG compared to the pre-training (p=0.001). Additionally, post-training, the elderly of balance training group had a shorter time used in TUG compared to that of the control group significantly (p=0.01) as shown in Figure 24.

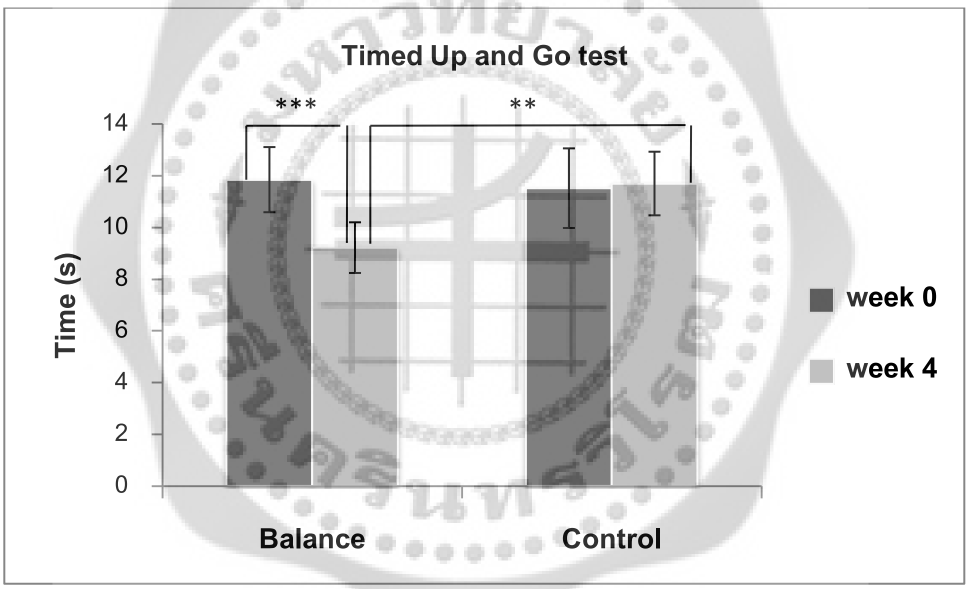


Figure 24 Comparison of the time used by Timed Up and Go test between balance training group and control group either before training (week 0) or week 4 after training.

** Statically significant difference at p=0.01

*** Statically significant difference at p=0.001

2. Ankle Proprioception

This study evaluated ankle proprioception of the elderly by measuring the absolute angular errors of ankle repositioning in dorsiflexion, plantarflexion, eversion, and inversion.

2.1 Absolute Angular Error of Ankle Reposition in Dorsiflexion

Post-training, the balance training group demonstrated a significant decrease in absolute angular error of ankle reposition in dorsiflexion when compared to the pre-training (p=0.05). While, the control group demonstrated no statistical difference in an absolute angular error of ankle reposition in dorsiflexion between pre- and 4th week post-training as shown in Figure 25.

A comparison between balance training and control group for absolute angular error of ankle reposition in dorsiflexion revealed no statistically significant difference between a balance training group and a control group at pre-training. However, after training in week 4, the balance training group showed a significant decrease in absolute angular error of ankle reposition in dorsiflexion when compared to the control group (*P*=0.01) as shown in Figure 25.

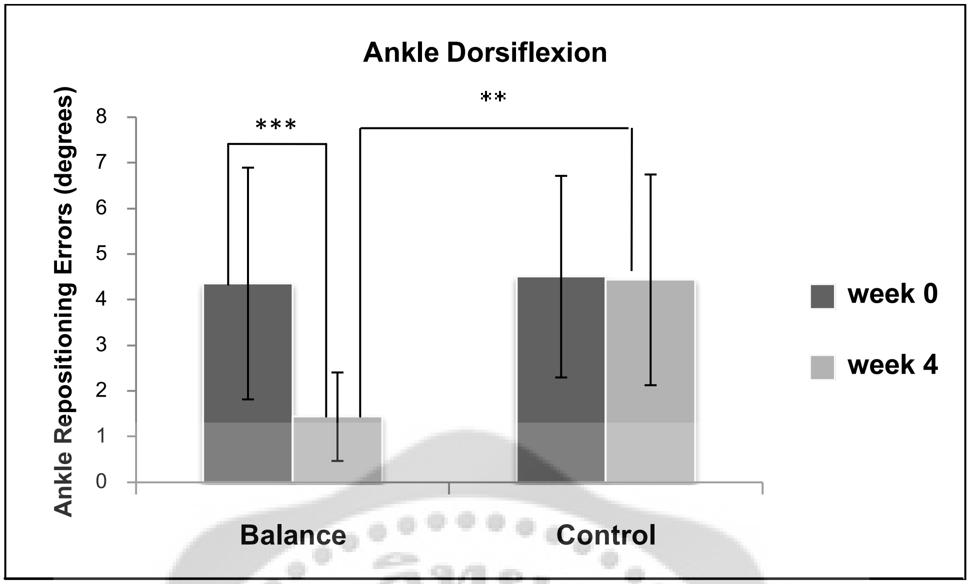


Figure 25 Comparison of the absolute angular error for ankle reposition in dorsiflexion between balance training group and control group either before training (week 0) or week 4 after training.

** Statically significant difference at p=0.01, *** Statically significant difference at p=0.05

2.2 Absolute Angular Error of Ankle Reposition in Plantarflexion

This study found that the balance training and control group demonstrated no statistical difference in absolute angular error of ankle reposition in plantarflexion between before and after training in the 4th week within group and also between groups (Figure 26). However, at week 4 post-training, the balance training group tended to have a reduction of the absolute angular error of ankle reposition in plantarflexion.

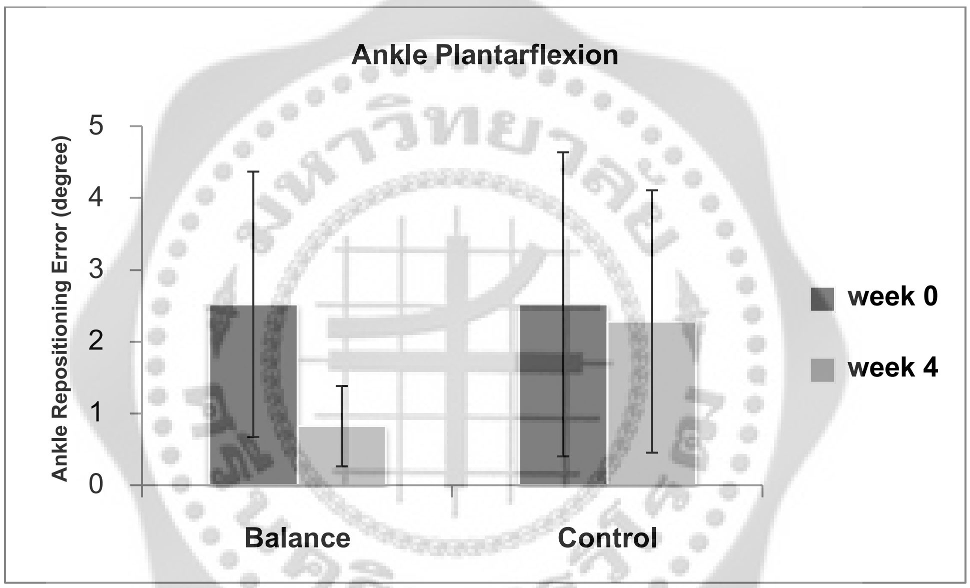


Figure 26 Comparison of the absolute angular error for ankle reposition in plantarflexion between balance training group and control group either before training (week 0) or week 4 after training.

2.3 Absolute Angular Error of Ankle Reposition in Eversion

This study found that the control group demonstrated no statistical difference in absolute angular error of ankle eversion repositioning between before and after training in the 4th week. Whereas the balance training group showed a significant decrease in absolute angular error of ankle eversion repositioning after 4 week of training compared to the before training (p=0.01) as presented in Figure 27.

A comparison between the balance training and control groups for absolute angular error of ankle eversion repositioning revealed no statistical differences between the balance training group and control group at before training. Then, after training in week 4, the balance training group presented a significant decrease in absolute angular error of ankle eversion repositioning compared to the control group (*P*=0.001) as shown in Figure 27.

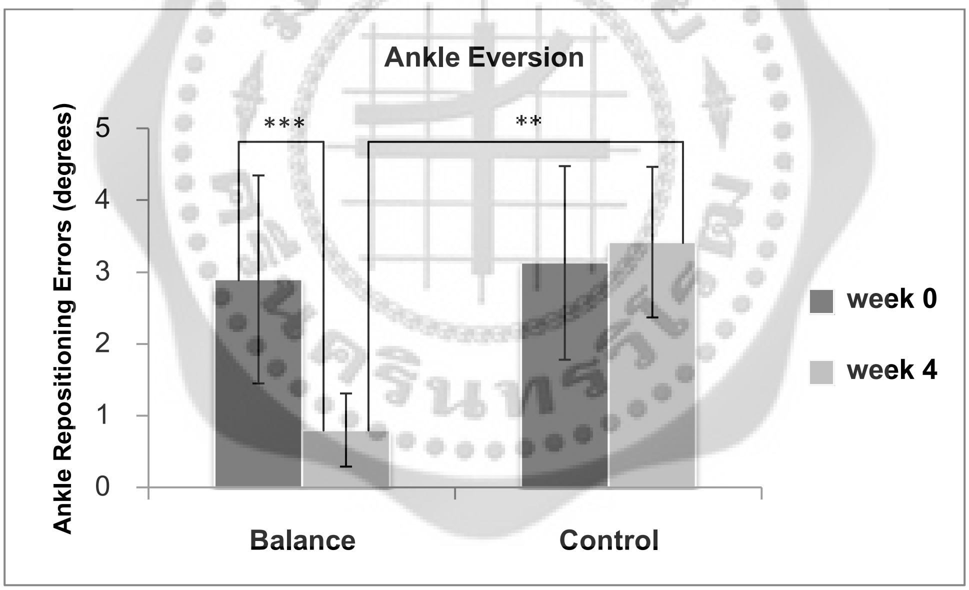


Figure 27 Comparison the degree of the absolute angular error for ankle reposition in eversion between balance training group and control group either before training (week 0) or week 4 after training.

** Statically significant difference at p=0.001, *** Statically significant difference at p=0.01

2.4 Absolute Angular Error of Ankle Reposition in Inversion

This study found that the control group demonstrated no statistical difference in absolute angular error of ankle inversion repositioning between before and after training in the 4th week. Whereas the balance training group showed a significant decrease in absolute angular error of ankle inversion repositioning after 4 week of training compared to the before training (p=0.05) as presented in Figure 28. For a comparison of absolute angular error of ankle inversion repositioning between the two groups, it revealed a significant reduction in the post-training absolute angular error of a balance training group when compared with either the pre- or post- training absolute angular error of a control group (*P*=0.001) as shown in Figure 28.

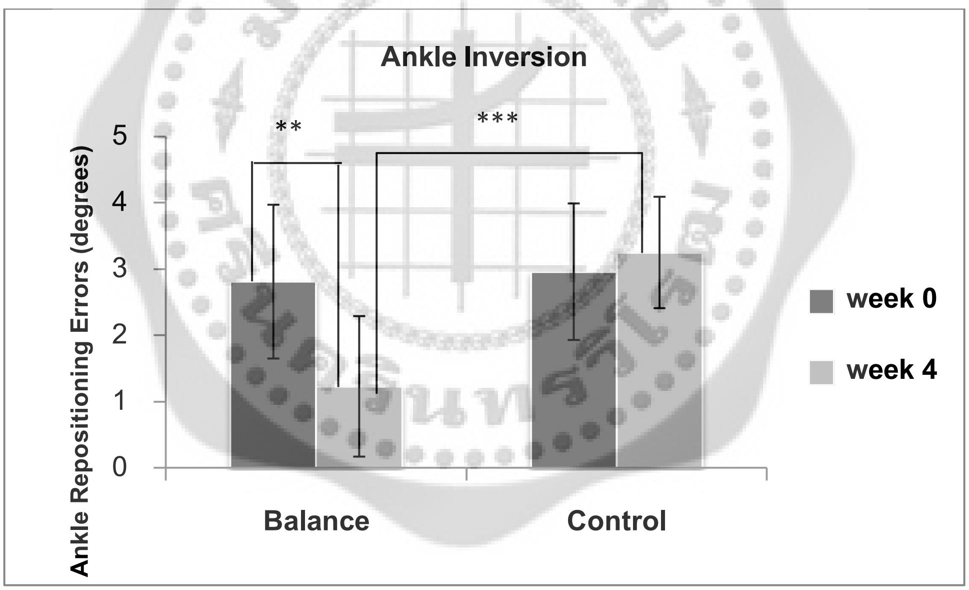


Figure 28 Comparison of the absolute angular error for ankle reposition in inversion between balance training group and control group either before training (week 0) or week 4 after training.

** Statically significant difference at p=0.05, *** Statically significant difference at p=0.001

3. Fear of Falling

This study evaluated fear of falling of the elderly by using Thai Geriatric Fear of Falling Questionnaire and found that both control and balance training groups demonstrated no statistical difference in Thai Geriatric Fear of Falling Questionnaire score at the pre-training. Post-training, only the fear of falling score of a balance training group was significantly reduced when compared to the before training (p=0.05) and to the pre and post-training of a control group (*P*=0.05) as shown in Figure 29.

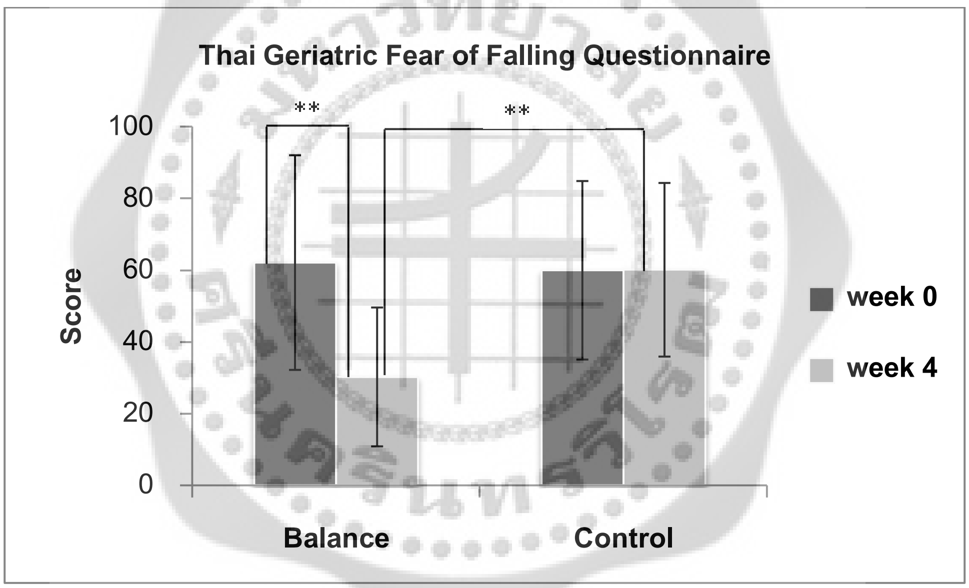


Figure 29 Comparison of Thai Geriatric Fear of Falling Questionnaire scores (total score) between balance training group and control group either before training (week 0) or week 4 after training.

** Statically significant difference at p=0.05

Moreover, the reduction in fear of falling scores after training of a balance training group was significantly found only in an environmental domain (*P*=0.05) from three domains of Thai Geriatric Fear of Falling Questionnaire while the other two domains, functional and psychosocial, were not found any statistically significant changes from the before training as shown in Figure 30. Although the total fear of falling score post-training of the balance training group was less than a control group significantly (*P*=0.05), there was no significant difference in the scores of each separated domain compared between a balance training group and a control group as shown in Figure 30.

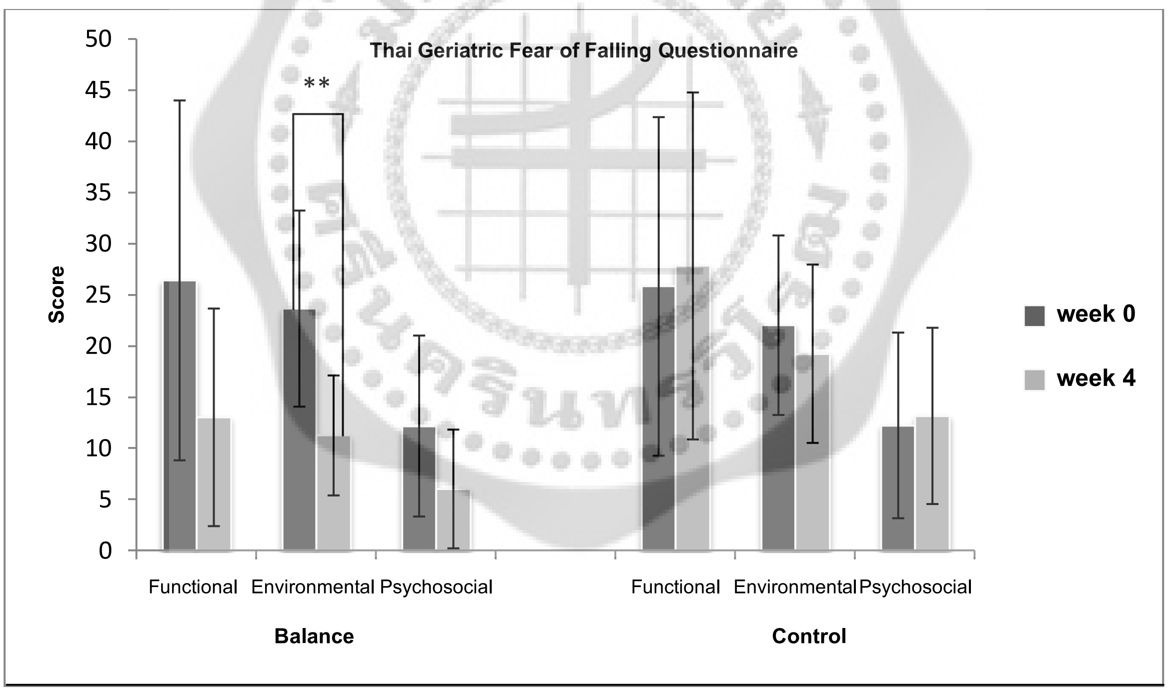


Figure 30 Comparison of scores in each domains of Thai Geriatric Fear of Falling Questionnaire between balance training group and control group either before training (week 0) or week 4 after training.

** Statically significant difference at p=0.05

4. Diabetic peripheral neuropathy assessment

Table 12 shows mean ± SD for the diabetic peripheral neuropathy assessment at the baseline and at the 4th week after training of the balance training and control groups.

Table 12

	Baseline		4th Week	
	Balance training group (n=13)	**Control group (n=14)**	**Balance training group (n=13)**	**Control group (n=14)**
MNSI				
- Questionnaire (score)	6.30 ± 1.88	6.42 ± 1.45	3.31 ± 1.25	6.43 ± 1.50
- Physical assessment (score)	3.61 ± 0.79	3.64 ± 1.06	2.46 ± 0.66	3.60 ± 1.11

Data are mean ± SD, MNSI = Michigan Neuropathy Screening Instrument

From two-way ANOVA analysis, there were statistically significant effects of the training, time, and training x time interaction on the Michigan Neuropathy Screening Instrument (MNSI) questionnaire and Michigan Neuropathy Screening Instrument (MNSI) physical assessment parameters as shown in table 13.

Table 13 The two-way ANOVA analysis of the effects of training, time, and training x time interaction on diabetic peripheral neuropathy assessment by Michigan Neuropathy Screening Instrument (MNSI) questionnaire and Michigan Neuropathy Screening Instrument (MNSI) physical assessment

Diabetic Peripheral Neuropathy Assessment	**Analysis of Variance**	**SS**	**df**	**MS**	**F**	**p**
MNSI Questionnaire (score)	Training effect	35.419	1	35.419	14.958	0.001**
	Time effect	30.333	1	30.333	12.810	0.001**
	Training x time interaction	30.333	1	30.333	12.810	0.001**
MNSI Physical assessment (score)	Training effect	4.638	1	4.638	5.317	0.025***
	Time effect	4.769	1	4.769	5.468	0.023***
	Training x time interaction	4.214	1	4.214	4.831	0.033***

** Significant difference at $p \leq 0.001$ *** Significant difference at $p \leq 0.05$

MNSI = Michigan Neuropathy Screening Instrument

This study found that the control group demonstrated no statistical difference in the score from MNSI questionnaire between before and after training in the 4th week. Whereas the balance training group showed a significant decrease in the score from MNSI questionnaire after 4 week of training compared to the before training (p=0.001) as presented in Figure 31.

A comparison between the balance training and control groups for the score of MNSI questionnaire revealed no statistical differences between the balance training group and control group at before training. Then, after training in week 4, the balance training group presented a significant decrease in score of MNSI questionnaire compared to the control group (p=0.001) as show in Figure 31.

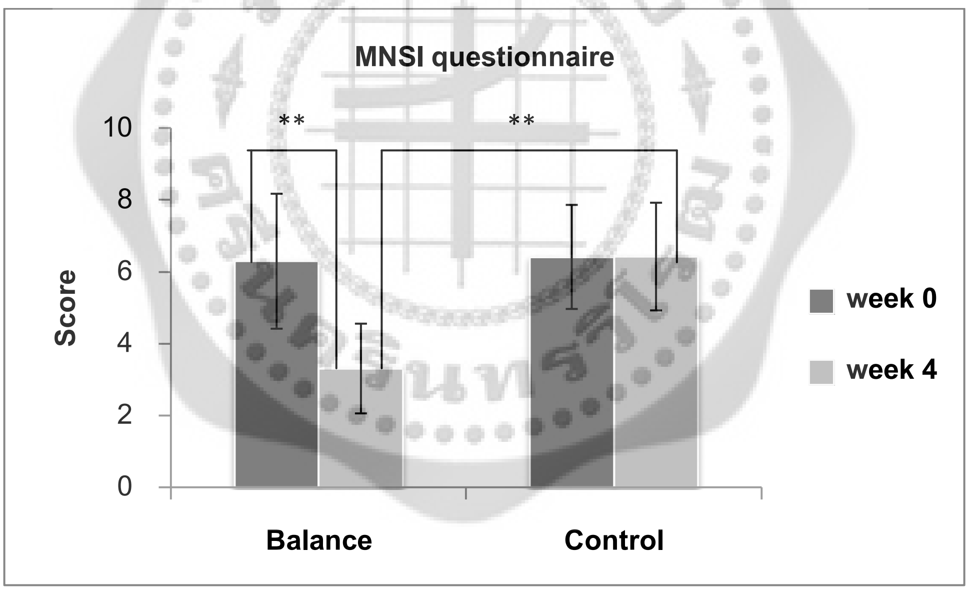


Figure 31 Comparison of Michigan Neuropathy Screening Instrument (MNSI) questionnaire score between balance training group and control group either before training (week 0) or week 4 after training.

** Statically significant difference at p=0.001

For MNSI physical assessment, it was found that the control group demonstrated no statistical difference in the score of MNSI physical assessment between before and after training in the 4th week. Whereas the balance training group showed a significant decrease in the score of MNSI physical assessment after 4 week of training compared to the before training (p=0.05) as presented in Figure 32.

A comparison between the balance training and control groups for score of MNSI physical assessment revealed no statistical differences between the balance training group and control group at before training. Then, after training in week 4, the balance training group presented a significant decrease in the score of MNSI physical assessment compared to a control group (p=0.05) as shown in Figure 32.

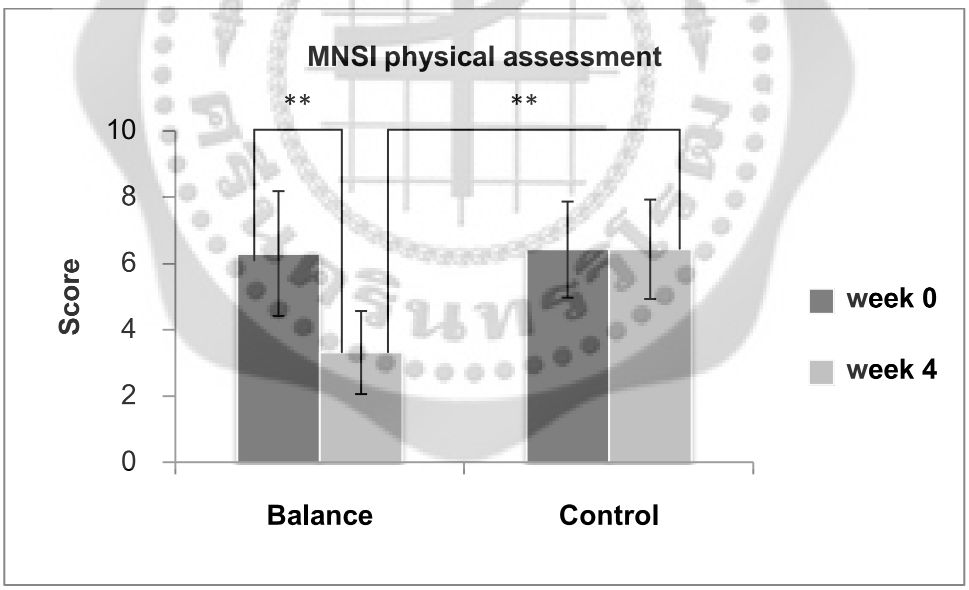


Figure 32 Comparison of Michigan Neuropathy Screening Instrument (MNSI) physical assessment scores between balance training group and control group either before training (week 0) or week 4 after training.

** Statically significant difference at p=0.05

CHAPTER 5

CONCLUSION AND DISCUSSION

Diabetic patients with peripheral neuropathy usually have impaired static and dynamic balances. The balance impairment in diabetic peripheral neuropathy is related to the underlying impaired somatosensory of the lower leg (10, 12). According to the balance impairment in elderly with diabetic peripheral neuropathy it is an important cause of increasing falls risk and developing fear of falling (15).

There were very few studies that conducted on improving balance performance and reducing fear of falling in elderly with diabetic peripheral neuropathy (19-21). And also, most of those studies used equipment for training which may be not feasible for elderly in Thai community. Furthermore, there was no studies about the interaction of ankle proprioception and balance performance in elderly with diabetic peripheral neuropathy (21).

Therefore, the effects of a developed balance training program on balance performance, ankle proprioception and fear of falling in the elderly women with diabetic peripheral neuropathy in Thai community were investigated in this study.

Discussion

Balance Performance Outcomes: Response to Balance Training Program

This study evaluated balance performances of the elderly by using Modified Clinical Test of Sensory interaction on Balance (mCTSIB), Berg Balance Scale (BBS), and Timed Up and Go test (TUG).

Modified Clinical Test of Sensory Interaction on Balance (Static balance)

Static balance of elderly with diabetic peripheral neuropathy in this study was evaluated by the Modified Clinical Test of Sensory Interaction on Balance (mCTSIB). It was found that no statistical differences for a total time of mCTSIB between the balance training group and control group at before training. However, it was noticed that both groups showed the shorter times for mCTSIB on foam surface with eyes open and with eye closed conditions than the firm surface with eye open and eye closed conditions. Therefore, this may confirm that the impairment of balance problem of the elderly with diabetic peripheral neuropathy at before training in this study may be resulted from the impairments of somatosensory and vestibular systems (68-70).

After 4 weeks of training, the study found that only the balance training group illustrated a significant increase in the total time of mCTSIB when compared to before training (P=0.001) and compared to the control group (P=0.001), especially on foam surface with eyes open (P=0.001) and foam surface with eyes closed conditions (P=0.001). These may indicate that the developed balance training program of this study can improve static postural control of the elderly women with DPN by promoting either somatosensory or vestibular functions (68, 70). It is because of the tasks in the developed balance training program, such as standing on a pillow, decrease visual cue (eye closed) and moving head during passing ball activities, which selectively manipulate sensory input from vestibular and/or somatosensory systems and also challenge inter-sensory interaction (94). Whereas, the control group showed no statistically significant difference in the total time of mCTSIB between pre- and post-training. This may indicate that the upper limb exercise in sitting position can not selectively manipulate sensory input from vestibular and/or lower limbs' somatosensory that are important for postural control in standing.

Therefore, the developed balance training program of this study can enhance inter-sensory interaction in postural control which leads to an effective improvement of static balance in elderly with diabetic peripheral neuropathy after 4 week training.

Berg Balance Scale (Functional balance)

Functional balance of elderly women with diabetic peripheral neuropathy in this study was evaluated by Berg Balance Scale (BBS). This study found that no statistical difference in the score of BBS between a balance training group and a control group at before training. The average $\pm$ SD of BBS for balance training group and control group were 48.77 ± 2.35 and 48.36 ± 2.13 respectively at baseline. Thus, at pre-training, the elderly women with diabetic peripheral neuropathy of both groups were classified as a relatively functional balance impairment with moderate risk of falls based on BBS cut off criterion from the study of Karuka and colleagues in 2011 (78) and Jernigan and colleagues in 2012 (95).

Additionally, this study noticed that the low score of BBS in elderly with diabetic peripheral neuropathy at baseline appeared specifically on the activities of single leg stance, tandem standing, and forward reaching in accordance with study in DPN patients of Ghanavati and et al in 2012 (96). So the develop group exercise program for balance training of this study can improve functional balance of the DPN elderly because the training focuses on facilitation of standing on one leg, tandem standing, and weight shift and reaching by passing ball with arms and legs. These can be confirmed by the finding of a significant increase in BBS of the balance training group at week 4 after training when compared to baseline (P=0.001). And also, after 4 week of training, the elderly in balance training group demonstrated a statistically significant higher BBS than a control group (P=0.001), especially on the three activities;1) reaching forward with outstretched arm while standing (P=0.001), 2) standing unsupported one foot in front (*P*=0.001), and 3) standing on one leg (*P*=0.001). Whereas, the control group showed no statistically significant difference in BBS between pre- and post training. These may indicate that the designed activities in the balance training program of this study really promotes body functions that related to balance ability in forward reaching and standing on a narrow base of support such as tandem and single-leg standiings. Contrastly, the activities of upper limb exercise in sitting position can not becase it did not facilitate adaptive learning of standing on one leg, tandem standing, and weight shift and reaching.

Jernigan and colleagues in 2012 suggested that the BBS has an accuracy cutoff score of 52 for a fall risk detection in people with diabetic peripheral neuropathy (95). And Donoghue and Stokes in 2009 reported that, if the initial assessment score of BBS within 45-56, a minimal change of 4 points of BBS is truly indicated a clinical change in balance performance (97). Therefore, the significant increase in an averaged BBS scores of the balance training group for this study from 48.77 ± 2.35 at the base line to 53.31 ± 1.54 at the week 4 after training (about 4.54 points increment) indicates that the balance training program of this study really improves balance performance and decreases falls risk of the elderly women with DPN according to the suggestions of Jernigan and colleagues in 2012 (95) and Donoghue and Stokes in 2009 (97).

Moreover, Shumway-cook et al in 1997 suggested that the Berg Balance Scale appeared to be the best predictor of fall status between community-dwelling older adults, a 1-point drop of the BBS scores within an interval of 54 to 46 score led to a 6% to 8% increase in falls risk (98). Therefore, the 4.5 points increment of BBS of a balance training group at post-training may imply that the developed group exercise program of this study may help to reduce a falls risk of the elderly women with DPN who attended the program around 27% - 36% .

Timed Up and Go test (Functional mobility)

Functional mobility of elderly with diabetic peripheral neuropathy in this study was evaluated by Timed Up and Go test (TUG). It was found that, at baseline, the balance training group and a control group had TUG 11.85 ± 1.26 sec and 11.52 ± 1.54 sec respectively. The times used in TUG at baseline of the elderly with DPN in both groups for this study were longer than a normal range of TUG in the same age people (63). Thus, this confirms that, at pre-training, the elderly with DPN of both groups in the present study showed a decrease in functional mobility when compared to normal elderly (63).

Additionally, this study noticed that there was a risk of falls in elderly with DPN at baseline because the TUG time was more than an accuracy cutoff score of 10.7 sec for a fall risk detection in people with DPN according to the suggestions of Jernigan and colleagues in 2012 (95). In this study, after the balance training, the time taken on TUG of the balance training group was reduced from 11.85 ± 1.26 sec to 9.22 ± 0.98 sec which gets into the normal range of TUG at the same age peoples (63) and it was also lower than an accuracy cutoff score of 10.7 sec for a fall risk detection in people with DPN (95).

Therefore, the developed balance training program of this study can efficiently improve functional balance and mobility, and reduce risk of falling in elderly with diabetic peripheral following 4 week training. Whereas, the control group showed no statistically significant difference in TUG between pre- and post training. These may because the control group did not receive any balance exercise, but received upper limb exercise in sitting position, which did not enhance functional mobility in standing and walking.

Fear of Falling Outcomes: Response to Balance Training Program

Fear of falling in elderly with diabetic peripheral neuropathy of this study was evaluated by Thai Geriatric Fear of Falling Questionnaire. This study found that, at baseline, the balance training and control groups had average total score of Thai Geriatric Fear of Falling Questionnaire of 62.15 ± 29.96 and 60.00 ± 24.91 respectively. Sangpring and colleagues in 2012 (73) recommended that the total scores of 66 and above were quite afraid of falling for the Geriatric Fear of Falling Questionnaire in Thai elderly people. Therefore, according to

Sangpring in 2012, the degree of fear of falling at baseline for the elderly with diabetic peripheral neuropathy of this study may be defined as a low level for fear of falling.

In this study, after the balance training, the total score on Thai Geriatric Fear of Falling Questionnaire was significantly reduced from 62.15 ± 29.96 score to 30.23 ± 19.38 score, especially in an environmental domain. The score of environmental domain was reduced from 23.62 ± 9.58 to 11.23 ± 5.86 in the 4^{th} week. In addition, Sangpring and colleagues in 2012 (73) recommended that the environmental factor was highly correlated with Modified Thai Fall Efficacy Scale, which environmental domains denoted the fear of falling related to self-efficacy concept. The study recommended that the concept of self-efficacy strongly addressed the association of the increased risk of falling and the decline in ability to perform activities of daily living and other physical tasks (73).

From results of the present study, elderly with diabetic peripheral neuropathy in a balance training group demonstrated a reduction of the Geriatric Fear of Falling Questionnaire score after training at the 4^{th} week, especially the environmental domain. Therefore, related to recommendation of Sangpring et al in 2012 (73), this may imply that the developed balance training program of this study can reduce fear of falls of the elderly by improving their self-efficacy in performing activities of daily living and other physical tasks.

On the other hand, the control group showed no statistically significant difference in Thai Geriatric Fear of Falling Questionnaire score between pre- and post training. These may indicate that the upper limb exercise in sitting position can not reduce fear of falls and not result in self-efficacy improvement.

Ankle Proprioception Outcomes: Response to Balance Training Program

This study represents the first investigation of the effects of balance training program on ankle proprioception in the elderly with diabetic peripheral neuropathy. The ankle joint was selected for the assessment of proprioception in this study because of its predominant role in postural control (99). The ankle proprioception is represented as an ability to recognize the position of the ankle by measuring the degree of absolute angular deviation of returning to its original assessed position with the electrogoniometer (85).

This study found the statistically significant improvement of ankle proprioception in all directions of movement in the balance training group, except the plantarflexion. This may be because of a starting position of ankle in relaxed sitting was already in plantarflexion which resulting in a narrow range of plantar movement and a very small absolute angular error of ankle repositioning in plantarflexion.

In the present study, the significant training effects of the 4-week balance training program on ankle proprioception might be one reason that helps to improve static balance when measured with mCTSIB in foam surface with eyes open and eyes closed conditions of the elderly with DPN. Therefore, the developed balance training program of this study can increase balance performance in elderly with diabetic peripheral neuropathy by an enhancement of the somatosensory feedback from ankle proprioception.

Although, it is still controversy whether balance training improves proprioception or proprioception plays in controlling balance (100), the results of this study provides an idea that balance training with challenging proprioception by reducing visual feedback and weight bearing on various base of support areas and surfaces is able to improve both proprioception and balance performance (100). Whereas, the control group demonstrated no statistical difference in absolute angular error of ankle repositioning between before and after training in the 4^{th} wee. These may due to the upper limb exercise in sitting position did not challenge ankle proprioception by weight bearing as in standing position activities.

Additionally, the study found that there were significant decreases in average scores of Michigan Neuropathy Screening Instrument (MNSI) questionnaire (from 6.30 ± 1.88 to 3.31 ± 1.25) and physical assessments (from 3.61 ± 0.79 to 2.46 ± 0.66) in the balance training group after training at the 4th week. Related to recommendation of MNSI in 2012 (60), this may imply that the developed balance training program of this study is also able to increasing pressure and vibration perception associated with the increase in ankle proprioception of the elderly with DPN after training. Moreover, Shaffer and Harrison in 2007 (53) recommended that improving of somatosensory input from the plantar surface of the feet is one of the most important sensory system for improving balance performance and may lead to a reduce fear of falling.

Therefore, the developed balance training program of this study can increase balance performances, an ability to recognize ankle position (proprioception), and reduce fear of falling in elderly women with diabetic peripheral neuropathy after 4 week training. The program of balance training in this study can be applied as a recommendation of health promotion for improving ankle proprioception and balance performance, and also for reducing fear of falling in elderly with diabetic peripheral neuropathy. Moreover, the results of this study can be used as basic information for the further studies related to proprioceptive and balance training.

Conclusions

The balance training program that was developed for the elderly women with diabetic peripheral neuropathy (DPN) by this study can efficiently increase balance performances, ankle proprioception, and reduce fear of falling of the elderly within 4 week. Moreover, the developed balance training program in this study relied only on simple equipment such as pillows and balls. Thus, this study can encourage healthcare provider and elderly people in community to concern on the importance of training or exercise for balance promotion in person with diabetic by inexpensive equipment. In conclusion, the developed balance training program in this study can be applied as a recommendation for health promotion to improve balance performances, ankle proprioception, and to reduce fear of falling in elderly with diabetic peripheral neuropathy in Thai community.

Strengths of the Study

This study was a single-blind, randomized controlled trial, which is one strongest design to evaluate affect relations (101). The study design has important features including the participants were randomly allocated to intervention groups. The participants were blinded from group assignments and from the randomization procedure. Furthermore, the training program of this study has a very good compliance because there were 27 from 28 participants, or 96.42% of the participants, completely followed up throughout the study with a very low drop out rate.

Limitations of the Study

Firstly, this study revealed the improvement of neuropathy by sign and symptom assessment with MNSI, but did not confirm the neuronal regeneration with nerve conduction velocity test. Secondly, this study did not assess the muscle strength of lower limbs so that we cannot conclude directly whether balance was improved by increase muscle strength after received the balance training program. Finally, this investigation did not include a further follow-up after the 4-week.

Suggestions for Further Studies

The effectiveness of balance training program on ankle proprioception, balance performance, and fear of falling in the elderly with diabetes peripheral neuropathy needs further study. The findings from the present study suggests that the developed balance training program can improve ankle proprioception, balance performance and reduce fear of falling in elderly with diabetic peripheral neuropathy in Thai community. However, these findings need to be confirmed by a larger population.

Future studies should examine the effect of exercise regimens on patient groups with different severity of neuropathy (patients without, with mild or with severe peripheral neuropathy, identified by a more complex instrument for peripheral neuropathy screening). Moreover, we need to develop different kinds of balance exercises to improve balance, proprioception, and to reduce fear of falling in DPN elderly with high falls risk in Thai community. Lastly, the next study should further follow-up the effects of the developed balance training program of this study more than 4 weeks to investigate the quality of life and falls prevention in elderly with diabetic peripheral neuropathy.

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APPENDICES

Appendix A

Pilot Study

The appendix A contains of pilot studies showing intrarater reliability of the researcher in using the research tools for this study. The tools that will be used in this study are Berg balance scale, timed up and go test, ankle proprioception measured by electrogoniometer, and Thai Geriatric Fear of Falling Questionnaire.

Berg Balance Scale

The Berg Balance Scale (BBS) is frequently used to assess balance in older people. The BBS consists of 14 tasks assessment. Each task is scored on a 5-point scale (0–4) ranking according to the quality of performance or the time taken to complete the task by the test developers. The maximum total score for this assessment is 56.

An intrarater reliability in using the BBS of the same assessor for this research was investigated in 10 older women aged between 60 to 79 years. Balance ability of each person was assessed with the BBS twice by the same assessor. Then a correlation between the first and the second assessment was analyzed by an intraclass correlation coefficient (ICC) to represents an intrarater reliability. The analysis by ICC show high intra-rater reliability (ICC = 0.891) as demonstrated in table A1. And the root mean squared error is 1.18 score as shown in table A2.

Table A1 Intrarater reliability for the Berg Balance Scale

	ICC	**95% CI**
Berg Balance Scale	0.891 *	0.561 -0.973

ICC = Intraclass correlation coefficient

95% CI = 95% confidence interval

* = significance at $p < 0.05$

Table A2 Raw data of balance ability of each subjects assessed with the BBS twice by the same assessor.

Age	Berg Balance Scale (score)		Score difference
	1st time	2^{nd} time	(1^{st}-2^{nd} time)
73	50	52	-2
61	55	55	0
68	56	56	0
69	54	52	2
65	54	56	-2
72	55	56	-1
75	52	52	0
65	55	56	-1
77	54	54	0
70	52	52	0
Root mean squared error (RMSE)			**1.18**

Timed Up & Go Test (TUGT)

The TUGT was measured with a stopwatch. The subject was instructed to move from a seated position on a chair to a standing position, walk 3 m (10 ft) at a normal and safe pace, turn around, walk back to the chair, and sit down. The pilot study was to investigate the intrarater reliability of the researcher for using the TUGT. The pilot was done in 10 older women aged between 60 to 79 years. The TUGT was assessed twice by the same assessor. An intraclass correlation coefficient (ICC) was used to evaluate intrarater reliability. Results of the pilot show high intra-rater reliability (ICC = 0.944) as demonstrated in table A3. And the root mean squared error is 0.75 seconds as shown in table A4.

Table A3 Intrarater reliability for the “Timed Up & Go Test

	ICC	**95% CI**
Timed “Up & Go” Test	0.944 *	0.775 -0.986

ICC = Intraclass correlation coefficient

95% CI = 95% confidence interval

*P < 0.05

Table A4 Raw data of Timed “Up & Go” Test for each subject by the same assessor

Age	Timed “Up & Go” Test (second)		Difference
	1st time	2nd time	(1st-2nd time)
73	9.00	8.66	0.34
61	7.00	6.66	0.34
68	7.00	6.00	1.00
69	9.66	9.00	0.66
65	7.41	7.44	-0.03
72	8.33	7.00	1.33
75	7.00	7.00	0
65	9.00	8.66	0.34
77	9.50	9.00	0.50
70	8.33	7.00	1.33
Root mean squared error (RMSE)			0.75

Ankle Proprioception measure

Electrogoniometers are usually used to measure lower extremity angular displacements in gait (running, cutting, stairs, etc) in healthy subjects and subjects with various lower extremity changes. Electrogoniometers consist of two potentiometers or strain gauge sensors placed between two plastic end-blocks. The customary biaxial electrogoniometer sensor for the ankle is recommended to place along the Achilles tendon, with the end-blocks in parallel (A-para) (SG110, Biometrics, Gwent, UK). The ankle proprioception is represented as an ability to recognize the ankle position by measuring the degree of angular deviation of the return to its original assessed position with the electrogoniometer (Biometrics SG 110®).

This pilot study was to check the intrarater reliability of the researcher in performing of ankle proprioception measure by testing in 10 older women aged 60-79 years. The data of right ankle joint in dorsiflexion and plantarflexion directions were analyzed. An intraclass correlation coefficient (ICC) was used to evaluate intrarater reliability. The tests show high intra-rater reliability on ankle dorsiflexion (ICC = 0.98) and ankle plantar flexion (ICC = 0.82). This pilot study demonstrated that the ankle proprioception measure with the electrogoniometer by the same assessor has good to excellent intrarater reliability. The root means squared error of ankle dorsiflexion and ankle plantar flexion are 0.44 and 1.31 degrees respectively as shown in table A6 and A7.

Table A5 Intrarater reliability for the right ankle proprioception measure

Direction	ICC	95% CI
dorsiflexion	0.977*	0.909-0.994
plantarflexion	0.817*	0.264-0.955

ICC = Intraclass correlation coefficient

95% CI = 95% confidence interval

*P < 0.05

Table A6 Raw data of ankle proprioception in dorsiflexion direction represented by angular deviation measured by the same assessor with electrogoniometer

Age (year)	1st ankle Proprioception measure (Degree)			2nd Ankle Proprioception measure (Degree)			Difference of angular deviation (1st-2nd measure)
	Original position	Return position	Angular deviation	Original position	Return position	Angular deviation	
70	17.15	16.97	0.18	17.87	17.96	0.09	0.09
62	18.32	20.48	2.16	24.66	22.59	2.07	0.09
75	29.48	30.02	0.54	18.99	17.69	1.31	-0.77
78	23.31	24.80	1.49	23.63	25.25	1.62	-0.13
73	20.97	25.29	4.32	25.20	20.97	4.23	0.09
61	5.90	5.36	0.54	6.35	6.53	0.18	0.36
65	23.45	24.75	1.31	24.48	22.95	1.53	-0.22
70	17.33	19.44	2.12	21.78	20.25	1.53	0.59
66	15.75	14.40	1.35	18.99	18.27	0.72	0.63
69	20.93	25.38	4.46	15.12	20.21	5.09	-0.63
Root mean squared error (RMSE)							0.44

Table A7 Raw data of ankle proprioception in plantarflexion direction represented by angular deviation measured by the same assessor with electrogoniometer

Age (year)	1st ankle Proprioception measure (Degree)			2nd Ankle Proprioception measure (Degree)			Difference of angular deviation (1st-2nd measure)
	Original position	Return position	Angular deviation	Original position	Return position	Angular deviation	
70	22.19	16.07	6.12	16.34	20.48	4.14	1.98
62	7.74	8.06	0.32	16.74	16.07	0.67	-0.35
75	29.34	34.11	4.77	20.16	15.30	4.86	-0.09
78	10.94	12.65	1.71	16.74	14.63	2.12	-0.41
73	5.13	3.56	1.58	9.05	4.37	4.68	-3.1
61	5.40	4.50	0.90	9.99	11.48	1.49	-0.59
65	6.03	7.38	1.35	8.19	7.92	0.27	1.08
70	4.77	3.33	1.44	17.51	20.30	2.79	-1.35
66	10.53	13.14	2.61	14.58	17.15	2.57	0.04
69	16.20	14.63	1.58	7.52	6.03	1.49	0.09
Root mean squared error (RMSE)							1.31

Thai Geriatric Fear of Falling Questionnaire

The “Thai Geriatric Fear of Falling Questionnaire” composes of thirty-four questions related to the feeling of fear or worry during performing physical and function, and also in environment and psychosocial risk to fall. The questionnaire was used to measure in Thai elderly over sixty years old. The pilot study of intrarater reliability of the researcher for the Thai Geriatric Fear of Falling Questionnaire in 10 elderly women aged between 60 to 79 years was done. The pilot’s results showed high intra-rater reliability (intraclass correlation coefficient [ICC] = 0.966) which according to the previous study of whom developed the questionnaire (73).

Table A8 Intrarater reliability for the Thai Geriatric Fear of Falling Questionnaire

	ICC	95% CI
Thai Geriatric Fear of Falling Questionnaire	0.966*	0.864 -0.992

ICC = Intraclass correlation coefficient

95% CI = 95% confidence interval

*P < 0.05

Table A9 Raw data of the score from Thai Geriatric Fear of Falling Questionnaire of each subjects by the same assessor

Age	Thai Geriatric Fear of Falling Questionnaire (score)	
	1st time	2nd time
73	48	44
61	33	29
68	23	27
69	40	44
65	27	36
72	38	41
75	30	35
65	10	14
77	14	18
70	21	25

Michigan Neuropathy Screening Instrument (MNSI)

The MNSI is a simple tool to assess symptoms in diabetic peripheral neuropathy. MNSI consists of two parts that are the questionnaire and the physical assessment. The questionnaire composes of 15 questions related to a history of neuropathic signs and symptoms of the patients with diabetes. The pilot study was to investigate the intrarater reliability of the researcher for using the Michigan Neuropathy Screening Instrument questionnaire (MNSIq). The pilot was done in 10 older women with diabetes aged between 60 to 79 years. The Michigan Neuropathy Screening Instrument questionnaire was assessed twice by the same assessor. An intraclass correlation coefficient (ICC) was used to evaluate intrarater reliability. Results of the pilot show high intra-rater reliability (ICC = 0.937) as demonstrated in table A10.

Table A10 Intrarater reliability for the Michigan Neuropathy Screening Instrument questionnaire

	ICC	**95% CI**
Michigan Neuropathy Screening Instrument questionnaire	0. 937*	0.747 -0.984

ICC = Intraclass correlation coefficient

95% CI = 95% confidence interval

*= significance at $p < 0.05$

Table A11 Raw data of neuropathy screening of each subjects assessed with the MNSIq twice by the same assessor.

Age	Michigan Neuropathy Screening Instrument questionnaire (score)	
	1st time	2^{nd} time
60	7	4
66	2	2
66	3	3
60	7	7
70	8	8
78	4	5
62	3	4
61	1	0
73	3	3
60	3	2

The physical assessment for Michigan Neuropathy Screening Instrument consists of foot inspection, vibration sensation, muscle stretch reflexes and monofilament testing. Intrarater reliability in using the physical assessment of Michigan Neuropathy Screening Instrument by the same assessor for this research was investigated in 10 older women with diabetes aged between 60 to 79 years. Neuropathy screening of each older was assessed with the physical assessment for Michigan Neuropathy Screening Instrument twice by the same assessor. Then a correlation between the first and the second assessment was analyzed by an intraclass correlation coefficient (ICC) to represents an intrarater reliability. The analysis by ICC show high intra-rater reliability (ICC = 0.997) as demonstrated in table A11.

Table A12: Intrarater reliability for the physical assessment of Michigan Neuropathy Screening Instrument

	ICC	95% CI
Michigan Neuropathy Screening Instrument questionnaire	0.997 *	0.987 - 0.999

ICC = Intraclass correlation coefficient

95% CI = 95% confidence interval

*= significance at $p < 0.05$

Table A13 Raw data of neuropathy screening of each subjects assessed with the physical assessment of Michigan Neuropathy Screening Instrument twice by the same assessor.

Age	**Physical assessment of Michigan Neuropathy Screening Instrument (score)**	
	1st time	**2nd time**
60	0	0
66	0.5	0.5
66	1	1
60	2.5	2
70	3	3
78	3	3
62	0	0
61	3	3
73	3	3
60	0	0

APPENDIX B

Berg Balance Scale

Name……………………………………………….Date ……………………………………………..

Activity	Instructions	Score
1. Sitting to standing	Please stand up. Try not to use your hands for support	(4) able to stand without using hands and stabilize independently (3) able to stand independently using hands (2) able to stand using hands after several tries (1) needs minimal aid to stand or to stabilize (0) needs moderate or maximal assist to stand
2. Standing unsupported	Please stand for two minutes without holding	4) able to stand safely 2 minutes (3) able to stand 2 minutes with supervision (2) able to stand 30 seconds unsupported (1) needs several tries to stand 30 seconds unsupported (0) unable to stand 30 seconds unassisted If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported. Proceed to item #4.
3. Sitting with back unsupported but feet supported on floor or on a stool	Please sit with arms folded for 2 minutes	4) able to sit safely and securely 2 minutes (3) able to sit 2 minutes under supervision (2) able to sit 30 seconds (1) able to sit 10 seconds (0) unable to sit without support 10 seconds

Activity	Instructions	Score
4. Standing to sitting	Please sit down	(4) sits safely with minimal use of hands (3) controls descent by using hands (2) uses back of legs against chair to control descent (1) sits independently but has uncontrolled descent (0) needs assistance to sit
5. Transfers	Arrange chairs(s) for a pivot transfer. Ask subject to transfer one way toward a seat with armrests and one way toward a seat without armrests. You may use two chairs (one with and one without armrests) or a bed and a chair	(4) able to transfer safely with minor use of hands (3) able to transfer safely definite need of hands (2) able to transfer with verbal cueing and/or supervision (1) needs one person to assist (0) needs two people to assist or supervise to be safe
6. Standing unsupported with eyes closed	Please close your eyes and stand still for 10 seconds	(4) able to stand 10 seconds safely (3) able to stand 10 seconds with supervision (2) able to stand 3 seconds (1) unable to keep eyes closed 3 seconds but stays steady (0) needs help to keep from falling

Activity	Instructions	Score
7.Standing unsupported with feet together	Place your feet together and stand without holding	(4) able to place feet together independently and stand 1 minute safely (3) able to place feet together independently and stand for 1 minute with supervision (2) able to place feet together independently but unable to hold for 30 seconds (1) needs help to attain position but able to stand 15 seconds feet together (0) needs help to attain position and unable to hold for 15 second
8. Reaching forward with outstretched arm while standing	Lift arm to 90 degrees. Stretch out your fingers and reach forward as far as you can. (Examiner places a ruler at end of fingertips when arm is at 90 degrees. Fingers should not touch the ruler while reaching forward. The recorded measure is the distance forward that the finger	(4) can reach forward confidently >25 cm (10 inches) (3) can reach forward >12 cm safely (5 inches) (2) can reach forward >5 cm safely (2 inches) (1) reaches forward but needs supervision (0) loses balance while trying/requires external

Activity	Instructions	Score
9. Pick up object from floor from a standing position	Pick up shoe/slipper which is placed in front of your feet	(4) able to pick up slipper safely and easily (3) able to pick up slipper but needs supervision (2) unable to pick up but reaches 2-5cm (1-2 inches) from slipper and keeps balance independently (1) unable to pick up and needs supervision while trying (0) unable to try/needs assist to keep from losing balance or falling
10.Turning to look behind over left and right shoulders while standing	Turn to look directly behind you over toward left shoulder. Repeat to the right. Examiner may pick an object to look at directly behind the subject to encourage a better twist turn.	4) looks behind from both sides and weight shifts well (3) looks behind one side only other side shows less weight shift (2) turns sideways only but maintains balance (1) needs supervision when turning (0) needs assist to keep from losing balance or falling
11. Turn 360 degrees	Turn completely around in a full circle. Pause. Then turn a full circle in the other direction.	(4) able to turn 360 degrees safely in 4 seconds or less (3) able to turn 360 degrees safely one side only in 4 seconds or less (2) able to turn 360 degrees safely but slowly (1) needs close supervision or verbal cueing (0) needs assistance while turning

Activity	Instructions	Score
12. Placing alternate foot on step or stool while standing Unsupported	Place each foot alternately on the step/stool. Continue until each foot has touched the step/stool four times	(4) able to stand independently and safely and complete 8 steps in 20 seconds (3) able to stand independently and complete 8 steps >20 seconds (2) able to complete 4 steps without aid with supervision (1) able to complete >2 steps needs minimal assist (0) needs assistance to keep from falling/unable to try
13. Standing unsupported one foot in front	(DEMONSTRATE TO SUBJECT) Place one foot directly in front of the other. If you feel that you cannot place your foot directly in front, try to step far enough ahead that the heel of your forward foot is ahead of the toes of the other foot. (To score 3 points, the length of the step should exceed the length of the other foot and the width of the stance should approximate the subject's normal stride width).	4) able to place foot tandem independently and hold 30 seconds (3) able to place foot ahead of other independently and hold 30 seconds (2) able to take small step independently and hold 30 seconds (1) needs help to step but can hold 15 seconds (0) loses balance while stepping or standing

Activity	Instructions	Score
14. Standing on one leg	Stand on one leg as long as you can without holding	4) able to lift leg independently and hold >10 seconds (3) able to lift leg independently and hold 5-10 seconds (2) able to lift leg independently and hold = or >3 seconds (1) tries to lift leg unable to hold 3 seconds but remains standing independently (0) unable to try or needs assist to prevent fall

APPENDIX C

แบบประเมินภาวะกลัวการล้มในผู้สูงอายุไทย

(Thai Geriatric Fear of Falling Questionnaire)

ชื่อ.. วันที่ ....

แบบประเมินภาวะกลัวการล้มในผู้สูงอายุไทย							
กิจกรรม		ระดับความกลัวการล้ม					
		ไม่กลัวเลย	กลัวเล็กน้อย	กลัวพอสมควร	กลัวค่อนข้างมาก	กลัวมาก	กลัวมากที่สุด
1	ตากเสื้อผ้าที่ราวตากผ้า						
2	เดินในบริเวณบ้าน						
3	ลุกขึ้น/นั่งลงบนเก้าอี้						
4	เอื้อมหยิบของจากชั้นระดับสายตาขึ้นไป						
5	ยืนบนเก้าอี้เตี้ยเพื่อหยิบของ						
6	อาบน้ำ						
7	ลุกขึ้น/นั่งลงบนโถส้วมชักโครก						
8	ก้มหยิบของจากพื้น						
9	ก้าวขึ้น/ลงรถยนต์						
10	ลุกขึ้น/นั่งลงบนพื้น						
11	นั่งยองๆ						
12	ใส่/ถอดกางเกงในท่ายืน						
13	เดินขึ้น/ลงบันไดโดยไม่จับราว						
14	ลุกขึ้น/นั่งลงบนโถส้วมคอห่าน						
15	เดินท่ามกลางฝูงชน						

แบบประเมินภาวะกลัวการล้มในผู้สูงอายุไทย							
สิ่งแวดล้อม		ระดับความกลัวการล้ม					
		ไม่กลัว เลย	กลัว เล็กน้อย	กลัว พอสมควร	กลัว ค่อนข้างมาก	กลัว มาก	กลัวมาก ที่สุด
16	เดินท่ามกลางฝูงชนแล้วถูกกระแทก						
17	เดินก้าวข้ามสิ่งกีดขวาง						
18	เดินบนพื้นขรุขระ						
19	เดินในตลาดสดที่พื้นเฉอะแฉะ						
20	เดินในที่แสงสว่างน้อย						
21	เดินข้ามถนน						
22	เดินขึ้น/ลงทางลาด						
23	เดินบนพื้นลื่น/พื้นห้องน้ำที่เปียก						

แบบประเมินภาวะกลัวการล้มในผู้สูงอายุไทย							
ความรู้สึก		ระดับความกลัวการล้ม					
		ไม่เกิดขึ้นเลย	เกิดขึ้นเล็กน้อย	เกิดขึ้นบางครั้ง	เกิดขึ้นค่อนข้างบ่อย	เกิดขึ้นบ่อยๆ	เกิดขึ้นตลอดเวลา
24	นอนไม่หลับ						
25	ลังเลใจกลัวผิดพลาดในการทำสิ่งต่างๆ						
26	เชื่อว่าตนเองมีโรคทางกายที่ทำให้ล้มได้ง่าย						
27	ใจสั่นหัวใจเต้นเร็วเมื่อนึกถึงการล้ม						
28	อ่อนไหวอารมณ์แปรปรวนง่าย						
29	ไม่มั่นใจในตนเอง						
30	ไม่สบายใจเมื่อต้องพบเจอผู้คน						
31	ไม่สามารถเข้ากับคนรอบข้างได้						
32	มีปัญหาเมื่อต้องขอความช่วยเหลือจากคนรอบข้าง						
33	มีปัญหาเมื่อไปรับบริการทางสุขภาพ						
34	มีปัญหาการเงิน						

APPENDIX D

แบบสอบถามกิจกรรมทางกายภาพรวม

(Global Physical Activity Questionnaire: GPAQ)

ชื่อ.. วันที่ ....

การเคลื่อนไหวออกแรง/ออกกำลัง

ต่อไปนี้ผม/ดิฉัน จะขอสอบถามเกี่ยวกับเวลาที่คุณใช้ทำกิจกรรมในการเคลื่อนไหวออกแรง/ออกกำลังภายในสัปดาห์หนึ่ง ๆ ขอความกรุณาในการตอบคำถามต่อไปนี้ ถึงแม้คุณจะคิดว่าตัวคุณเองจะไม่ค่อยได้เคลื่อนไหวกระฉับกระเฉงก็ตามก่อนอื่นขอให้คิดถึงเวลาที่ใช้ในการทำงาน

การทำงาน หมายถึง การทำงานทั้งที่ได้รับหรือไม่ได้รับผลตอบแทน การเรียน/การอบรม กิจกรรมการทำงานบ้าน การเพาะปลูกและเก็บเกี่ยว การหาปลา/หาอาหาร การแสวงหางาน เป็นต้น (อาจเพิ่มเติมตัวอย่างอื่น)

ในการตอบคำถามเกี่ยวกับความหนักหรือความแรงของกิจกรรมนั้น มีความหมาย ดังนี้

กิจกรรมที่ต้องเคลื่อนไหวออกแรง/ออกกำลังระดับหนัก หมายถึง กิจกรรมที่ต้องใช้พละกำลังอย่างหนัก จนทำให้หายใจแรง หรือหัวใจเต้นเร็วขึ้นมาก

กิจกรรมที่ต้องเคลื่อนไหวออกแรง/ออกกำลังระดับปานกลาง หมายถึง กิจกรรมที่ต้องใช้พละกำลังในระดับปานกลาง ทำให้หายใจเร็ว หรือหัวใจเต้นเร็วขึ้นจากปกติเล็กน้อย

	คำถาม	คำตอบ	รหัส
กิจกรรมในการทำงาน			
1.	ท่านทำงานออกแรง/ออกกำลังระดับหนัก ซึ่งทำให้หายใจแรงและเร็วกว่าปกติมากหรือหอบ ติดต่อกันเป็น ระยะเวลาอย่างน้อย 10 นาที เช่น การยกหรือแบกของหนักๆ การขุดดิน งานก่อสร้าง เป็นต้น ใช่หรือไม่	☐ ใช่ ☐ ไม่ใช่ (ถ้าตอบว่า ไม่ใช่ ให้ข้ามไปตอบ P4)	P1
2.	โดยปกติท่านทำงานออกแรง/ออกกำลังกายระดับหนัก ในแต่ละสัปดาห์เป็นจำนวนกี่วัน	จำนวนวัน .... วัน ต่อสัปดาห์	P2
3.	โดยปกติท่านทำงานออกแรง/ออกกำลังกายระดับหนักนั้น ในแต่ละวันท่านทำเป็นระยะเวลานานเท่าไร นึกถึงเฉพาะงานที่ติดต่อกัน 10 นาทีขึ้นไป	☐☐ : ☐☐ ชั่วโมง: นาที	P3 (a-b)
4.	ท่านทำงานออกแรง/ออกกำลังระดับปานกลาง ซึ่งทำให้หายใจเร็วขึ้นพอควรไม่ถึงกับหอบติดต่อกันเป็นระยะเวลาอย่างน้อย 10 นาที เช่น การก้าวเดินเร็ว ๆหรือการยกถือของเบาๆ เป็นต้น ใช่หรือไม่	☐ ใช่ ☐ ไม่ใช่ (ถ้าตอบว่า ไม่ใช่ ให้ข้ามไปตอบ P7)	P4
5.	โดยปกติท่านทำงานออกแรง/ออกกำลังกายระดับปานกลาง ในแต่ละสัปดาห์เป็นจำนวนกี่วัน	จำนวนวัน .... วันต่อสัปดาห์	P5
6.	โดยปกติท่านทำงานออกแรง/ออกกำลังกายระดับปานกลางนั้น ในแต่ละวันท่านทำเป็นระยะเวลานานเท่าไร นึกถึงเฉพาะงานที่ติดต่อกัน 10 นาทีขึ้นไป	☐☐ : ☐☐ ชั่วโมง: นาที	P6

คำถาม		คำตอบ	รหัส
กิจกรรมในการเดินทางจากที่หนึ่งไปยังอีกที่หนึ่ง			
คำถามต่อไปนี้ไม่รวมถึงกิจกรรมออกแรงออกกำลังกายในการประกอบอาชีพการงาน ที่กล่าวมาแล้วในตอนที่ผ่านมา อยากจะถามถึงการเดินทางที่ทำโดยปกติในที่ต่าง ๆ เช่น การเดินทางไปทำงาน ไปตลาด ไปซื้อข้าว-ของ ไปวัด-โบสถ์ เป็นต้น (ให้ยกตัวอย่างกิจกรรมการเดินทางไป-กลับอื่น ๆ)			
7.	ท่านเดินหรือถีบจักรยานจากที่หนึ่งไปยังอีกที่หนึ่งติดต่อกันเป็นระยะเวลาอย่างน้อย 10 นาที ใช่หรือไม่	☐ ใช่ ☐ ไม่ใช่ (ถ้าตอบว่า ไม่ใช่ ให้ข้ามไปตอบ P10)	P7
8.	โดยปกติท่านเดินหรือถีบจักรยานจากที่หนึ่งไปยังอีกที่หนึ่งติดต่อกันเป็นระยะเวลาอย่างน้อย 10 นาที ในแต่ละสัปดาห์เป็นจำนวนกี่วัน	จำนวนวัน .... วันต่อสัปดาห์	P8
9.	โดยปกติท่านเดินหรือถีบจักรยานนั้น ในแต่ละวันท่านทำเป็นระยะเวลานานเท่าไร	☐☐:☐☐ ชั่วโมง: นาที	P9 (a-b)
กิจกรรมที่ทำในเวลาว่างเพื่อพักผ่อนหย่อนใจ/นันทนาการ			
คำถามต่อไปนี้ไม่รวมถึงกิจกรรมที่ใช้ในการประกอบอาชีพการงาน และการเดินทางที่ได้กล่าวมาแล้วใน 2 ตอนข้างต้น ต่อไปนี้อยากจะถามเกี่ยวกับการเล่นกีฬา การเล่นฟิตเนส และกิจกรรมสันทนาการ ที่คุณปฏิบัติในเวลาที่ว่างจากการทำงาน (ให้ยกตัวอย่าง)			
10.	ท่านเล่นกีฬา ออกกำลังกายหรือทำกิจกรรมนันทนาการระดับหนัก ซึ่งทำให้หายใจแรงและเร็วกว่าปกติมาก หรือหอบติดต่อกันเป็นระยะเวลาอย่างน้อย 10 นาที เช่น วิ่ง หรือเล่นฟุตบอล ใช่หรือไม่	☐ ใช่ ☐ ไม่ใช่ (ถ้าตอบว่า ไม่ใช่ ให้ข้ามไปตอบ P13)	P10
11.	โดยปกติท่านเล่นกีฬา ออกกำลังกายหรือทำกิจกรรมนันทนาการระดับหนัก ในแต่ละสัปดาห์เป็นจำนวนกี่วัน	จำนวนวัน .... วันต่อสัปดาห์	P11
12.	โดยปกติท่านเล่นกีฬา ออกกำลังกายหรือทำกิจกรรมนันทนาการระดับหนักนั้น ในแต่ละวันท่านทำเป็นระยะเวลานานเท่าไร	☐☐:☐☐ ชั่วโมง:นาที	P12 (a-b)

	คำถาม	คำตอบ	รหัส
13.	ท่านเล่นกีฬา ออกกำลังกายหรือทำกิจกรรมนันทนาการระดับปานกลาง ซึ่งทำให้หายใจเร็วขึ้นพอควรไม่ถึงกับหอบ ติดต่อกันเป็นระยะเวลาอย่างน้อย 10 นาที เช่น การก้าวเดิน ถีบจักรยาน ว่ายน้ำ เล่นวอลเล่ย์บอล	☐ ใช่ ☐ ไม่ใช่ (ถ้าตอบว่า ไม่ใช่ ให้ข้ามไปตอบ P16)	P13
14.	โดยปกติท่านเล่นกีฬา ออกกำลังกายหรือทำกิจกรรมนันทนาการระดับปานกลาง ในแต่ละสัปดาห์เป็นจำนวนกี่วัน	จำนวนวัน .... วันต่อสัปดาห์	P14
15.	โดยปกติท่านเล่นกีฬา ออกกำลังกายหรือทำกิจกรรมนันทนาการระดับปานกลางนั้น ในแต่ละวันท่านทำเป็นระยะเวลานานเท่าไร	☐☐:☐☐ ชั่วโมง:นาที	P15 (a-b)
พฤติกรรมนั่ง ๆนอน ๆ			
คำถามต่อไปนี้เป็นคำถามเกี่ยวกับการนั่ง การนั่ง ๆ นอน ๆ ที่บ้าน หรือ ณ ที่ใด ๆ จะเป็นการนั่งเพื่อเดินทางไปในที่ต่าง ๆ หรือ การนั่งพูดคุยกับเพื่อน นั่งทำงาน นั่งดูโทรทัศน์ แต่ไม่รวมเวลาที่ใช้ในการนอน (ยกตัวอย่างเพิ่มเติม)			
16.	โดยปกติในแต่ละวัน ท่านใช้เวลานั่งเอนกายรวมแล้วเป็นระยะเวลานานเท่าไร	☐☐:☐☐ ชั่วโมง : นาที ต่อวัน	P16

APPENDIX E

MICHIGAN NEUROPATHY SCREENING INSTRUMENT

1. Are you legs and/or feet numb? ☐ 1 Yes ☐ 0 No

2. Do you ever have any burning pain in your legs and/or feet? ☐ 1 Yes ☐ 0 No

3. Are your feet too sensitive to touch? ☐ 1 Yes ☐ 0 No

4. Do you get muscle cramps in your legs and/or feet? ☐ 0 Yes ☐ 0 No

5. Do you ever have any prickling feelings in your legs or feet? ☐ 1 Yes ☐ 0 No

6. Does it hurt when the bed covers touch your skin? ☐ 1 Yes ☐ 0 No

7. When you get into the tub or shower, are you able to tell the

hot water from the cold water? ☐ 0 Yes ☐ 1No

8. Have you ever had an open sore on your foot? ☐ 1 Yes ☐ 0 No

9. Has your doctor ever told you that you have diabetic neuropathy? ☐ 1 Yes ☐ 0 No

10. Do you feel weak all over most of the time? ☐ 0 Yes ☐ 0 No

11. Are your symptoms worse at night? ☐ 1 Yes ☐ 0 No

12. Do your legs hurt when you walk? ☐ 1 Yes ☐ 0 No

13. Are you able to sense your feet when you walk? ☐ 0 Yes ☐ 1 No

14. Is the skin on your feet so dry that it cracks open? ☐ 1 Yes ☐ 0 No

15. Have you ever had an amputation? ☐ 1 Yes ☐ 0 No

Total: ____ (13 maximum)

MICHIGAN NEUROPATHY SCREENING INSTRUMENT

Physical Assessment

1. Appearance of Feet

	Right			**Left**	
a. Normal	☐0 Yes	☐1 No	Normal	☐0 Yes	☐1 No

b. If no, check all that apply:

Right		Left	
Deformities	☐	Deformities	☐
Dry skin, callus	☐	Dry skin callus	☐
Infection	☐	Infection	☐
Fissure	☐	Fissure	☐
Other	☐	Other	☐
Specify: ____________		Specify:____________	

	Right		**Left**	
	Absent	Present	Absent	Present
2. Ulceration	☐ 0	☐1	☐0	☐1

	Right			Left		
	Present	Reinforcement	Absent	Present	Reinforcement	Absent
3. Ankle Reflexes	☐ 0	☐ 0.5	☐ 1	☐ 1	☐ 0.5	☐ 1
	Present	Decrease	Absent	Present	Decrease	Absent
4. Vibration perception at great toe	☐ 0	☐ 0.5	☐ 1	☐ 0	☐ 0.5	☐ 1
5. Monofilament	Normal	Reduced	Absent	Normal	Reduced	Absent
	☐ 0	☐ 0.5	☐ 1	☐ 0	☐ 0.5	☐1

Total Score ____________/10

APPENDIX F

Modified Clinical Test of Sensory Interaction in Balance (CTSIB-M)

Name……………………………………………Date…………………………………

Condition One: **Eyes Open, Firm Surface**

Trial One Total Time: _______ / 30 sec

Trial Two Total Time: _______ / 30 sec

Trial Three Total Time: _______ / 30 sec

Condition Two: **Eyes Closed, Firm Surface**

Trial One Total Time: _______ / 30 sec

Trial Two Total Time: _______ / 30 sec

Trial Three Total Time: _______ / 30 sec

Condition Three: **Eyes Open, Foam Surface**

Trial One Total Time: _______ / 30 sec

Trial Two Total Time: _______ / 30 sec

Trial Three Total Time: _______ / 30 sec

Condition Four: **Eyes Closed, Foam Surface**

Trial One Total Time: _______ / 30 sec

Trial Two Total Time: _______ / 30 sec

Trial Three Total Time: _______ / 30 sec

TOTAL: _______ / 120 sec

APPENDIX G

Rating of Perceived Exertion (RPE)

Name……………………………………………….. Date……………………………………………

BORG 6-20 Rate of Perceived Exertion Scale (RPE)		
6	No Exertion	Little to no movement, very relaxed
7	Extremely Light	Able to maintain pace
8		
9	Very Light	Comfortable and breathing harder
10		
11	Light	Minimal sweating, can talk easily
12		
13	Somewhat Hard	Slight breathlessness, can talk
14		Increased sweating, still able to hold conversation but with difficulty
15	Hard	Sweating, able to push and still maintain proper form
16		
17	Very Hard	Can keep a fast pace for a short time period
18		
19	Extremely Hard	Difficulty breathing, near muscle exhaustion
20	Maximally Hard	STOP exercising, total exhaustion

APPENDIX H

แบบสัมภาษณ์ผู้ป่วยเบาหวาน

คำชี้แจงเกี่ยวกับแบบสัมภาษณ์

แบบสัมภาษณ์นี้เป็นส่วนหนึ่งในการดำเนินโครงการวิจัยเรื่อง “ผลของโปรแกรมการฝึกการทรงตัวต่อการรับความรู้สึกของข้อเท้า ประสิทธิภาพการทรงตัวและภาวะกลัวการล้มในผู้สูงอายุที่มีประสาทส่วนปลายเสื่อมจากเบาหวาน” โดย นางสาวระพีพรรณ เทือกทักษ์ นิสิตปริญญาโท สาขากายภาพบำบัด คณะสหเวชศาสตร์ มหาวิทยาลัยศรีนครินทรวิโรฒ ซึ่งมีวัตถุประสงค์เพื่อศึกษาข้อมูลเบื้องต้นในผู้ป่วยเบาหวาน ผู้วิจัยจึงใคร่ขอความร่วมมือจากท่านในการเสียสละเวลาเพื่อตอบแบบสัมภาษณ์ตามความเป็นจริง และขอขอบพระคุณที่ท่านได้กรุณาสละเวลาในการตอบแบบสัมภาษณ์มา ณ โอกาสนี้

โดยแบบสอบถามมีทั้งหมด 6 หน้า แบ่งออกเป็น 5 ส่วน คือ

ส่วนที่ 1 ข้อมูลทั่วไปของผู้ป่วยโรคเป็นเบาหวาน

ส่วนที่ 2 ข้อมูลเกี่ยวกับสุขภาพ

ส่วนที่ 3 ข้อมูลเกี่ยวกับการออกกำลังกาย

ส่วนที่ 4 ข้อมูลเกี่ยวกับการประเมินเท้า

ส่วนที่ 5 ประวัติการหกล้มในรอบ 6 เดือนที่ผ่านมา

หากมีข้อสงสัยประการใดสามารถติดต่อสอบถามได้ที่

นางสาวระพีพรรณ เทือกทักษ์

นิสิตปริญญาโท สาขากายภาพบำบัด มหาวิทยาลัยศรีนครินทรวิโรฒ

ส่วนที่ 1 ข้อมูลทั่วไปของผู้ป่วยโรคเป็นเบาหวาน

1.ชื่อ…………………………………… นามสกุล …………………………………..

2.อายุ……………. ปี เพศ ………….. เชื้อชาติ …………… ศาสนา …………………….

3.สถานภาพ ☐ โสด ☐ สมรส

☐ หย่าร้าง/แยกกันอยู่ ☐ คู่สมรสเสียชีวิต

4. การศึกษาสูงสุด ☐ ไม่ได้ศึกษา ☐ เทียบเท่าประถมศึกษา

☐ เทียบเท่ามัธยมศึกษา ☐ เทียบเท่าอนุปริญญา

☐ เทียบเท่าปริญญาตรี ☐ เทียบเท่าปริญญาโทหรือสูงกว่า

5. อาชีพ ☐ ไม่ได้ประกอบอาชีพ ☐ ข้าราชการ/รัฐวิสาหกิจ

☐ รับจ้าง/ลูกจ้าง ☐ ทำสวน/ทำไร่

☐ ค้าขาย ☐ อื่นๆ โปรดระบุ……………………

6. น้ำหนัก ……………….. กิโลกรัม

7. ส่วนสูง ………………… เซนติเมตร

8. ดัชนีมวลกาย……………………… กก./ม.^{2}

9. อัตราการเต้นของหัวใจ……………………………. ครั้งต่อนาที

10. ความดันโลหิต …………………………………… มม.ปรอท

11. น้ำตาลในเลือดหลังงดอาหาร 8-12 ชั่วโมง ……………………. มิลลิกรัม% (ว/ด/ป) …………

12. ระดับ HbA1c ………………………..% (ระยะเวลา 3 เดือนที่ผ่านมา)

13. ระยะเวลาเป็นเบาหวาน........................ ปี

14. ประวัติการใช้ยารักษาโรคเบาหวาน

Metformin	☐ ไม่ใช้	☐ ใช้
Sulfonylurea	☐ ไม่ใช้	☐ ใช้
Glinide	☐ ไม่ใช้	☐ ใช้
Thiazolidinedione	☐ ไม่ใช้	☐ ใช้
Alpha-glucosidase Inhibitor	☐ ไม่ใช้	☐ ใช้
DPP-4 inhibitor	☐ ไม่ใช้	☐ ใช้
GLP-1 Analog	☐ ไม่ใช้	☐ ใช้
Insulin	☐ ไม่ใช้	☐ ใช้

ประวัติการใช้ยารักษาโรคเบาหวานอื่นๆ โปรดระบุ..

ส่วนที่ 2 ข้อมูลเกี่ยวกับสุขภาพ

โรคหัวใจ	☐ ไม่มี	☐ มี
โรคหลอดเลือดสมอง	☐ ไม่มี	☐ มี
โรคหลอดเลือดส่วนปลาย	☐ ไม่มี	☐ มี
อาการปวดรุนแรงที่หัวใจ	☐ ไม่มี	☐ มี
ความดันโลหิตสูง	☐ ไม่มี	☐ มี

โรคหอบหืด	☐ ไม่มี	☐ มี
โรคไต	☐ ไม่มี	☐ มี
จอประสาทตาเสื่อม	☐ ไม่มี	☐ มี
ปัญหาเกี่ยวกับหลัง	☐ ไม่มี	☐ มี
ปัญหาเกี่ยวกับข้อเข่า	☐ ไม่มี	☐ มี
ไขมันในเลือดสูง	☐ ไม่มี	☐ มี
กระดูกพรุน	☐ ไม่มี	☐ มี
สูบบุหรี่	☐ ไม่มี	☐ มี
การผ่าตัดเมื่อเร็วๆ นี้	☐ ไม่มี	☐ มี โปรดระบุ....................................

ประวัติการรักษาพยาบาลอื่นๆ โปรดระบุ...

ยาที่ได้รับปัจจุบัน..

ส่วนที่ 3 ข้อมูลเกี่ยวกับการออกกำลังกาย (ระยะเวลา 6 เดือนที่ผ่านมา)

1.ออกกำลังกาย ☐ ไม่ใช่ ☐ ใช่ โปรดระบุชนิด ....

2. จำนวนวันออกกำลังกาย......................วัน / สัปดาห์

3. ระยะเวลาออกกำลังกาย......................นาที / วัน

ส่วนที่ 4 ข้อมูลเกี่ยวกับการประเมินเท้า

1. ประวัติเคยตัดขา/เท้า ☐ ไม่เคย ☐ เคย โปรดระบุตำแหน่ง ....

2. ประวัติเท้าเป็นแผล	☐ ไม่เคย	☐ เคย โปรดระบุตำแหน่ง ....
3. ปัจจุบันเท้าเป็นแผล	☐ ไม่ใช่	☐ ใช่ โปรดระบุตำแหน่ง........................
4. เนื้อตาย	☐ ไม่ใช่	☐ ใช่ โปรดระบุตำแหน่ง........................
5. เท้าผิดรูป	☐ ไม่ใช่	☐ ใช่ โปรดระบุตำแหน่ง........................
6. อาการชาที่เท้า	☐ ไม่มี	☐ มี โปรดระบุ(บางส่วน/ทั้งหมด) ....
7. สวมรองเท้าในบ้าน	☐ ไม่ใช่	☐ ใช่ โปรดระบุชนิด...........................
8. สวมรองเท้านอกบ้าน	☐ ไม่ใช่	☐ ใช่ โปรดระบุชนิด ....
9. สวมถุงเท้าในบ้าน	☐ ไม่ใช่	☐ ใช่ โปรดระบุชนิด ....
10. สวมถุงเท้านอกบ้าน	☐ ไม่ใช่	☐ ใช่ โปรดระบุชนิด ....

ส่วนที่ 5 ประวัติการหกล้มในรอบ 6 เดือนที่ผ่านมา

1.ในระยะ 6 เดือนที่ผ่านมา เคยล้มหรือไม่

☐ ไม่เคย ☐ เคย โปรดระบุ (ครั้ง)..................

(ถ้าไม่เคยล้มให้หยุดเพียงเท่านี้ หากเคยล้มให้ทำแบบสอบถามต่อไป)

2. ล้มที่ไหน

☐ ภายในบ้าน

ขณะก้าวขึ้นหรือลงต่างระดับ	☐ ไม่ใช่	☐ ใช่
ขณะก้าวข้ามสิ่งกีดขวาง	☐ ไม่ใช่	☐ ใช่
ขณะลุกจากเตียง	☐ ไม่ใช่	☐ใช่

ขณะลุกจากเก้าอี้	☐ ไม่ใช่	☐ ใช่
ขณะอาบน้ำ	☐ ไม่ใช่	☐ ใช่
ขณะเข้าห้องส้วม	☐ ไม่ใช่	☐ ใช่
ขณะขึ้นหรือลงบันได	☐ ไม่ใช่	☐ ใช่
	☐ อื่นๆ โปรดระบุ...	

☐ ทางเข้าบ้าน / สวนบริเวณรอบบ้าน

ขึ้นหรือลงบันได	☐ ไม่ใช่	☐ ใช่
ในสวน	☐ ไม่ใช่	☐ ใช่
ทางเดิน	☐ ไม่ใช่	☐ ใช่
	☐อื่นๆ โปรดระบุ...	

☐ ที่อื่นๆ

บาทวิถี	☐ไม่ใช่	☐ ใช่
ขอบถนน / ท่อน้ำ	☐ ไม่ใช่	☐ ใช่
อาคารสำนักงาน	☐ ไม่ใช่	☐ ใช่
ขณะลงจากรถยนต์/รถโดยสาร	☐ ไม่ใช่	☐ ใช่
บ้านผู้อื่น	☐ ไม่ใช่	☐ ใช่
	☐อื่นๆ โปรดระบุ...	

3. ล้มได้อย่างไร (เลือกตอบได้มากกว่า 1 ข้อ)

สะดุด	☐ ไม่ใช่	☐ ใช่
ลื่น	☐ ไม่ใช่	☐ ใช่
สูญเสียการทรงท่า	☐ ไม่ใช่	☐ ใช่
เข่าอ่อน	☐ ไม่ใช่	☐ ใช่
เป็นลม	☐ ไม่ใช่	☐ ใช่
วิงเวียนศีรษะ / มึนงง	☐ ไม่ใช่	☐ ใช่
ไม่แน่ใจ	☐ ไม่ใช่	☐ ใช่
4. ได้รับการบาดเจ็บจากการล้ม	☐ ไม่ใช่	☐ ใช่

5. ถ้าได้รับบาดเจ็บ บาดเจ็บอย่างไร

ฟกช้ำ	☐ ไม่ใช่	☐ ใช่
ถลอก	☐ ไม่ใช่	☐ ใช่
ข้อมือหัก	☐ ไม่ใช่	☐ ใช่
ข้อสะโพกหัก	☐ ไม่ใช่	☐ ใช่
กระดูกซี่โครงหัก	☐ ไม่ใช่	☐ ใช่
ปวดหลัง	☐ ไม่ใช่	☐ ใช่

☐ อื่นๆ โปรดระบุ...

APPENDIX I

หนังสือให้ความยินยอมเข้าร่วมในโครงการวิจัย

วันที่ ....

ข้าพเจ้า..อายุ.........ปี อยู่บ้านเลขที่.......... ถนน...........ที่..........แขวง/ตำบล.............................เขต/อำเภอ.......................... จังหวัด..โทรศัพท์...

ขอทำหนังสือนี้ให้ไว้ต่อหัวหน้าโครงการวิจัยเพื่อเป็นหลักฐานแสดงว่า

ข้อ 1. ข้าพเจ้า ได้รับทราบโครงการวิจัยของ นางสาวระพีพรรณ เทือกทักษ์ นิสิตปริญญาโท สาขากายภาพบำบัด คณะสหเวชศาสตร์ มหาวิทยาลัยศรีนครินทรวิโรฒ เรื่อง ผลของโปรแกรมการฝึกการทรงตัวต่อการรับความรู้สึกของข้อเท้า ประสิทธิภาพการทรงตัวและภาวะกลัวการหกล้มในผู้สูงอายุที่มีประสาทส่วนปลายเสื่อมจากเบาหวาน

ข้อ 2. ข้าพเจ้า ยินยอมเข้าร่วมโครงการวิจัยนี้ ด้วยความสมัครใจ โดยมิได้มีการบังคับขู่เข็ญหลอกลวงแต่ประการใด และจะให้ความร่วมมือในการวิจัยทุกประการ

ข้อ 3. ข้าพเจ้า ได้รับการอธิบายจากผู้วิจัยเกี่ยวกับวัตถุประสงค์ของการวิจัย วิธีการวิจัย ประสิทธิภาพ ความปลอดภัย อาการหรืออันตรายที่อาจเกิดขึ้น รวมทั้งแนวทางป้องกันและแก้ไข หากเกิดอันตราย ค่าตอบแทนที่จะได้รับ ค่าใช้จ่ายที่ข้าพเจ้าจะต้องรับผิดชอบจ่ายเอง โดยได้อ่านข้อความ ที่มีรายละเอียดอยู่ในเอกสารชี้แจงผู้เข้าร่วมโครงการวิจัยโดยตลอด อีกทั้งยังได้รับคำอธิบายและตอบข้อสงสัยจากหัวหน้าโครงการวิจัยเป็นที่เรียบร้อยแล้ว และตกลงรับผิดชอบตามคำรับรองในข้อ 5 ทุกประการ

ข้อ 4. ข้าพเจ้า ได้รับการรับรองจากผู้วิจัยว่าจะเก็บข้อมูลส่วนตัวของข้าพเจ้าเป็นความลับ จะเปิดเผยเฉพาะผลสรุปการวิจัยเท่านั้น

ข้อ 5. ข้าพเจ้า ได้รับทราบจากผู้วิจัยแล้วว่า หากมีอันตรายใด ๆ **อันเกิดขึ้นจากการวิจัยดังกล่าว** ข้าพเจ้า จะได้รับการรักษาพยาบาลจากคณะผู้วิจัย โดยไม่คิดค่าใช้จ่ายและจะได้รับค่าชดเชยรายได้ที่สูญเสียไปในระหว่างการรักษาพยาบาลดังกล่าว ตลอดจน มีสิทธิ์ได้รับค่าทดแทนความพิการที่อาจเกิดขึ้นจากการวิจัยตามสมควร

ข้อ 6. ข้าพเจ้า ได้รับทราบแล้วว่าข้าพเจ้ามีสิทธิ์จะบอกเลิกการร่วมโครงการวิจัยนี้ และการบอกเลิกการร่วมโครงการวิจัย จะไม่มีผลกระทบต่อการดูแลรักษาโรคที่ข้าพเจ้าจะพึงได้รับต่อไป

ข้อ 7. หากข้าพเจ้ามีข้อข้องใจเกี่ยวกับขั้นตอนของการวิจัย หรือหากเกิดผลข้างเคียงที่ไม่พึงประสงค์จากการวิจัย สามารถติดต่อกับ นางสาวระพีพรรณ เทือกทักษ์

ที่อยู่ คณะสหเวชศาสตร์ มหาวิทยาลัยศรีนครินทรวิโรฒ โทร 0862666035

ข้อ 8. หากข้าพเจ้า ได้รับการปฏิบัติไม่ตรงตามที่ระบุไว้ในเอกสารชี้แจงผู้เข้าร่วมการวิจัย ข้าพเจ้าจะสามารถติดต่อกับประธานคณะกรรมการจริยธรรมสำหรับการพิจารณาโครงการวิจัยที่ทำในมนุษย์หรือผู้แทน ได้ที่ โรงพยาบาลท่าศาลา จังหวัดนครศรีธรรมราช

ข้าพเจ้าได้อ่านและเข้าใจข้อความตามหนังสือนี้โดยตลอดแล้ว เห็นว่าถูกต้องตามเจตนาของข้าพเจ้า จึงได้ลงลายมือชื่อไว้เป็นสำคัญพร้อมกับหัวหน้าโครงการวิจัยและต่อหน้าพยาน

ลงชื่อ .... ลงชื่อ ....

(...) (...)

ผู้ยินยอม ผู้ให้ข้อมูลและขอความยินยอม/หัวหน้าโครงการวิจัย

ลงชื่อ ....พยาน ลงชื่อ ....พยาน

(...) (...)

ในกรณีที่ผู้เข้าร่วมการวิจัย อ่านหนังสือไม่ออก ผู้ที่อ่านข้อความทั้งหมดแทนผู้เข้าร่วมการวิจัยคือ

....

....

จึงได้ลงลายมือชื่อไว้เป็นพยาน

ลงชื่อ ....พยาน

(...)

หมายเหตุ

1. กรณีผู้ยินยอมตนให้ทำวิจัย ไม่สามารถอ่านหนังสือได้ ให้ผู้วิจัยอ่านข้อความในหนังสือให้ความยินยอมนี้ให้แก่ผู้ยินยอมตนให้ทำวิจัยฟังจนเข้าใจแล้ว และให้ผู้ยินยอมตนให้ทำวิจัยลงนาม หรือพิมพ์ลายนิ้วหัวแม่มือรับทราบ ในการให้ความยินยอมดังกล่าวด้วย

APPENDIX J

แบบคำชี้แจงอาสาสมัคร

1. ชื่อโครงการ

ผลของโปรแกรมการฝึกการทรงตัวต่อการรับความรู้สึกของข้อเท้า ประสิทธิภาพการทรงตัว และภาวะกลัวการล้มในผู้สูงอายุที่มีเส้นประสาทส่วนปลายเสื่อมจากเบาหวาน

2. ชื่อผู้รับผิดชอบโครงการ

นางสาวระพีพรรณ เทือกทักษ์ นิสิตปริญญาโท คณะสหเวชศาสตร์ มหาวิทยาลัยศรีนครินทรวิโรฒ

สถานที่ติดต่อ คณะสหเวชศาสตร์ มหาวิทยาลัยศรีนครินทรวิโรฒ

หมายเลขโทรศัพท์ที่สามารถติดต่อได้ในกรณีฉุกเฉิน โทร 0862666035

3.เหตุที่ต้องทำวิจัยและเหตุผลที่ต้องการศึกษาในคน รวมทั้งเหตุผลที่อาสาสมัครที่ได้รับเชิญเข้าร่วมโครงการ

จากการสำรวจจำนวนผู้ป่วยเบาหวานในประเทศไทยพบว่าเพิ่มสูงขึ้นทุกปี ซึ่งผู้ป่วยเบาหวานนั้นเกิดจากภาวะน้ำตาลในเลือดสูงซึ่งส่งเสริมให้เกิดภาวะแทรกซ้อนต่าง ๆตามมา โดยเฉพาะเส้นประสาทส่วนปลายเสื่อม ซึ่งจากการสำรวจโรงพยาบาลชุมชนในประเทศไทยพบจำนวน 34 เปอร์เซ็นต์ ซึ่งพบมากที่สุดเป็นอันดับหนึ่งของผู้ป่วยเบาหวานทั้งหมด ผู้ป่วยเบาหวานที่มีเส้นประสาทส่วนปลายเสื่อมพบมีความผิดปกติเกี่ยวกับการทรงตัว ทำให้ความสามารถในการทรงตัวลง ซึ่งผู้หญิงที่เป็นเบาหวานพบมีอัตราการหกล้มสูงกว่าผู้หญิงที่ไม่เป็นเบาหวาน ทำให้เพิ่มการเกิดภาวะกลัวการหกล้มตามมา ทำให้ผู้ป่วยที่มีเส้นประสาทส่วนปลายเสื่อมจากเบาหวานเกิดความกลัวการทำกิจกรรมต่าง ๆและจากการออกกำลังกายที่ไม่เหมาะสม

จากการศึกษาโปรแกรมการฝึกการทรงท่าในผู้ป่วยที่มีเส้นประสาทส่วนปลายเสื่อมจากเบาหวานก่อนหน้านี้พบว่าสามารถเพิ่มประสิทธิภาพการทรงตัวและป้องกันการหกล้มหลังจากฝึก

โปรแกรมการทรงตัว อย่างไรก็ตามการศึกษาส่วนใหญ่ใช้เครื่องมือหรืออุปกรณ์ที่มีราคาแพง ซึ่งอาจจะไม่เหมาะสมสำหรับการฝึกในชุมชนไทย ซึ่งพบว่าการศึกษาที่เกี่ยวกับการฝึกโปรแกรมการทรงตัวสำหรับผู้ป่วยที่มีเส้นประสาทส่วนปลายเสื่อมจากเบาหวาน ยังไม่มีการศึกษาในชุมชนประเทศไทย

การออกกำลังกายแบบกลุ่มเป็นอีกแนวทางหนึ่งที่ช่วยเพิ่มประสิทธิภาพในการฝึกออกกำลังกาย เนื่องจากเป็นการกระตุ้นการเข้าสังคมและสร้างความสนุกสนาน เป็นแรงจูงใจให้อยากร่วมกิจกรรม ในกรณีศึกษาพบว่าผู้ป่วยที่ได้รับการฝึกเป็นกลุ่มสามารถทำตามกิจกรรมที่แนะนำได้ดี ทั้งมีความประหยัด สามารถฝึกได้ครั้งละหลายคนเหมาะสำหรับนำไปใช้ส่งเสริมสุขภาพแก่กลุ่มประชากรในชุมชน

ดังนั้นการศึกษานี้จึงสนใจที่จะใช้โปรแกรมการออกกำลังกายแบบกลุ่มเพื่อฝึกการทรงตัวเพื่อใช้ง่ายในชุมชน สามารถเพิ่มประสิทธิภาพการรับรู้ของข้อเท้า ประสิทธิภาพการทรงตัว และลดภาวะความกลัวการหกล้ม อย่างเหมาะสมสำหรับผู้สูงอายุที่มีเส้นประสาทส่วนปลายเสื่อมจากเบาหวานในชุมชนของประเทศไทย

4. วัตถุประสงค์ของโครงการ

เพื่อศึกษาผลของการพัฒนาโปรแกรมการฝึกการทรงตัวต่อการรับรู้สึกของข้อเท้า ประสิทธิภาพการทรงตัว และภาวะความกลัวการล้มในผู้สูงอายุที่มีเส้นประสาทส่วนปลายเสื่อมจากเบาหวาน

5. ขั้นตอนและกระบวนการทำวิจัย

ประกอบด้วยขั้นตอนดังนี้

1). อธิบายวัตถุประสงค์ ประโยชน์ และ วิธีการเก็บข้อมูล ให้กับอาสาสมัครทราบ

2).สอบถามข้อมูลส่วนตัว เช่น น้ำหนัก ส่วนสูง ข้อมูลเกี่ยวกับประวัติโรคเบาหวาน ประวัติการรักษา โรคประจำตัวอื่นๆข้อมูลเกี่ยวการทำกิจกรรมทางกายและการออกกำลังกายของอาสาสมัคร

3). ตรวจประเมินความสามารถในการรับรู้การเคลื่อนไหวของข้อเท้า ตรวจประเมินประสิทธิภาพการทรง และตรวจประเมินภาวะความกลัวการหกล้ม

4). ให้การฝึกโปรแกรมการออกกำลังกายแบบกลุ่ม เป็นระยะเวลา 4 สัปดาห์ (50 นาที/วัน, 3 วัน / สัปดาห์) และการให้ความรู้เรื่องโรคเบาหวานและการป้องกันภาวะแทรกซ้อนจากเบาหวาน (30 นาที / วัน, 1 วัน/สัปดาห์) เป็นระยะเวลา 4 สัปดาห์

5). ตรวจประเมินความสามารถในการรับรู้การเคลื่อนไหวของข้อเท้า ตรวจประเมินประสิทธิภาพการทรง ท่า และตรวจประเมินภาวะความกลัวการหกล้มในสัปดาห์ที่ 4 หลังจากการฝึกโปรแกรมการออกกำลังกาย

6. ประโยชน์ที่คาดว่าจะเกิดขึ้นจากการทำวิจัย

1). โปรแกรมสำหรับการฝึกการทรงท่าสามารถนำมาใช้แนะนำเพื่อส่งเสริมสุขภาพ ต่อการเพิ่มการรับความรู้สึกของข้อเท้า ประสิทธิภาพการทรงตัวและลดภาวะกลัวการล้มในผู้สูงอายุที่มีเส้นประสาทส่วนปลายเสื่อมจากเบาหวาน

2). ส่งเสริมให้บุคลากรทางสุขภาพและผู้สูงอายุในชุมชนเห็นความสำคัญของการฝึกหรือออกกำลังกายโดยไม่ต้องอาศัยเครื่องมือที่มีราคาแพง

7. สิ่งที่อาสาสมัครจะต้องปฏิบัติและไม่ปฏิบัติระหว่างการศึกษา และระยะเวลาของการวิจัย

1). อาสาสมัครจะต้องปฏิบัติเพื่อรับโปรแกรมการออกกำลังกายอย่างต่อเนื่อง (3 ครั้ง/สัปดาห์, 50 นาที/วัน, ระยะเวลา 4 สัปดาห์) และการสอนความรู้เรื่องโรคเบาหวานและการป้องกันภาวะแทรกซ้อน (1 ครั้ง/สัปดาห์, 30 นาที/วัน, ระยะเวลา 4 สัปดาห์)

2). อาสาสมัครไม่ปฏิบัติในการรับโปรแกรมการออกกำลังกายอย่างอื่นนอกเหนือจากโปรแกรมการฝึกที่ใช้ในการศึกษา

8. ความเสี่ยงหรืออันตรายที่จะเกิดขึ้นและหรือความไม่สะดวกสบายของอาสาสมัครที่อาจได้รับและมาตรการที่ผู้วิจัยเตรียมไว้ป้องกัน

1). การเกิดภาวะน้ำตาลต่ำในผู้ป่วยเบาหวานขณะทำการออกกำลังกาย

การป้องกันแก้ไข:

- อธิบายอาการเกิดภาวะน้ำตาลต่ำให้กับอาสาสมัครและสังเกตอาการตลอดการฝึก หากมีอาการผิดปกติ เช่น เวียนศีรษะ หน้าซีด ใจสั่น หอบเหนื่อย จะให้หยุดการฝึกและให้การปฐมพยาบาลเบื้องต้น หากอาการไม่ดีขึ้นจะรีบนำส่งห้องฉุกเฉินของโรงพยาบาลหรือสถานพยาบาลที่ใกล้ที่สุดทันที

- มีการเจาะวัดระดับน้ำตาลที่ปลายนิ้วก่อนและหลังการฝึก ถ้าก่อนการฝึกอาสาสมัครมีระดับน้ำตาลน้อยกว่า 100 มก./ดล. จะให้กินคาร์โบไฮเดรต 15 กรัม เช่น ขนมปัง 1 แผ่นสไลด์, น้ำผึ้ง 3 ช้อนชา และ กล้วย 1 ผล เป็นต้น

2). การเกิดการหกล้มของอาสาสมัครขณะทำการออกกำลังกาย

การป้องกันแก้ไข:

- มีผู้ช่วยนักวิจัยเพื่อดูแลผู้เข้าร่วมโครงการขณะทำการฝึก เพื่อป้องกันการหกล้มและอันตรายต่าง ๆที่จะเกิดขึ้น

3). การเกิดความดันโลหิตต่ำขณะทำการออกกำลังกาย

การป้องกันแก้ไข:

- มีการวัดชีพจรก่อนการฝึก ระหว่างการฝึกทุก 10 นาที และหลังการฝึก 2 นาที ในขณะที่มีการวัดความดันโลหิตก่อนและหลังจากการฝึกโปรแกรมออกกำลังกายให้แก่อาสาสมัครทุกคน

4). การบาดเจ็บที่เท้าหลังจากการฝึก

การป้องกันแก้ไข:

- ผู้วิจัยมีการตรวจเท้าก่อนและหลังการฝึกโปรแกรมออกกำลังกาย ให้อาสาสมัครทุกครั้ง ซึ่งอาจมีความเสี่ยงต่อการบาดเจ็บ

9. กรณีเกิดภาวะแทรกซ้อนที่เกี่ยวข้องกับการวิจัยผู้วิจัยจะให้การดูแลรักษาพยาบาลหรือชดเชยอาสาสมัครอย่างไร

อาสาสมัครจะได้รับการรักษาพยาบาลจากคณะผู้วิจัย โดยไม่คิดค่าใช้จ่ายและจะได้รับค่าชดเชยรายได้ที่สูญเสียไปในระหว่างการรักษาพยาบาลดังกล่าว ตลอดจน มีสิทธิ์ได้รับค่าทดแทนความพิการที่อาจเกิดขึ้นจากการวิจัยตามสมควร โดยผู้วิจัยจะรับผิดชอบในการดูแล แก้ไข อันตรายที่เกิดขึ้นแก่ผู้ทดลองโดยทันที โดยจะเตรียมอุปกรณ์ต่าง ๆที่จำเป็น ในการช่วยเหลือขณะทำการทดลองอย่างถูกต้องและปลอดภัย

10. การรักษาความลับเกี่ยวกับอาสาสมัคร

ผู้วิจัยจะเก็บข้อมูลส่วนตัวของอาสาสมัครเป็นความลับ จะเปิดเผยเฉพาะผลสรุปการวิจัยเท่านั้น

11. สิทธิของอาสาสมัครในการถอนตัวออกจากโครงการเมื่อไรก็ได้ โดยไม่กระทบต่อการรักษาพยาบาลของอาสาสมัครที่เป็นผู้ป่วย

อาสาสมัครมีสิทธิ์จะบอกเลิกการร่วมโครงการวิจัยนี้ และการบอกเลิกการร่วมโครงการวิจัย จะไม่มีผลกระทบต่อการดูแลรักษาโรคที่อาสาสมัครจะพึงได้รับต่อไป

12. โครงการวิจัยได้รับความเห็นชอบจากคณะกรรมการจริยธรรมการวิจัยในมนุษย์

จากโรงพยาบาลท่าศาลา จังหวัดนครศรีธรรมราช

APPENDIX K

Raw Data

Table K1 Raw data of characteristics of elderly with diabetic peripheral neuropathy in balance training group at baseline

No	Age (years)	Weight (kg)	Height (cm)	Body mass index (kg/m^2)	Year s since diabetes diagnosis	HbA1c level (%)	Fall in 6 months (n)	Physical Activity Level
1	74	62	153	26.48	15	7.0	0	High
2	66	65	150	28.88	5	7.4	0	Low
3	71	63	162	24.00	11	7.1	0	Moderate
4	67	72	163	27.09	13	8.5	0	Moderate
5	69	56	158	22.43	25	10.3	0	Low
6	62	55	148	25.10	10	7.3	2	Low
7	68	61	158	24.43	7	7.0	0	Moderate
8	64	74	162	28.19	4	7.0	1	Moderate
9	74	59	157	23.93	1	5.5	0	Moderate
10	71	78	163	29.35	5	8.1	0	High
11	66	75	153	32.03	3	5.0	0	Low
12	73	46	152	19.90	20	8.1	0	Low
13	64	58	163	21.82	12	4.8	0	Moderate
Mean	68.38	63.38	157.07	25.66	10.07	7.16	0.23	
(SD)	(3.99)	(9.22)	(5.37)	(3.41)	(7.00)	(1.48)	(0.59)	

Table K2 Raw data of characteristics of elderly with diabetic peripheral neuropathy in control group at baseline

No	Age (years)	Weight (kg)	Height (cm)	Body mass index (kg/m^2)	Year s since diabetes diagnosis	HbA1c level (%)	Fall in 6 months (n)	Physical Activity Level
1	67	66	147	30.54	5	6.3	0	Low
2	77	60	154	25.29	7	8.0	0	Low
3	74	49	148	22.37	30	5.3	0	Moderate
4	70	76	162	28.95	15	7.5	0	High
5	67	73	154	30.78	5	8.1	0	Moderate
6	64	72	159	28.47	5	7.4	0	Moderate
7	73	60	153	25.63	15	5.0	1	Low
8	65	72	161	27.77	4	8.2	0	Low
9	68	54	157	21.90	12	7.1	0	High
10	67	73	152	31.59	7	9.9	0	Moderate
11	74	57	155	23.72	12	7.2	0	Moderate
12	67	72	151	31.57	15	7.1	1	Low
13	72	48	153	20.50	13	7.0	0	Moderate
14	66	57	162	25.14	8	7.4	0	Low
Mean	69.35	63.50	154.85	26.73	10.92	7.25	0.14	
(SD)	(3.97)	(9.64)	(4.81)	(3.75)	(6.86)	(1.21)	(0.36)	

Table K3 Raw data of Michigan Neuropathy Screening Instrument (MNSI) questionnaire and physical assessment of elderly with diabetic peripheral neuropathy in balance training group at baseline and 4th week

No	MNSI questionnaire		MNSI physical assessment	
	Baseline	**4th Week**	**Baseline**	**4th Week**
1	4	2	3.5	2
2	6	2	3.5	2
3	6	4	4	2.5
4	6	4	2.5	2
5	8	3	4	3
6	6	3	3.5	2.5
7	7	4	3	2.5
8	4	2	3	2.5
9	5	3	3.5	2.5
10	10	6	5	3.5
11	4	2	2.5	1
12	9	5	4	2.5
13	7	3	5	3.5
Mean	6.30	3.31	3.61	2.46
(SD)	(1.88)	(1.25)	(0.79)	(0.66)

Table K4 Raw data of Michigan Neuropathy Screening Instrument (MNSI) questionnaire and physical assessment of elderly with diabetic peripheral neuropathy in control group at baseline and 4th week

No	MNSI questionnaire		MNSI physical assessment	
	Baseline	**4th Week**	**Baseline**	**4th Week**
1	6	5	5.5	5.0
2	5	5	2.5	2.5
3	6	6	3.0	3.0
4	4	5	3.0	3.0
5	8	8	3.0	3.5
6	5	5	3.5	3.5
7	7	7	2.5	2.5
8	8	8	3.0	3.0
9	5	4	3.5	3.0
10	6	6	2.5	2.0
11	8	8	5.0	5.0
12	6	7	4.0	4.0
13	7	7	5.0	5.0
14	9	9	5.0	5.5
Mean	6.42	6.43	3.64	3.60
(SD)	(1.45)	(1.50)	(1.06)	(1.11)

Table K5 Raw data of ankle repositioning error of elderly with diabetic peripheral neuropathy in balance training group at baseline and 4th week

No	Dorsiflexion		Plantarflexion		Eversion		Inversion	
	Baseline	**4th Week**	**Baseline**	**4th Week**	**Baseline**	**4th Week**	**Baseline**	**4th Week**
1	11.27	2.89	1.03	1.30	3.28	0.91	4.63	3.06
2	2.29	0.35	1.08	0.49	5.4	0.28	2.04	1.71
3	3.49	1.26	1.08	0.35	3.16	0.34	1.74	0.54
4	2.94	0.50	4.18	1.14	2.74	0.26	2.49	0.36
5	2.91	0.45	1.32	0.67	2.38	0.42	1.75	0.58
6	6.48	2.88	2.58	0.77	6.22	1.41	1.39	0.69
7	3.54	1.66	2.52	0.21	2.48	0.52	1.48	0.71
8	5.23	2.16	7.53	2.34	2.65	0.25	4.68	1.06
9	6.50	2.38	2.52	0.71	2.48	0.73	3.46	3.87
10	2.98	0.43	2.92	0.26	2.85	1.13	3.28	0.76
11	4.16	2.17	1.39	0.74	1.41	1.08	3.9	1.43
12	1.62	0.38	0.91	1.03	1.26	1.23	3.48	0.75
13	3.39	1.27	3.71	0.66	1.44	1.86	2.22	0.59
Mean (SD)	4.36 (2.54)	1.44 (0.97)	2.52 (1.85)	0.82 (0.56)	2.90 (1.45)	0.80 (0.51)	2.81 (1.16)	1.23 (1.06)

Table K6 Raw data of ankle repositioning error of elderly with diabetic peripheral neuropathy in control group at baseline and 4th week

No	Dorsiflexion		Plantarflexion		Eversion		Inversion	
	Baseline	4th Week	Baseline	4th Week	Baseline	4th Week	Baseline	4th Week
1	2.52	2.35	0.81	1.06	1.58	1.93	1.08	2.43
2	1.58	1.69	6.75	6.43	1.76	1.95	4.52	3.98
3	4.47	4.23	0.46	0.64	2.99	3.05	1.87	2.53
4	2.16	2.07	0.32	0.36	1.26	2.32	3.42	3.54
5	7.32	8.03	1.58	1.47	5.42	4.45	3.6	3.31
6	2.49	1.93	1.72	1.13	3.31	3.64	3.24	2.76
7	4.46	5.08	1.49	1.58	1.53	2.68	3.08	3.38
8	5.21	4.68	6.78	5.26	4.16	4.87	2.93	3.35
9	3.46	3.06	3.65	3.11	2.47	3.48	2.28	3.34
10	7.32	6.01	4.38	4.18	2.49	2.32	1.47	2.74
11	8.96	9.35	1.03	1.13	4.56	3.73	3.37	2.27
12	5.74	5.63	2.63	2.76	3.87	4.23	4.49	5.63
13	2.87	3.03	1.82	1.20	5.04	4.95	3.75	2.74
14	4.61	5.02	1.93	1.68	3.48	4.32	2.43	3.63
Mean (SD)	4.51 (2.21)	4.44 (2.31)	2.52 (2.12)	2.28 (1.83)	3.13 (1.35)	3.42 (1.05)	2.96 (1.03)	3.25 (0.84)

Table K7 Raw data of berg balance scale of elderly with diabetic peripheral neuropathy in balance training group at baseline and 4th week

No	Berg Balance Scale (score)	
	Baseline	**4th Week**
1	49	55
2	52	55
3	49	53
4	51	55
5	47	53
6	46	52
7	46	51
8	52	55
9	47	52
10	49	53
11	48	53
12	46	51
13	52	55
Mean	48.77	53.31
(SD)	(2.35)	(1.54)

Table K8 Raw data of berg balance scale of elderly with diabetic peripheral neuropathy in control group at baseline and 4th week

No	Berg Balance Scale (score)	
	Baseline	**4th Week**
1	46	47
2	49	50
3	46	46
4	48	50
5	50	49
6	52	52
7	47	46
8	52	53
9	46	46
10	51	49
11	48	48
12	47	48
13	48	47
14	47	46
Mean	48.36	48.36
(SD)	(2.13)	(2.27)

Table K9 Raw data of activity in berg balance scale of elderly with diabetic peripheral neuropathy in balance training group at baseline and 4th week

No	Berg Balance Scale (score)														
	Activity	1		2		3		4		5		6		7	
	Week	0	4	0	4	0	4	0	4	0	4	0	4	0	4
1		4	4	4	4	4	4	4	4	4	4	4	4	3	4
2		4	4	4	4	4	4	4	4	4	4	4	4	4	4
3		4	4	4	4	4	4	4	4	4	4	4	4	4	4
4		4	4	4	4	4	4	4	4	4	4	4	4	4	4
5		4	4	4	4	4	4	4	4	4	4	4	4	3	4
6		3	4	4	4	4	4	4	4	4	4	4	4	4	4
7		3	4	4	4	4	4	4	4	4	4	4	4	3	4
8		4	4	4	4	4	4	4	4	4	4	4	4	4	4
9		4	4	4	4	4	4	4	4	4	4	4	4	3	4
10		3	4	4	4	4	4	4	4	4	4	4	4	3	4
11		4	4	4	4	4	4	4	4	4	4	4	4	4	4
12		3	3	4	4	4	4	4	4	4	4	4	4	3	4
13		4	4	4	4	4	4	4	4	4	4	4	4	4	4
Mean		3.69	3.92	4	4	4	4	4	4	4	4	4	4	3.57	4
(SD)		(0.48)	(0.27)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0.51)	(0)

1 = Sitting to standing, 2 = Standing unsupported, 3 = Sitting with back unsupported but feet supported on floor or on a stool, 4 = Standing to sitting, 5 = Transfers, 6 = Standing unsupported with eyes closed, 7 = Unsupported with feet together

Table K10 Raw data of activity in berg balance scale of elderly with diabetic peripheral neuropathy in balance training group at baseline and 4th week (Continue)

No	Berg Balance Scale (score)													
Activity	8		9		10		11		12		13		14	
Week	0	4	0	4	0	4	0	4	0	4	0	4	0	4
1	3	4	4	4	4	4	4	4	4	4	1	3	2	4
2	3	4	4	4	4	4	4	4	4	4	3	4	2	3
3	3	4	4	4	4	4	4	4	4	4	1	2	1	3
4	3	4	4	4	4	4	4	4	4	4	3	4	1	3
5	3	4	4	4	4	4	3	4	4	4	1	3	1	2
6	2	4	4	4	4	4	3	4	4	4	1	2	1	2
7	3	3	4	4	3	4	3	3	4	4	2	3	1	2
8	3	4	4	4	4	4	4	4	4	4	3	4	2	3
9	3	4	4	4	3	4	4	4	4	4	1	2	1	2
10	3	4	4	4	4	4	4	4	4	4	2	3	1	2
11	2	3	4	4	4	4	4	4	4	4	1	3	1	3
12	3	4	4	4	4	4	3	4	4	4	1	3	1	1
13	3	4	4	4	4	4	4	4	4	4	2	3	3	4
Mean	2.84	3.84	4	4	3.84	4	3.69	3.92	4	4	1.69	3	1.38	2.61
(SD)	(0.37)	(0.37)	(0)	(0)	(0.37)	(0)	(0.48)	(0.27)	(0)	(0)	(0.85)	(0.70	(0.65)	(0.86)

8 = Reaching forward with outstretched arm while standing, 9 = Pick up object from floor from a standing position, 10 = Turning to look behind over left and right shoulders while standing, 11 = Turn 360 degrees, 12 = Placing alternate foot on step or stool while standing Unsupported, 13 = Standing unsupported one foot in front, 14 = Standing on one leg

Table K11 Raw data of activity in berg balance scale of elderly with diabetic peripheral neuropathy in control group at baseline and 4th week

No	Berg Balance Scale (score)													
Activity	1		2		3		4		5		6		7	
Week	0	4	0	4	0	4	0	4	0	4	0	4	0	4
1	3	4	4	4	4	4	4	4	4	4	4	4	4	4
2	3	4	4	4	4	4	4	4	4	4	4	4	3	4
3	3	3	4	4	4	4	4	4	4	4	4	4	4	3
4	4	4	4	4	4	4	4	4	4	4	4	4	4	4
5	4	4	4	4	4	4	4	4	4	4	4	4	4	4
6	4	4	4	4	4	4	4	4	4	4	4	4	4	4
7	3	3	4	4	4	4	4	4	4	4	4	4	3	3
8	4	4	4	4	4	4	4	4	4	4	4	4	4	4
9	4	4	4	4	4	4	4	4	4	4	4	4	3	3
10	4	3	4	4	4	4	4	4	4	4	4	4	4	3
11	4	4	4	4	4	4	4	4	4	4	4	4	3	3
12	3	3	4	4	4	4	4	4	4	4	4	4	3	4
13	4	4	4	4	4	4	4	4	4	4	4	4	3	3
14	3	3	4	4	4	4	4	4	4	3	4	4	3	3
Mean	3.57	3.64	4	4	4	4	4	4	4	3.92	4	4	3.50	3.50
(SD)	(0.51)	(0.49)	(0)	(0)	(0)	(0)	(0)	(0)	(0)	(0.26)	(0)	(0)	(0.52)	(0.51)

1 = Sitting to standing, 2 = Standing unsupported, 3 = Sitting with back unsupported but feet supported on floor or on a stool, 4 = Standing to sitting, 5 = Transfers, 6 = Standing unsupported with eyes closed, 7 = Unsupported with feet together

Table K12 Raw data of activity in berg balance scale of elderly with diabetic peripheral neuropathy in control group at baseline and 4th week (Continue)

No	Berg Balance Scale (score)													
Activity	8		9		10		11		12		13		14	
Week	0	4	0	4	0	4	0	4	0	4	0	4	0	4
1	3	3	4	4	3	3	3	4	4	4	1	1	1	1
2	3	3	4	4	4	4	4	4	4	4	2	2	1	1
3	2	3	4	4	4	4	4	3	4	4	1	1	1	1
4	3	3	4	4	4	4	3	4	4	4	1	1	1	2
5	3	3	4	4	4	4	4	3	4	4	2	2	1	1
6	3	2	4	4	4	4	4	4	4	4	3	2	2	1
7	3	2	4	4	4	4	3	4	4	4	1	1	1	1
8	3	4	4	4	4	4	4	4	4	4	3	3	1	1
9	2	2	4	4	4	4	4	4	4	4	1	1	1	1
10	3	3	4	4	4	4	3	3	4	4	2	2	2	2
11	3	3	4	4	4	4	4	4	4	4	1	1	1	1
12	3	3	4	4	4	4	3	3	4	4	2	2	1	1
13	3	3	4	4	4	4	4	3	4	4	1	1	1	1
14	2	3	4	4	4	4	3	3	4	4	2	2	2	1
Mean	2.78	2.85	4	4	3.92	4	3.57	3.57	4	4	1.64	1.57	1.21	1.14
(SD)	(0.42)	(0.53)	(0)	(0)	(0.26)	(0)	(0.51)	(0.51)	(0)	(0)	(0.74)	(0.64)	(0.42)	(0.36)

8 = Reaching forward with outstretched arm while standing, 9 = Pick up object from floor from a standing position,

10 = Turning to look behind over left and right shoulders while standing, 11 = Turn 360 degrees,

12 = Placing alternate foot on step or stool while standing Unsupported, 13 = Standing unsupported one foot in front

14 = Standing on one leg

Table K13 Raw data of timed up and go test of elderly with diabetic peripheral neuropathy in balance training group at baseline and 4th week

No	Timed Up and Go test (sec)	
	Baseline	**4th Week**
1	11.11	8.21
2	11.89	9.2
3	13.48	10.84
4	12.88	9.84
5	10.72	8.21
6	14.06	10.90
7	12.91	8.27
8	10.50	8.45
9	10.12	8.43
10	11.74	10.29
11	11.04	8.65
12	12.91	9.67
13	10.78	8.92
Mean	11.85	9.22
(SD)	(1.26)	(0.98)

Table K14 Raw data of timed up and go test of elderly with diabetic peripheral neuropathy in control group at baseline and 4th week

No	Timed Up and Go test (sec)	
	Baseline	4th Week
1	14.20	14.77
2	11.72	11.48
3	15.25	13.14
4	11.74	12.98
5	10.23	11.16
6	10.19	10.53
7	10.84	10.23
8	10.20	11.06
9	10.53	11.35
10	12.37	12.56
11	11.25	10.97
12	10.81	11.53
13	11.76	10.69
14	10.19	11.38
Mean	11.52	11.70
(SD)	(1.54)	(1.23)

Table K15 Raw data of modified clinical test of sensory interaction on balance of elderly with diabetic peripheral neuropathy in balance training group at baseline and 4^{th} week

No	Modified Clinical Test of Sensory Interaction on Balance (sec)									
	Condition 1		Condition 2		Condition 3		Condition 4		Total	
	Baseline	4^{th} Week	Baseline	4^{th} Week	Baseline	4^{th} Week	Baseline	4^{th} Week	Baseline	4^{th} Week
1	30	30	30	30	15.06	27.70	4.31	26.85	79.37	114.55
2	30	30	30	30	7.83	25.84	3.92	9.23	71.75	95.07
3	30	30	30	30	2	14.76	0	3.87	62	78.63
4	30	30	30	30	15.29	28.43	5.09	25.64	80.38	114.07
5	30	30	30	30	4.62	19.05	3.42	3.51	68.04	82.56
6	30	30	25.5	30	2.35	30	1.81	12.77	59.66	102.77
7	30	30	30	30	1.41	13.87	1	4.78	62.41	78.65
8	30	30	30	30	11.18	23.63	2.7	8.32	73.88	91.95
9	30	30	30	30	10.01	23.58	3.66	9.34	73.67	92.92
10	30	30	30	30	9.36	22.68	2.65	8.45	72.01	91.13
11	30	30	30	30	10.30	24.87	3.13	9.97	73.43	94.84
12	30	30	30	30	1.02	14.64	0	3.90	61.02	78.54
13	30	30	30	30	10.23	26.87	3.09	12.64	73.32	99.51
Mean	30.00	30.00	29.65	30	7.74	22.76	2.67	10.71	70.07	93.47
(SD)	(0.00)	(0.00)	(1.24)	(0.00)	(4.99)	(5.50)	(1.57)	(7.56)	(6.87)	(2.19)

Table K16 Raw data of modified clinical test of sensory interaction on balance of elderly with diabetic peripheral neuropathy in control group at baseline and 4th week

No	Modified Clinical Test of Sensory Interaction on Balance (sec)									
	Condition 1		Condition 2		Condition 3		Condition 4		Total	
	Baseline	4th Week	Baseline	4th Week	Baseline	4th Week	Baseline	4th Week	Baseline	4th Week
1	30	30	30	30	1.60	1.56	1.32	0	62.92	61.56
2	30	30	22.16	25.64	14.59	16.36	1.70	0	68.45	72
3	30	30	15.46	12.49	10.46	8.63	0	0	55.91	51.12
4	30	30	30	30	7.32	9.87	2.47	1.93	69.79	71.8
5	30	30	30	30	1.07	1.89	0	0	61.07	61.89
6	30	30	30	30	7.54	5.81	3.46	2.69	71	68.5
7	30	30	30	30	10.85	12.34	3.77	3.26	74.62	75.6
8	30	30	30	30	16.04	13.32	4.32	3.67	80.36	76.99
9	30	30	30	30	4.78	3.83	3.31	2.19	68.09	66.02
10	30	30	30	30	14.39	15.68	5.53	4.32	79.92	80
11	30	30	30	30	7.64	10.85	3.86	3.48	71.50	74.33
12	30	30	30	30	10.19	7.05	3.76	3.98	73.95	71.03
13	30	30	30	30	8.23	9.01	3.75	2.89	71.98	71.9
14	30	30	30	30	10.62	9.67	4.21	3.86	74.83	73.53
Mean (SD)	30.00 (0.00)	30.00 (0.00)	28.40 (4.27)	28.43 (4.73)	8.95 (4.49)	8.99 (4.64)	2.96 (1.64)	2.30 (1.64)	70.31 (6.82)	69.73 (7.51)

Table K17 Raw data of Thai geriatric fear of falling questionnaire score of elderly with diabetic peripheral neuropathy in balance training group at baseline and 4th week

No	Thai Geriatric Fear of Falling Questionnaire (score)							
	Functional domain		Environmental domain		Psychosocial domain		Total	
	Baseline	4th Week	Baseline	4th Week	Baseline	4th Week	Baseline	4th Week
1	18	3	20	5	5	1	43	9
2	25	6	19	8	6	6	50	20
3	59	40	34	23	29	18	122	81
4	16	7	17	6	5	1	38	14
5	16	13	16	18	11	4	43	35
6	24	18	17	17	11	6	52	41
7	47	13	39	6	11	7	97	26
8	9	4	9	5	7	3	25	12
9	61	29	34	11	4	1	99	41
10	11	7	12	9	3	1	26	17
11	22	12	30	13	26	17	78	42
12	15	7	30	8	17	3	62	18
13	20	10	30	17	23	10	73	37
Mean (SD)	26.38 (17.58)	13.00 (10.63)	23.62 (9.58)	11.23 (5.86)	12.15 (8.84)	6.00 (5.80)	62.15 (29.96)	30.23 (19.38)

Table K18 Raw data of Thai geriatric fear of falling questionnaire score of elderly with diabetic peripheral neuropathy in control group at baseline and 4th week

No	Thai Geriatric Fear of Falling Questionnaire (score)							
	Functional domain		Environmental domain		Psychosocial domain		Total	
	Baseline	4th Week	Baseline	4th Week	Baseline	4th Week	Baseline	4th Week
1	14	16	15	12	5	7	34	35
2	13	14	12	10	6	5	31	29
3	32	38	24	20	36	36	92	94
4	15	16	15	10	10	12	40	38
5	16	18	32	28	19	18	67	64
6	20	26	9	6	12	12	41	44
7	67	68	33	26	6	8	106	102
8	19	20	18	16	6	9	43	45
9	16	17	16	17	10	10	42	44
10	17	18	28	25	18	18	63	61
11	22	20	32	36	24	25	78	81
12	27	31	21	18	6	7	54	56
13	25	26	17	15	8	11	50	52
14	58	61	36	30	5	6	99	97
Mean	25.79	27.79	22.00	19.21	12.21	13.14	60.00	60.14
(SD)	(16.54)	(16.95)	(8.77)	(8.71)	(9.07)	(8.61)	(24.91)	(24.23)

VITAE

VITAE

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