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The purpose of this study was to identify the differences in fall risk factors between diabetic and non-diabetic homebound adults in a population identified at high risk for falls. The sample compared 210 non-diabetic homebound adults to 74 diabetic homebound adults. Five research hypotheses supported this study. It was hypothesized that, 1) incidence and severity of somatosensory changes in the feet of diabetics surpassed that of non-diabetics; 2) incidence of lower leg and foot pain in diabetics surpassed that of non-diabetics; 3) deficits in sensory integration would be greater in diabetics than non-diabetics; 4) balance deficits were more evident in diabetics and non-diabetics; and 5) fear of falling was more prominent in diabetics than in non-diabetics.

An one-way ANOVA showed a significant difference in sensation between groups, with diabetics reporting less sensation than non-diabetics in all age categories. A small effect size limited external validity. No other significant differences emerged for the other fall risk factors. Gender and age category failed to influence differences between diagnostic groups.

DIFFERENCES BETWEEN RISK FACTORS FOR FALLING IN HOMEBOUND DIABETICS AND NON-DIABETICS

by

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_____
Committee Chair

To every member of the Migliarese family who sacrificed precious time and provided endless support throughout this long journey of graduate school, I am forever grateful. This educational exercise in patience and persistence would not have a happy ending without the love and confidence of my husband and children who knew this goal could be accomplished.

APPROVAL PAGE

This dissertation has been approved by the following committee of the Faculty of The Graduate School at The University of North Carolina at Greensboro.

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CHAPTER I

INTRODUCTION

The purpose of this study was to identify the differences in fall risk factors between diabetic and non-diabetic homebound adults. Diabetes Mellitus is very common among older adults and has been identified as an important risk factor for falls in this growing older population, though the exact complications that lead to falling are not fully understood (McCoy, 2003). Diabetes as a risk factor for falls in general has been identified in urban community-dwelling older adults, persons in rural communities, and in elderly nursing home residents with diabetes (Barr, Browning, Lord, Menz, and Kendig, 2005, Quandt, Stafford, and Bell, 2006, Volpato, Leveille, Blaum, Fried, and Guralnik, 2005). Adults with diabetes may have a higher prevalence of neuropathy or impaired gait and balance, which can lead to an increased risk of falling (Schiller, Kramarow, and Dey, 2007). One 3-year longitudinal study looked at 446 adults with diabetes and identified reduced peripheral nerve function, poor vision, weight loss, and poor renal function as predictors of falls (Barclay and Lei, 2008). These researchers proposed that reducing diabetes-related complications may prevent falls (Schwartz, Vitinghoff, Sellmeyer, Feingold, De Rekeneire, and Strotmeyer 2008). None of these studies included homebound older adults.

A cohort of older adults missing from the geriatric research databases is the homebound elderly, including the homebound diabetic older adult. The Centers for Medicare and Medicaid (CMS) define “homebound” as the inability to leave home without considerable and taxing effort. A person may leave home for medical treatment or short, infrequent absences for non-medical

reasons, such as a trip to attend religious services (CMS, 2003). Conducting clinical research is difficult with this population that may fear medical establishment, have trouble following complicated procedures, lack transportation, or want to avoid lengthy forms (Ritchie and Dennis, 1999), though evidence points to the disproportionate share of morbidity and disability in this group (Ganguli, Fox, and Gilby, 1996). Older adults who meet this definition would find it very difficult to participate in traditional medical research studies based in laboratories, medical centers, or doctor's offices. Unfortunately, these homebound elderly are in need of more intensive healthcare and are associated with poor social support, poor self-rated general health, weight loss, stroke, angina, arthritis of the spine, and falls (Ganguli et al, 1996).

Falls are associated with several negative health consequences. Falls can be markers of poor health and declining function, and they are often associated with significant morbidity (Fuller, 2000). Compared with children, elderly persons who fall are 10 times more likely to be hospitalized and eight times more likely to die as the result of a fall (Runge, 1993). Falls are the leading cause of injury-related visits to emergency departments in the United States and the primary etiology of accidental deaths in persons over the age of 65 years (Burt and Fingerhut, 1998, Centers for Disease Control [CDC], fatal falls, 2003). The mortality rate for falls increases dramatically with age in both sexes and in all racial and ethnic groups, with falls accounting for 70 percent of accidental deaths in persons 75 years of age and older (Tibbits, 1996). More than 90 percent of hip fractures occur as a result of falls, with most of these fractures occurring in persons over 70 years of age (Greenhouse, 1994). More than 325,000 hip fractures occur each year in the United States, a figure that is predicted to grow to 650,000 per year by 2040 (Kozak, Hall, and Owings, 2002). In 2005, a total of 15,802 persons 65 years of age or older died as a result of injuries from falls (Stevens, Mack, and Paulozzi, 2008). One third of community-dwelling elderly persons and 60 percent of nursing home residents fall each year (Adams, Day, and Vickerie,

2007). Risk factors for falls in the elderly include increasing age, medication use, cognitive impairment and sensory deficits (Fuller, 2000). The growing elderly population, incidence of diabetes, and consequences of falls support investigation of fall risk factors in elderly with and without diabetes, especially for those homebound elderly who need more answers from traditional medical research. This information can help identify prevention strategies for older adults who may be at higher risks for fall injuries, such as homebound elderly and diabetic older adults.

Based on previous research and clinical data, it was hypothesized that diabetic homebound adults will demonstrate poorer scores on multiple measures of fall risk factors that impact the ability to safely maintain postural control than do non-diabetic homebound adults, including impaired somatosensation in the feet, increased lower extremity and foot pain, decreased sensory integration, decreased balance, and fear of falling. It was expected that these differences will exist between diabetic and non-diabetic homebound adults due to the multiple complications that result from diabetes, even when both cohorts are identified as having an increased risk for falls. It was hypothesized that these diabetic complications will negatively impact all five fall risk factors, distinguishing the diabetic cohort from the non-diabetic homebound older adult.

Research Hypotheses

This study tested five research hypotheses. It was hypothesized that: 1)the incidence and severity of somatosensatory loss in the feet, as measured by Semmes-Weinstein monofilaments, are significantly different between homebound Type 2 diabetic adults and non-diabetic homebound adults, 47 years of age and older; 2) the incidence of lower leg and foot pain as measured by a verbal rating scale (VRS) specific to neuropathic foot and leg pain is greater in diabetic homebound adults than non-diabetic homebound adults; 3)deficits in sensory integration

as measured by the modified Clinical Test for Sensory Integration and Balance (m-CTSIB) are greater in homebound diabetic adults than in non-diabetic homebound adults; 4) balance, as measured by the Dynamic Gait Index, is significantly different between homebound Type 2 diabetic adults and non-diabetic homebound adults; and 5)fear of falling as measured by the Modified Falls Efficacy Scale (MFES) is greater in homebound diabetic adults than in homebound non-diabetic adults.

In conclusion, many studies have documented increased fall risk in the diabetic population, but few of them assessed differences between fall risk factors in non-diabetic and diabetic homebound elderly. Understanding the differences between homebound diabetic and non-diabetic populations can potentially improve quality of life through earlier screenings for fall risk, more complete diabetic education, and effective healthcare that targets appropriate deficits.

Hypothesis I

It was hypothesized that the incidence and severity of somatosensory changes in the feet, as measured by Semmes-Weinstein monofilaments, are significantly different between homebound Type 2 diabetic adults and non-diabetic homebound adults, 47 years of age and older, because there is a higher incidence of sensory loss in the diabetic population. Approximately one half of people with diabetes have some form of peripheral neuropathy (Dyck, Kratz, and Karnes, 1993) with 40% of the estimated 20.8 million US diabetic adults experiencing loss of foot sensation during their lifetimes (Narayan,, Boyle, and Geiss, 2006).

Hypothesis II

It was hypothesized that incidence of lower leg and foot pain as measured by a verbal rating scale (VRS) is greater in diabetic homebound adults, 47 years of age and older, than non-diabetic homebound adults because diabetics have a higher incidence of neuropathic pain than do non-diabetic adults. The prevalence of these somatosensory changes that result in painful diabetic

peripheral neuropathy is estimated at 26.4 % for Type II diabetes (Davies, Brophy, Williams, and Taylor, 2006). Others estimate the incidence of neuropathic pain from 11% to 32% in diabetics with polyneuropathy (Slyke, 2000, Vinik, Park, Stansberry, and Pitteneger, 2000).

Hypothesis III

It was hypothesized that deficits in sensory integration as measured by the modified Clinical Test for Sensory Integration and Balance (m-CTSIB) is greater in homebound diabetic adults, 47 years of age and older, than in non-diabetic homebound adults because diabetics are characterized by having a higher incidence of visual and somatosensory changes than non-diabetics adults which could negatively impact sensory integration. Diabetic retinopathy (DR) is a complication that can affect the peripheral retina, the macula, or both and is the leading cause of visual disability and blindness in diabetics (World Health Organization, 2007). The prevalence of DR increases with prolonged duration of the disease; most people with diabetes over 30 years have some form of DR (Kempen, Colmain, and Leske, 2004). This loss of normal vision, coupled with the previously described somatosensory loss, will have a negative impact on sensory integration related to balance.

Hypothesis IV

It was hypothesized that balance, as measured by the Dynamic Gait Index, is significantly different between homebound Type 2 diabetic adults, 47 years of age and older, and non-diabetic homebound adults because diabetics in general have a higher incidence of falling due to impaired balance. Uccioli and colleagues found a direct correlation between presence of peripheral neuropathy and postural instability (Uccioli, Giacomini, and Pasqualetti, 1997). Since diabetics experience an increased prevalence of peripheral neuropathy, they could also experience an increased incidence of postural instability or poor balance.

Hypothesis V

It was hypothesized that fear of falling as measured by the Modified Falls Efficacy Scale (MFES) is more significant in homebound diabetic adults, 47 years of age and older, than in homebound non-diabetic adults because the higher incidence of falls in diabetics is associated with an increase in fear of falling. An estimated one third of adults who fall develop a fear of falling (Vellas, Wayne, and Romero, 1997) and because adults with diabetes have an increased risk of falling (Schiller, 2007), they could experience more fear of falling than non-diabetic older adults.

CHAPTER II

REVIEW OF THE LITERATURE

Incidence and Prevalence of Diabetes

Type 2 diabetes mellitus, also known as adult-onset diabetes or non-insulin dependent diabetes mellitus (NIDDM), is a major, global health problem that affects over 124 million individuals worldwide (American Diabetes Association [ADA], 2002). In the United States, Type 2 diabetes accounts for 90% of the 15.7 million Americans who are suffering from diabetes (Quinn, 2001). The true number of Americans with diabetes may be closer to 17 million because of the large number of people who meet current criteria for diabetes and do not know they have the disease (Halter, 2002). Marked increases in incidence have been noted in children, adolescents, and young males in their 30s (Quinn, 2001, McDougall, 2001). The public may be aware of the more severe consequences of long-term diabetes, such as impotence, blindness, heart attack, stroke, amputation, or death. What individuals may not be aware of are the subtle early warning signs of the onset of this condition because they can mimic typical signs of age-related physical decline. These signs can include mild numbness in the hands or feet, unusual thirst, loss of weight, or difficulty with wound healing (Goodman and Boissonnault, 1998). These signs may not be recognized as diabetic symptoms and can go untreated for years. This lack of education regarding diabetes contributes to the high incidence of non-diagnosis and to the loss of opportunity to prevent disability and decrease mortality rates associated with this disease. Newly diagnosed diabetics may actually exhibit disease-related declines resulting from years of diabetic pathology because they did not recognize the subtle, progressive changes in physical function.

The incidence of Type 2 diabetes in America has dramatically increased over the past 50 years, from fewer than 2 million cases in 1958 to an estimate of 17 million cases today (Halter, 2002). The incidence increases with age and the percentage of adults with diabetes rises to over 50 percent for those 75 years and older (CDC [diabetes statistics], 1999). The long-term complications of diabetes in elderly people can be devastating to functional independence and include coronary heart disease, stroke, and amputation (Halter, 2002). The consequences of this epidemic disease demand attention from health care providers and researchers in order to find more effective methods of detection, intervention, and cure.

The incidence of diabetes in homebound older adults is difficult to determine, but several federal databases attempt to track and record this information. The US Department of Health and Human Services compiled a report on Trends in Health and Aging (CDC [national fact sheet], 2004) that lists diabetes as the fourth most common morbidity in adults aver the age of 65, behind hypertension, arthritis, and heart disease. North Carolina has the fifth highest incidence of diabetes with a total of 19.8 % of the population with this disease between the 2002-2004 period (CDC [health statistics], 2004).

Approximately 16 million households in the United States contain a householder 60 years of age or older, but how many of them are homebound is unknown (Administration on Aging, 2000). The Center for Medicare Services does report that 3% of the US healthcare expenditures is spent on homecare (CMS, 2002). In one study in rural Pennsylvania, 10.3 % of their sample was classified as homebound, which was associated with being female, older, widowed, with poorer cognitive and functional impairment, more depressive symptoms, poorer social support, fair to poor self-rated general health, weight loss, and histories of stroke, angina, arthritis of the spine, and falls (Ganguli et al, 1996). As our population ages and health care costs increase, it is

imperative to understand the impact of diabetes on what is considered as the most vulnerable subgroup of elders for functional decline, homebound elders (Sharkey and Branch, 2004).

Diabetes was reported as one of the leading causes of death in the US among persons aged 65 or older during the period from 1980 to 1997 (CDC [National Center for Health Statistics], 1997). In 2002, diabetes was the sixth leading cause of death in the United States, doubling the risk of death for diabetics compared to non-diabetics (CDC [diabetes], 2005). An issue that results in both financial and emotional strain is the degree of disability resulting directly or indirectly from this serious condition. A significant degree of disability, or the inability to perform necessary daily activities, can prevent older adults from fulfilling social roles, engaging in healthy interactions with friends and family, and maintaining a strong sense of self-hood (Marshall, 1996). As the incidence of chronic conditions increases with age, as is the case with DM, older adults may also suffer from negative changes in stress management, coping skills, mental health, and emotional support networks (George, 1996). If chronic diabetes can accelerate the aging process and speed the onset of disability, then researchers are compelled to identify interventions that can prevent or slow the onset of these negative consequences.

Etiology, Signs, and Symptoms

Diabetes mellitus is a disease involving the body's inability to produce or properly use insulin. This hormone is needed for the conversion of sugar and starches into energy. Insulin is also crucial for maintaining safe glucose levels in the blood stream because of the role in promoting glucose entry into the cells. Environmental factors and genetics (Goodman and Boissonnault, 1998) are thought to play a role in the etiology of this disease, but the full explanation for the cause of DM is unknown. Obesity has been identified as a continuous risk factor for diabetes onset (Hillier and Pedula, 2001). One study reported an inverse relationship

between socioeconomic status and prevalence of Type 2 DM in the middle years of life (40-69 years) (Connolly, Unwin, and Sherriff, 2000).

Classification

Two major types of DM have been identified. Type 1 diabetes is defined as an autoimmune disease in which the body does not produce insulin secondary to the destruction of insulin-producing beta cells in the pancreas. This type of DM occurs more often in children and young adults and accounts for 5-10 % of all diabetes cases (ADA , 2002). Type 2 DM is the most common form of the disease and is classified as a metabolic disorder resulting from the lack of, or dysfunction in the use of, insulin. The prevalence of this disease in older Americans rises as obesity and sedentary lifestyle increases. Risk factors for Type 2 diabetes include being over 45 years of age, having a family history of DM, being overweight, lack of regular exercise, high triglycerides or low HDL cholesterol, women who had gestational diabetes, or being a member of certain ethnic groups (African Americans, Latinos, Asian and Pacific Islanders, and Native Americans)(ADA, 2002). Often people with Type 2 diabetes have no symptoms or may ignore the early warning signs for either Type 1 or Type 2 diabetes. Common symptoms for Type 1 disease include frequent urination, unusual thirst, extreme hunger, unusual weight loss, extreme fatigue, and irritability. Signs for Type 2 diabetes include any of the Type 1 symptoms and may also involve blurred vision, slow healing wounds, tingling or numbness in the hands or feet, and recurring skin, gum or bladder infections.

The American Diabetes Association describes a period of pre-diabetes prior to the development of Type 2 DM, during which individuals can adopt lifestyle changes in order to prevent or delay onset of this disease (ADA, 2002). They define pre-diabetes as a period during which blood glucose levels are higher than normal but not yet high enough to be diagnosed as diabetes. The ADA reports that recent research has shown that some long-term damage to the

body, especially to the heart and circulatory system, may already be occurring during the pre-diabetes period. Studies have shown clear benefit of glucose lowering in pre-diabetics to prevent or retard the progression of microvascular complications (UK Prospective Diabetes Study, 1998, Ohkubo, Kishikwa, and Araki, 1995, Reichard, Nilsson, and Rosenqvist, 1993), and that microvascular disease is already present in many individuals with undiagnosed or newly diagnosed Type 2 diabetes (Tuomilehto, Lindstom, and Eriksson, 2001, The Diabetes Prevention Research Group, 1999 & 2000).

Diagnosing Diabetes

The diagnosis of diabetes mellitus must be made by a physician. A diagnosis of diabetes is based on blood glucose levels, which can be measured by two different tests. The fasting plasma glucose test (FPG) defines pre-diabetes as a level between 110 and 125 mg/dl. The oral glucose tolerance test (OGTT) defines this pre-clinical period as a level between 140 and 199 mg/dl. (ADA, 2000). The FPG is used more often for diagnosis because it is less complicated, but can lead to under-diagnosis in older adults (Halter, 2002). For the FPG scale, a reading of less than 110 mg/dL is considered normal, 110-125 mg/dL is the impaired range, and a reading of more than 125 mg/dL is classified as diabetes. The American Diabetes Association recommends that the FPG show elevated plasma glucose twice before establishing a diagnosis for diabetes (Halter, 2002). For the OGTT, a reading less than 140 mg/dL is considered normal, 140-199 mg/dL is in the impaired range, and over 200 mg/dL is classified as diabetes. The current standard of practice is the FPG screening using the ADA ranges listed (Halter, 2002).

Most diabetics do not recognize the early warning signs of this disease and may go undiagnosed for an extended period of time. The CDC reports as many as 7 million adults with undiagnosed diabetes (CDC, 2004). Duration of the disease is one of the most prominent factors in degree and severity of neuropathy, so accurately determining onset is very important to

understanding and staging nervous system changes. Some studies have defined newly diagnosed as 2 months post-physician diagnosis, with follow-up at 12, 24, and 36 months of study. Other investigators set the definition of "newly diagnosed" from one-day post-diagnosis to one-year post-diagnosis. Recently diagnosed diabetic adults was defined as 3-4 years of duration in one study (Bornmyr, Castenfors, and Svensson, 1999), but this does not appear to be a conservative approach as many adults may go undiagnosed for up to 10 years (Harris, Hadden, Knowler, and Bennett, 1987). A national health survey in 2005 estimated that almost 30% of all diabetes cases were undiagnosed by physicians (National Center for Health Statistics, Centers for Disease Control [NHANES], 2005). Adult diabetics who have been diagnosed for 1-5 years are generally categorized as having the illness for a short duration, 6-10 years as a moderate duration, and over 10 years as a long duration (Koltringer, Langsteger, Lind, Klima, Wakonig, and Reisecker, 1992, Toyry, Partanen, Niskanen, Lansimies, and Uusitupa, 1997).

Normal Aging and Diabetes

Older adult diabetics who miss the opportunity for prevention of this condition must deal with the normal changes associated with aging as well as the devastating symptoms associated with diabetes. The "normal" physical changes associated with aging may include loss of flexibility and muscle strength, decreased endurance, impaired balance and postural control, impaired fluid intelligence (abstract reasoning), sensory deficits, and the resulting decreased functional mobility and independence (Spirduso, 1995). Several changes in cognition with aging that are well documented include cognitive slowing, decreases in working memory, decreases in overall cognitive resource capacity, and poorer long-term memory function (Park, 2000). Making a bleak picture even more disappointing is the multitude of other factors that influence cognitive performance of the elderly population. Education, income and race were significant predictors of

cognitive performance in a cohort of 1,192 community-dwelling elders (Inouye, Albert, and Mohs, 1993).

Other typical physical consequences of growing older can include presbyopia (normal changes in vision due to aging), presbycusis (hearing loss), weakened immune system, and a varying degree of memory impairment (Roush, 1999). The endocrine system also changes with age and may lead to changes in the production and secretion of several hormones, including insulin (Wise, 1999). These declines in physical health do not have to be absolute, despite the common opinion that they are inevitable. The myths about declines with advanced age include loss of functional muscle strength, poor cardiac function, little to no desire for an active sex life, and dementia (Spirduso, 1995).

Another clear finding related to aging and physical change is that disuse accelerates aging-related changes and pathology and can diminish physiologic reserves (Timiras, 1994). Muscle strength declines with age are attributed largely to a loss of muscle mass resulting from a loss of muscle fibers. The muscle wasting associated with aging is referred to as sarcopenia and is present in 6% to 15% of older adults (Cech & Martin, 2002). Other mechanisms also are thought to be involved in muscle wasting because older individuals who undergo strength training have increases in strength that are greater than their increases in muscle mass (Fiatarone, 1994). Strength training may also have beneficial effects on the neurons that innervate the active muscles because neural fibers atrophy when their target muscle is not used. Other physical changes that accompany advancing age are increase in body fat and decrease in bone density (Pahor and Kritchevsky, 1998). Inactivity contributes to both of these changes that can result in decreased function and quality of life (Gersten, 1991).

Aging Confounded by Diabetes

The consequences of diabetes mellitus can mimic "typical" signs of age-related declines in health. Clinical manifestations of diabetes usually include the cardinal signs of polyuria (excessive urination), polydipsia (excessive thirst), polyphagia (excessive hunger), weight loss, and fatigue (Goodman and Boissonnault, 1998). A common complaint of older adults may be more frequent trips to the bathroom at night and changes in appetite or eating habits. The normally aging population may not recognize changes in thirst or hunger or frequent urination as abnormal for their age. Some older adults may also consider weight loss and fatigue as typical changes with aging and not as potential warning signs for diabetes. Symptoms more easily identifiable as diabetes-related are visual blurring, neuropathic complications such as foot pain, or infections (Goodman and Boissonnault, 1998). Type 2 diabetes is commonly diagnosed while the person is hospitalized or receiving medical care for another problem associated with DM (neuropathy, retinopathy, or nephropathy). Because normal aging and the clinical course of DM share many physical complications, diabetes can go undetected for months or years, resulting in more severe long-term consequences.

Other declines associated with aging are also potentially related to the diabetic disease process. Cardiorespiratory function and endurance decrease with aging in the average older adult (Spirduso, 1995). Factors such as maximum heart rate, cardiac output, and oxygen consumption decline with age (Spirduso, 1995). Other changes are also observed with aging. These include a decline in maximal exercise capacity and maximum heart rate, an increase in systolic blood pressure and left ventricle wall thickness, and deterioration in glucose and lipid metabolism, which can be accelerated by diabetes. Some cardiac measures change very little with age, including heart size, end-systolic volume, and volume of blood ejected at rest (Spirduso, 1995). One very important physiologic measure, that of systolic and diastolic blood pressure, increases

with age, due primarily to a thickening and hardening of the aorta and arterial tree and to an increase in peripheral resistance. This increased blood pressure is also a common problem with diabetes and is a risk factor for more serious cardiac dysfunction such as stroke, postural hypotension, or aneurysm. In contrast to cardiac changes, in general, healthy older adults have pulmonary systems that function very well under resting and moderate exercise conditions. If older adults are sedentary, the maximum amount of oxygen they can consume during work declines about 10% each decade.

Changes in cognition are another commonality of aging and diabetes. High blood pressure is associated with cognitive impairment in healthy, drug-free older adults, as well as being a major risk factor for multi-infarct dementia (Starr, Whalley, and Inch, 1993). High blood pressure and diabetes coexist in 60-65% of diabetic adults (Contreras, River, and Vasques, 2000) magnifying the risk for poorer cognitive performance in diabetic adults, which may impact speed of decision-making especially in physically challenging situations. Both diabetes and hypertension share the same predisposing factors and increase in frequency with age. This may lead to an increased risk for falls for cognitively impaired older adults with diabetes.

Controlling the onset of unfavorable long-term consequences requires early diagnosis and treatment for three major metabolic problems associated with diabetes: 1) decreased utilization of glucose, 2) increased fat mobilization, and 3) impaired protein utilization (Goodman and Boissonnault, 1998). If untreated long-term complications of diabetes may include microvascular problems resulting in retinopathy (retinal disease), nephropathy (kidney disease), and peripheral (motor and sensory) and autonomic neuropathy (nerve disease). Atherosclerosis begins earlier and is more extensive in this population and can result in skin and nail changes, poor tissue perfusion, decreased or absent pedal pulses, and impaired wound healing. Hyperglycemia impairs resistance to infection so skin and urinary infections may occur. The loss of normal

sensation in diabetic neuropathy predisposes joints to repeated trauma and progressive joint destruction. Sensory neuropathies may cause tingling, burning, numbness, or complete loss of feeling in hands and feet. This lack of protective sensation contributes to the cycle of repeated trauma, potential infection, lack of healing, more trauma, and more infection. Motor neuropathies produce muscle weakness and joint deformity, such as claw toes or flat feet. Autonomic neuropathy may result in loss of sweating regulation, temperature control, and blood flow in the limbs.

Understanding the microvascular changes that result from diabetes is critical for understanding the accelerated aging process and clinical picture of diabetics. One method for studying the link between vascular health and diabetic course involves examining the vasoconstrictor response in normal adults as compared to diabetic adults. To do this, skin blood flow response to deep inspiration has been studied using laser Doppler flowmetry (Smith, Thomas, and Torgersen, 1994). Laser Doppler flowmetry is an innovative technique used to measure the erythrocyte (red blood cell) volume and velocity in the upper horizontal plexus of the skin via a noninvasive laser signal. Terminal arterioles, capillaries, and postcapillary venules are monitored to obtain flow in units of milliliters per minute per 100 gram of tissue. Deep inspiration is known to cause an abrupt reduction in skin blood flow in the extremities by inducing vasoconstriction. This activity tests the peripheral sympathetic function that controls blood flow to the extremities. In healthy adults a deep inspiration causes an abrupt reduction in skin blood flow response with a latency of a few seconds. This transient decrease in skin blood flow is impaired or absent in adults with moderate to severe diabetic autonomic neuropathy (Yoshimasa, Toshihiko, and Yoshihiro, 1997). Postural hypotension has also been measured in diabetic patients and is a clinical hallmark of advanced diabetic autonomic neuropathy, as well as being a somewhat common occurrence with advanced age. Lack of vasoconstriction is thought to

be the primary cause of diabetic postural hypotension. These vasomotor responses in diabetic adults appear to be completely abolished in DM adults with foot ulceration and poor wound healing (Cacciatori, Dellera, and Bellavere, 1997).

Answers to why and how vascular dysfunction impacts adults with diabetes are still forthcoming. One potential explanation centers on peripheral nerve function. Poor nerve function in the extremities can be shown to impact control of vasoconstriction and has been linked to increased age, glycemic control, and diabetic duration. Determining which dysfunction develops first, either poor nerve function or vascular dysfunction, is hard to predict, but some researchers suggest that the vascular factors participate in the development of the nerve lesions (Valensi, Girous, and Seeboth-Ghalayni, 1997). Glycemic control seems to be an important risk factor in the deterioration of nerve function in Type 2 DM. Most diabetic adults have poor glycemic control and disturbed nerve function at the time of diagnosis (Lehtinen, Nishanen, and Hyvonen, 1993). A promising result from one study demonstrated that restoring lower extremity blood flow improved nerve conduction velocity (an indicator of nerve function) in diabetics presumably due to an increase in tissue oxygenation (Young, Veves, and Smith, 1995). Risk factors for microvascular complications involving nerve function include hyperglycemia, age, tobacco use, dyslipidemia, hypertension, duration of diabetes, and microalbuminuria (Cade, 2008). Without intervention peripheral nerves will begin to show axonal thickening and eventual axonal loss, basement membrane thickening, loss of microfilaments that form actin and myosin, and decreased capillary blood flow to C fibers that carry pain signals (Cade, 2008). Improvement in microvascular blood flow, control of glycemia, and control of blood pressure present areas in need of research in order to find interventions that can impact the onset of diabetic symptoms.

An example of these investigations is work focusing on cutaneous microvascular flow in the hands and feet using laser Doppler flowmetry. Comparisons have been made between control

and diabetic subjects using this technique to study the normal age-related decline in microvascular function in the extremities and the resulting pattern of blood flow. Results of one study using deep inspiration as the stimulus indicate that diabetic adults do not have a typical negative slope, or decline, in microvascular function, as do normal adults because the diabetic subjects started with a lower baseline and display blunted responses to stimuli. Younger diabetic subjects display a blood flow pattern similar to that seen in the advanced aging process. (Stansberry, Hill, Bril, Kojic, and Ngo, 1997). The abnormal vascular reactivity displayed in these adults was described as either a decreased vascular response to stimuli or loss of autonomic nerve supply. It is unclear whether this loss of autonomic nerve function occurs at the local, reflex, or centrally mediated level for microvasculature reactivity. Stansberry also found diminished amplitude and frequency of the normal spontaneous vasomotion resulting from rhythmic vasoconstriction of the arterioles. Potential mechanisms for these changes were decreased arteriolar wall reactivity and stiffening of the vessel walls due to an excessive accumulation of proteins as a result of advanced glycosylation (Stansberry, 1996). The process of glycosylation is also associated with accelerated aging. In addition, aging has been linked to a loss of superficial nutritional dermal capillaries (in the skin) that mimics the altered sympathetic regulation of pre-capillary sphincter tone in the vessel walls of diabetic adults. Stansberry also proposed that decreased vasomotor amplitude correlates with the loss of thinly myelinated C-fiber function, which is the type of nerve fiber that carries afferent pain and temperature information (Stansberry, 1996).

Diabetic peripheral neuropathy can be manifested as loss of lower extremity sensation and is one of the common negative consequences of diabetes. Sensory loss places diabetic adults at risk for falls, foot ulcers, and amputation. (Mayfield and Sugarman, 2000, Conner-Kerr and Templeton, 2002, Richardson and Hurvitz, 1995, Armstrong, Laverly, and Harkless, 1998).

Diabetic neuropathy begins with symmetrical nerve damage and motor loss in the feet, with pain and eventual insensitivity beginning in the toes and continuing proximally (Elftman, 1992). Typically, sensory involvement begins in the lower extremities before the upper extremities. Sensory testing of the hands is indicated once the pattern of sensory loss extends up the calf (Abbott, Carrington, and Ashe, 2002, Olaleye, Perkins, and Bril, 2001). The diabetic neuropathy process can begin regardless of the person's history of disease control, although poor compliance with prescribed treatment results in more severe complications (Elftman, 1992).

Older adults who suffer from Type 2 diabetes must deal with the normal changes associated with aging as well as symptoms of significant sensory loss associated with diabetes. The typically aging older adult does not have to compensate for peripheral neuropathy, but may experience some combination of the "normal" changes, such as loss of flexibility and muscle strength, impaired balance and postural control, impaired cognition, and the resulting decreased functional mobility and independence (Tideikssar, 1994). Consequences of aging negatively impact postural stability, especially for standing tasks that involve visual and spatial manipulation, such as backward digit recall while standing on a force platform (Maylor and Wing, 1996). The visual, vestibular and somatosensory systems are known as the three influential systems involved in postural control and also undergo age-related changes. Horak places these sensory inputs under a larger umbrella of sensory orientation, one of six components that comprise the concept of balance (Horak, Wrisley, and Frank, 2009). Older adults who are multiple fallers have been found to have reduced vision, decreased peripheral sensation, slower reaction times, and decreased stability compared with non-multiple fallers (Lord, Clark, and Webster, 1991, Lord, Lloyd, and Li, 1996). Sensory impairments and visual disorders were also part of a longer list of fall risk factors for older adults, accompanied by history of falls, use of assistive devices, muscle weakness, gait and balance impairments, polypharmacy, cognitive

impairments, orthostatic hypotension, and environmental hazards (Peel, Brown, and Lane, 2008). The degree of impairment in several of these age-related changes is intensified in adults with diabetes and some experts recommend diabetic screenings as early as 45 years of age in order to detect initial signs of sensory deficits resulting from the disease (ADA, 2002).

Research Problem and Implications

It was hypothesized that diabetic homebound adults would exhibit a higher severity of fall risk factors that impact the ability to safely maintain postural control than do non-diabetic homebound adults, including impaired somatosensation in the feet, increased lower extremity and foot pain, decreased sensory integration, decreased balance, and fear of falling. These differences were anticipated even though both homebound groups are identified as having a high fall risk.

This study was comprised of five research hypotheses: 1) It was hypothesized that the incidence and severity of somatosensory changes in the feet, as measured by Semmes-Weinstein monofilaments, are significantly different between homebound Type 2 diabetic adults and non-diabetic homebound adults, 47 years of age and older, because there is a higher incidence of sensory loss in the diabetic population; 2) It was hypothesized that incidence of lower leg and foot pain as measured by a verbal rating scale (VRS) is greater in diabetic homebound adults, 47 years of age and older, than non-diabetic homebound adults because diabetics have a higher incidence of neuropathic pain; 3) It was hypothesized that deficits in sensory integration as measured by the modified Clinical Test for Sensory Integration and Balance (m-CTSIB) are greater in homebound diabetic adults, 47 years of age and older , than in non-diabetic homebound adults because diabetics have a higher incidence of visual and somatosensory changes than non-diabetics adults which could negatively impact sensory integration; 4) It was hypothesized that balance, as measured by the Dynamic Gait Index, is significantly different between homebound

Type 2 diabetic adults ,47 years of age and older, and non-diabetic homebound adults because diabetics in general have a higher incidence of falling; and 5) It was hypothesized that fear of falling as measured by the Modified Falls Efficacy Scale (MFES) is more significant in homebound diabetic adults, 47 years of age and older, than in homebound non-diabetic adults because the higher incidence of falls in diabetics is associated with an increase in fear of falling.

Earlier detection of these deficits in diabetic adults before they become homebound can lead to interventions tailored toward improvement of postural control and prevention of falls. These interventions can impact the economic burden of diabetes, which is estimated at $21.5 million spent annually on diabetic complications (Elftman, 1992). The personal burden of diabetes cannot be measured.

Sensory Changes and Diabetes: Hypothesis I

It was hypothesized that the incidence and severity of somatosensory changes in the feet, as measured by Semmes-Weinstein monofilaments, are significantly different between homebound Type 2 diabetic adults and non-diabetic homebound adults, 47 years of age and older, because there is a higher incidence of sensory loss in the diabetic population.

Postural instability and falls are common complaints of the elderly with or without diabetes. Several studies have linked peripheral nerve dysfunction and the resulting sensory loss in the elderly with impaired balance and postural control (Hong, Chia, and Ling, 1997, Katoulis, Ebdon-Parry, and Hollis, 1997, Miller, Lui, Perry, Kaiser, and Morley, 1999, Richardson et al, 1995, Uccioli et al, 1997). A common cause of sensory dysfunction in older adults includes complications resulting from diabetes mellitus (DM), which in 1996 affected 10% of Americans aged 65 years or older (CDC [National Diabetes Fact Sheet], 1999). A frequent long-term manifestation of DM is the neurologic complication of diabetic neuropathy and the resulting loss of sensation and motor control in both upper and lower extremities (Goodman and Boissonnault,

1998). Researchers have supported the intuitive relationship between increasing loss of sensation due to diabetic peripheral neuropathy and the increasing loss of balance and falls (Ducic, Short, and Dillon, 2004). The diabetes-related complications of reduced peripheral nerve function, renal function, and vision contribute to risk of falls in older adults with diabetes (Barclay, 2008).

The microvascular pathology accompanying DM is thought by some researchers to follow a sequence of: 1) autonomic neuropathy, followed by 2) peripheral sensorimotor (somatomotor) neuropathy, followed by 3) local ischemic changes associated with diabetic foot ulcers (Smith, 2002). This sequence may occur quickly (e.g. when plasma glucose levels are poorly controlled), or more slowly, when plasma glucose levels are aggressively maintained by optimization of glycemic control. Microvascular pathology (abnormal basement membranes, altered nitric oxide levels) due to diabetes is not thought by some researchers to be directly the result of alterations in peripheral autonomic function (Smith, 2002). However, abnormal autonomic regulation of the microvasculature in diabetes occurs early in the disease process and may contribute to abnormalities in tissue perfusion associated with the peripheral microvascular vasculopathy that accompanies diabetes. This sequence of nervous system dysfunction is not well established, but could lead to linking autonomic peripheral dysfunction to sensorimotor peripheral dysfunction.

Autonomic Neuropathy

The changes in autonomic nervous system function can occur in either the central or peripheral systems. Recent investigators have focused attention on the incidence and progression of autonomic dysfunction in both Type 1 and Type 2 diabetes and the potential causal links to peripheral somatic neuropathies. McLeod stated that the autonomic system is affected by most conditions that cause peripheral neuropathy and that both sympathetic and parasympathetic function should be evaluated when diagnosing conditions such as diabetes (McLeod, 1992). McLeod also compared the pathological changes in the peripheral autonomic nervous system to

those in the peripheral somatic nerves, suggesting that they are similar and that autonomic changes are more likely to occur when there is acute demyelination or damage to small myelinated and unmyelinated nerve fibers (McLeod, 1992). Several other investigators also link autonomic and peripheral nervous system changes (Flynn, O'Brien, and Corrall, 1995, Ward, 1989, Zander, Heinke, and Herfurth, 1997).

Descriptions of clinical symptoms usually differentiate between autonomic neuropathy and peripheral somatic neuropathy. Manifestations of autonomic neuropathy can include variability in heart rate (parasympathetic) and blood pressure (sympathetic) during postural changes or physical stress. A common protocol for testing autonomic function includes three tests for parasympathetic control: (cardiac rate response to postural change from lying-to-standing, deep breathing, and during Valsalva maneuvers); and two sympathetic control measures: (orthostatic hypotension as when standing from sitting and blood pressure response to the handgrip test). Autonomic changes are more strongly correlated with people who are diagnosed at less than 20 years of age for Type 1 diabetes. These changes seem to peak at age 40-49 years of age. In contrast, the prevalence of peripheral somatic changes increases progressively with age (Husstedt, Grotemeyer, and Evers, 1997).

Evidence supports the coexistence of autonomic and peripheral dysfunction in the same person, but the causal relationship between these two diabetic complications is still unclear. Okada's early research results indicate that diabetic somatic neuropathy and cardiomyosympathetic neuropathy develop independently in the Type 2 condition (Okada, Ishii, and Tamnokuchi, 1995). However, a subsequent study by Okada correlated diabetic neuropathy with blood pressure and glucose control in Type 2 diabetes (Okada, Tamnokuchi, and Ishii, 1996). Glucose control also was a significant factor in stabilizing autonomic dysfunction in newly diagnosed children with Type 1 diabetes (Adler, Boyko, and Ahroni, 1997), indicating that

glucose control may be one contributing factor to the variability in neuropathic complications in diabetic people of any age. Not all researchers agree with this link between glucose control and neuropathy, as their results showed no significant improvement in autonomic neuropathy with good glycemic control (Gupta, Chittora, and Jain, 1995).

Conflicting theories exist in the literature regarding the role of central nervous conduction deficits, whether they are present in diabetes, and whether they are linked to autonomic and/or peripheral sensory changes. It has been suggested that predisposition to neuropathy may be better predicted by central conduction rates versus peripheral conduction pathways in Type 2 diabetes (Misra, Mittal, and Jain, 1999). Another variable associated with the conflicting arguments for a direct or indirect relationship between somatic and autonomic changes in the peripheral nervous system is the pathogenesis of nerve damage associated with diabetes. As mentioned previously, duration of this disease plays a pivotal role in presence of nervous system changes, the variability of which may be explained by the degree of functional versus structural nerve damage and may account for the lack of clinical signs despite presence of physiologic dysfunction.

Peripheral Somatic Neuropathy

A common form of sensory dysfunction related to diabetes mellitus is that of peripheral somatic neuropathies. This impairment affects people with either Type 1 or Type 2 diabetes and typically manifests as tingling and numbness in the hands and feet. Changes associated with peripheral system dysfunction or neuropathy can be divided into functional and structural nerve damage. Functional nerve changes, such as decreased nerve conduction velocity, occur initially in the first period of diabetic disease and can be followed by structural changes as the disease progresses, leading to many of the clinical manifestations of this condition. Structural changes involve physical degradation of the nerves that inhibit the ability of the nerves to perform normally (Ward, 1989). The presence of peripheral somatic neuropathy in adults with diabetes

mellitus of moderate to long duration has been strongly linked to a decrease in postural stability due to changes in the somatosensory input necessary for normal balance (Horak, Nashner, and Dienr, 1990, Inglis, Horak, and Shupert, 1994). Few researchers have assessed the presence of peripheral somatic changes in early-onset diabetes, which is admittedly difficult to do as many adults have the disease several years before actual diagnosis. Older adults diagnosed with Type 2 diabetes mellitus may mistake warning signs for this condition with what they consider as typical signs of aging. This confusion of diabetic warning signs with the typical aging process can result in delays in assessment and intervention for postural instability and identification of risk for falls.

Another type of peripheral neuropathy that can affect postural stability in persons with early-onset diabetes involves the autonomic components of the peripheral nervous system. Autonomic changes may be linked to somatosensory changes (and indirectly to balance through influence on somatosensation) by affecting blood supply to sensory nerves (Smith, 2002). Researchers are attempting to understand the potential links between changes in the autonomic peripheral nervous system and the peripheral somatic nervous system. Evidence of autonomic and peripheral changes exists for adults with Type 2 diabetes of moderate duration, or approximately 5-10 years (Belmin and Valensi, 1996). Evidence also exists that links peripheral somatic system changes and postural instability (Hong, Chia, and Ling, 1997, Simoneau, Ulbrecht, and Derr, 1994, Uccioli, Giacomini, and Monticone, 1995). The prevalence of these somatosensory changes that result in painful diabetic peripheral neuropathy is estimated at 26.4 % for Type II diabetes (Davies et al, 2006).

Local Ischemic Changes

Local ischemic changes secondary to diabetes represents a very serious complication of the disease. Loss of normal blood flow to the lower extremities can lead to ulceration, which is the most common single precursor to amputation and has been identified as a factor in 85% of

lower-extremity amputations (Armstrong et al, 1998). Diabetics are known to be at high risk for lower extremity amputation, which increases their risk for re-amputation of the same extremity, amputation of the contralateral leg, an elevated mortality rate in the first 3-5 years after amputation, and placement in nursing homes or extended care facilities (Armstrong et al, 1998). Amputations are commonly preceded by peripheral neuropathy, ulceration, infection, and peripheral vascular disease (Pecoraro, Reiber, and Burgess, 1990). Ulceration rarely develops without some degree of peripheral neuropathy that contributes to a loss of "protective sensation." The majority of diabetic screens used to assess risk for foot ulceration include sensation testing, assessment of circulation, and evaluation of skin integrity in an attempt to prevent lower extremity amputation.

Measuring Peripheral Neuropathy

An issue regarding measurement methods involves how to measure peripheral somatic neuropathy and autonomic peripheral neuropathy. Vibration threshold using a biothesiometer can be used to measure peripheral somatosensory function (Flynn et al, 1995). This instrument is a handheld device with a rubber tactor that vibrates at 100 Hz. The unit can apply voltage of varying degrees that is increased until the subject can perceive a vibration. It is usually used in combination with other assessment tools. Another reliable means of testing peripheral somatosensation incorporates monofilament wire systems of varying thicknesses that are applied to the skin. This system is widely used for identifying diabetic patients at risk for foot ulceration (Armstrong et al, 1998). Another standard method for assessing peripheral somatic neuropathy is the analysis of sensory nerve conduction velocity, typically of the tibial, sural, and/or peroneal nerves (Belmin and Valensi, 1996). Standard electrophysiological examinations measure nerve conduction velocity, distal latency and potential amplitude for these nerves. Using this method alone to determine the extent of peripheral neuropathy has been criticized by some investigators.

Some investigators propose the combination of neurological examination, nerve conduction velocity, quantitative sensory tests, and quantitative autonomic tests to estimate severity of peripheral neuropathy (Dyck, Melton, and O'Brien, 1997). This type of system considers both impairments and symptoms. Braune used a neurophysiological approach for early detection of diabetic neuropathy (Braune, 1997). This approach includes a clinical examination, nerve conduction velocity of five nerves, evoked sensory and motor action potentials, and electromyography of at least four muscles of the lower limbs, and sympathetic skin response for hands and feet. Results of this comprehensive battery suggest that most changes leading to pathological values of nerve conduction velocity and heart rate variation measurement take place in an early clinical stage, prior to actual clinical signs of diabetic neuropathy. Researchers propose that this battery be used with early-diagnosed diabetics in order to reveal the beginning of neuropathic disturbances, with the exception of EMG examinations, which were preferred in later stages of the disease (Cheng, Jiang, and Chuang, 1999). In addition to clinical measurements, many investigators stage the degree of peripheral neuropathy for subjects using various scales that differentiate between minimal, moderate, and severe degrees of neuropathy (Dyck, 1988). Some of these scales include the Michigan Neuropathy Screening Instrument, the Michigan Diabetic Neuropathy Score (Feldman, Stevens, and Thomas, 1994), the San Antonio Consensus Statement (Feldman et al, 1994), and the Mayo Clinic protocol (Dyck, Karnes, and O'Brien, 1992). Staging alone or reliance solely on patient self-evaluation has not proven reliable enough to accurately measure neuropathies. Clinical investigators support the use of the Semmes-Weinstein monofilaments as the measure of choice for assessing peripheral sensation, based on reliability, cost, and practicality (Elftman, 1992).

Autonomic peripheral neuropathy has been measured in several different ways and is not as widely studied as peripheral somatic neuropathy. Autonomic changes are known to affect

cardiovascular function, so one method of studying these changes includes thermographic circulatory patterns following body stressors of warmth or cold. This method can detect vasosympathetic abnormalities that prevent normal changes in skin temperature due to microangiopathy (Fushimi, Inoue, and Nishikawa, 1985). Other autonomic function tests of cardiosympathetic function include blood pressure response to standing up, the handgrip test for blood pressure changes, Valsalva ratio, heart rate response to deep breathing tests, and an orthostatic test on a tilt table. A newer technique using laser Doppler signals looks promising for the detection of circulatory abnormalities in peripheral skin. This technique involves applying a body stressor such as heat or cold to the hands or feet and then measuring red blood cell movement with a laser as an indicator of normal circulatory responses in the extremities. This type of test appears to be a more direct measure of peripheral autonomic function versus measures of central cardiosympathetic function, such as heart rate, in the diabetic population. This method is non-invasive, depending on the type of autonomic stressor applied to the extremities (Uccioli et al, 1997).

Non-invasive laser Doppler fluxmetry has been used as a clinical evaluation of skin perfusion. This technique uses a small fiberoptic cable to project coherent light into the skin. The electronic circuitry of the instrument then measures the shifts in wavelength of the reflected light produced by the Doppler effect of light waves interacting with moving particles (blood cells) within the sample area (Smith et al, 1994). With rapid sampling (approximately 10 samples per second), the measurements of Doppler- shifted light yield information about the pattern of movement of red blood cells within the illumination area. Spectral analysis of these waveforms provides quantitative information about specific portions of these waveforms. For example, Lindqvist has demonstrated that nervous afferents from the cutaneous thermoreceptors and nervous efferents to the skin blood vessels mediate the 0.01 - 0.10 Hz thermo-regulatory

oscillations in the forearm skin perfusion waveform (Lindqvist, 1990). Similar findings have been reported by Rossi and by Bernardi using laser Doppler fluxmetry (Bernardi, Rossi, and Leuzzi, 1997, Rossi, Ricordi, and Mevio, 1990). This frequency range also is represented in the power spectral analysis of cutaneous perfusion in the finger pulp, an area of the skin highly invested with arteriovenous anastomoses and predominantly involved with thermoregulation (Stansberry, 1996).

Measuring Peripheral Sensory Loss

Evaluation of lower extremity sensation is a common component of diabetic risk assessment and is central to diagnosing peripheral neuropathy. Historically, neuropathy was identified using subjective symptoms and crude superficial sensory testing. Quantitative sensory testing to determine presence of neuropathy now includes Semmes-Weinstein monofilament (SWM) testing, nerve conduction velocity, vibration perception threshold, and/or tactile circumferential discriminators (Schox, 2002). Electrodiagnostic testing such as nerve conduction velocity is precise, but is uncomfortable, expensive, and time consuming when compared to other more practical approaches to sensory testing. Biothesiometers measure sensitivity to vibrations using voltmeters, but require subjective input from the subject during testing, which negatively influences reliability (Schox, 2002). Tactile circumferential discriminators are new, simple, handheld sensory testing devices consisting of a disc with eight protruding rods of increasing diameter. They are highly sensitive, but less specific than vibratory threshold testing and SWM (Vileikyte, Hutchings, Hollis, and Boulton, 1997). Semmes-Weinstein monofilaments are nylon filaments of varying diameters that are used to apply tactile pressure to the skin in order to detect thresholds of pressure sensation. They have been shown to be reliable when used to test multiple sites, but unreliable when used to test a single site (Schox, 2002). They are inexpensive and can be self-administered by diabetics with moderate reliability. Sensitivity and specificity of this

method of sensory testing was reported to be 97% and 83%, respectively (Armstrong et al, 1998). One study reported 60.0% sensitivity and 73.8% specificity for diagnosing diabetic peripheral neuropathy and recommend their use (Kamei, Yamane, and Nakanishi, 2005). Most clinicians use disposable monofilaments to increase the reliability that can be impacted by continual utilization (Yong, Veves, and Smith, 2000).

Several investigators support the use of SWM as the assessment of choice when screening diabetic adults for sensory loss and risk for neuropathy because they are portable, inexpensive, painless, easy to administer, acceptable to patients, and provides good predictive ability for the risk of foot ulceration and amputation (Mayfield and Sugarman, 2000, Elftman, 1992). In a meta-analysis of the use of SWM for sensory testing and neuropathy screening, Mayfield found strong support for continued application of this method in diabetic populations (Mayfield and Sugarman, 2000). SWM was identified as one of three important screening tools in general medical practice involving diabetics, along with the neuropathy disability score, and palpation of foot pulses (Abbott et al, 2002). SWM, superficial pain sensation, and vibration testing were also found to significantly and positively correlate with nerve conduction velocity testing in diabetic subjects, with SWM able to differentiate subjects with diabetes with and without neuropathy (Olaleye et al, 2001). While this study suggested use of one type of sensory testing for diabetic screening purposes, other researchers support the use of a composite assessment protocol when determining risk for neuropathy, ulceration, or amputation (Armstrong, Lavery, and Harkless, 1996).

To accurately assess sensation using SWM, the monofilament is applied to the subject's upper arm as a practice trial. Testing begins with the 4.17-g monofilament indicating normal sensation, but never of damaged skin (ulcer site, callus, and scar tissue). If the subject cannot detect sensation with this initial monofilament, then testing is continued with the 5.07 and the

6.10 monofilaments. The monofilament is applied perpendicular to the skin surface with enough pressure to bend the monofilament shaft to 45 degrees for about one second, and then removed. The subject responds verbally to the size of monofilament that they can feel while blinded to the procedure. Several areas are tested and sensory "maps" are drawn to determine areas of sensory loss. Protocols to screen for diabetic foot complications typically use at least four sites for testing the soles of the feet (Diabetic Foot, 2002). Normative data for sensory thresholds for the foot typically use the 4.17g monofilament as the indicator for normal sensation, while the inability to feel the 5.07 monofilament represents a 98% loss of sensory ability (Jeng, Michelson, and Mizel, 1999). Some authors criticize the accuracy of the sensation levels described in SWM commercial kits, stating that these norms were based on small numbers of young subjects, making generalization to the older population unadvisable (Jordanova, 1999). The threshold for normal lower extremity sensation of 4.17 monofilament is currently the most widely accepted value (Mayfield and Sugarman, 2000). Areas of the foot that are commonly mapped include the heel, mid-arch, first, third and fifth metatarsal heads, and the great toe. The clinical acceptance, repeatability, and sensitivity of SWM testing, along with the ease of application, makes this method of sensory assessment the logical choice for identifying sensory changes in newly diagnosed diabetic adults and non-diabetic control subjects. No special training or certifications are required in order to safely and reliably assess sensation using SWM commercial kits.

Sensory Changes and Diabetes: Hypothesis II

It was hypothesized that incidence of lower leg and foot pain as measured by a verbal rating scale (VRS) is greater in diabetic homebound adults, 47 years of age and older, than non-diabetic homebound adults because diabetics have a higher incidence of neuropathic pain.

Pain has been identified as a predictor for falls in community-dwelling older adults (Stel, Pluijm, and Deeg, 2003). Neuropathic pain, or peripheral neuropathy that manifests itself as pain,

is a symptom commonly experienced by diabetic adults as their loss of peripheral sensation progresses from intermittent tingling, burning, and pain, to total numbness. The etiology of neuropathic pain has been explained previously in the section on sensory changes with diabetes and typically occurs in people with intermediate duration of DM. As neuropathies progress and become painful, a pain assessment is added to the clinical examination, such as the verbal rating scale (VRS) or the visual rating scale (VAS), or the less familiar brief pain inventory survey (BPI). The VRS data is preferred by some for pain intensity assessment in a geriatric population (Lund, Lundegerg, Kowalski, and Sandberg, 2005), while others prefer the VRS even though the two tests correlate highly (0.97 – 0.89) (Clark, Gironda, and Young, 2003). The prevalence of these somatosensory changes that result in painful diabetic peripheral neuropathy is estimated at 26.4 % for Type II diabetes (Davies et al, 2006). The high incidence of this diabetic complication supports the inclusion of pain surveys in yearly screenings for peripheral neuropathy (Harkless, DeLellis, and Carnegie, 2006, Perkins, Olalaye, and Zinman, 2001).

As mentioned previously, superficial pain sensation, was found to significantly and positively correlate with nerve conduction velocity testing in diabetic subjects, assisting in differentiating between adults with diabetes with and without neuropathy (Olaleye et al, 2001). Assessing lower extremity pain is a purely subjective task and is typically performed using visual or verbal analog scales. The typical scale ranges from 0-10, increasing from no pain (0) to severe pain (10). VAS and VRS methods for pain assessment have been found to be reliable and valid (Clark, Vavielle, and Martinez, 2003, Lund et al, 2005). Inadequate pain control was found to be a risk factor for falls in community-dwelling older adults (Nazarko, 2006), and is a required part of patient assessment for every homecare visit with Medicare patients. Lower leg and foot pain can result in an altered gait pattern, including decreased stance time on the painful limb, decreased gait speed, and decreased walking endurance. Thus, subjective pain assessment is

indicated in assessing overall postural control of diabetic adults due to the complex nature of the disease and the dynamic nature of postural control that can be influenced by lower extremity pain.

Postural Control and Diabetes: Hypothesis III

It was hypothesized that deficits in sensory integration as measured by the modified Clinical Test for Sensory Integration and Balance (m-CTSIB) are greater in homebound diabetic adults, 47 years of age and older, than in non-diabetic homebound adults because diabetics have a higher incidence of visual and somatosensory changes than non-diabetics adults which could negatively impact sensory integration.

Sensory Integration and Diabetes

Poor postural stability in older adults has been associated with an increased fall risk (Buatois, Gueguen, Gauchard, Benetos, and Perrin, 2006). Several of the impairments of Type 2 diabetes have a significant impact on maintenance of postural control and normal sensory integration, which contributes to loss of functional mobility. People with DM who display peripheral neuropathy have been found to have decreased plantar flexor muscle peak torque compared with control subjects (Mueller, Diamond, and DeLitto, 1989). Several authors have documented decreased ankle joint motion in this population (Andersen and Mogenson, 1997, Mueller et al, 1989, Vlassara, 1990). Gait characteristics such as amount of heel strike and gait velocity (Potter, Evans, and Duncan, 1995) and postural stability (increased sway) also are impaired (Simoneau et al, 1994). Impaired peripheral sensory input and vision associated with DM also may directly influence maintenance of postural stability and appropriate reactions to postural pertubations. People with Type 2 diabetes may have impaired input from two of these systems, especially those with retinopathy and/or peripheral somatic neuropathies (PSN). People with DM and PSN display increasing prevalence of neuropathies over time (Partanen, Niskanen, and Lehtinen, 1995) as well as increased postural sway (Boucher, Teasdale, and Courtemanche,

1995), shifting in postural strategies (Giamomini, Bruno, and Maonticone, 1996), postural instability with head turning tasks (Oppenheim, Kohen-Raz, and Alex, 1999), and eventually can be at increased risk for falls.

Many older adults are at risk for falls, especially those adults who experience deficits that impact vision, somatosensation, and vestibular function (Horak et al, 1990). Dysfunction of the sensory and/or motor systems is a major contributor to an increase in the risk for falls among people 65 years of age or older. Diabetic adults can have deficits that impact vision, sensation, and motor control and are at an increased risk for postural instability when compared to non-diabetic older adults. Aging diabetic adults in both an urban and a rural setting were found to have an increased risk for chronic falling, especially when protective sensation was impaired in the lower extremities (Conner-Kerr and Templeton, 2002). Both urban and rural diabetics in this study shared similar risk factors for chronic falling, including positive fall history, daily medication intake, number of medical diagnoses, poor performance on the Tinetti Balance tool and impaired lower extremity sensation. Diabetic peripheral neuropathy has been directly linked to an increased risk for falls (Richardson and Hurvitz, 1995). Diabetics with peripheral neuropathy leading to foot ulceration have also exhibited postural instability as measured by body sway (Katoulis et al, 1997). Peripheral neuropathy was identified as the main factor leading to postural instability in diabetics without foot ulceration as measured by body sway and center of pressure trace length (Uccioli et al, 1997). Peripheral neuropathy was indicated as a significant factor associated with unstable body sway parameters, along with age, weight, and visual impairment secondary to cataracts (Hong et al, 1997). Most of these studies that linked peripheral neuropathy with postural instability involved chronic diabetic adults with obvious loss of lower extremity sensation. Newly diagnosed diabetics were not targeted, as it is assumed that the neuropathy process has not begun.

Measuring Sensory Integration

Research has shown that peripheral sensory input from the ankle and foot proprioceptors, visual input, and vestibular input are pivotal to normal postural responses. Diabetic adults show significant losses in peripheral sensation and are potentially at risk for falls for several reasons. Loss of cutaneous sensation has been correlated with impaired postural control and increased risk for falling in young adults (Maki and McIlroy, 1999, van Deursen and Simoneau, 1999). Altering sensory feedback from the feet with ice results in changes in muscular activation patterns and gait kinematics in healthy adults (Nurse and Nigg, 2001). Activation of the anterior tibialis was highly variable in a group of diabetic adults with impaired sensation in response to an unexpected disturbance to upright standing (Simmons and Richardson, 2001). This variability in muscle activation was consistent with greater postural sway and a decrease in stretch reflex response at the ankle. Plantar sensation is also suggested to play an important role in postural control, specifically, 1) sensing posterior stability limits during initiation of backward steps, 2) sensing and controlling heel-contact and subsequent weight transfer during termination of forward steps, and 3) maintaining stability during the prolonged swing phase of lateral crossover steps (Perry, McIlroy, and Make, 2000). Diabetics with bilateral cutaneous sensory deficit in the foot have demonstrated an atypical shift from ankle to hip strategy during sensory organization testing, as well as compromised foot mechanics (Simmons and Richardson, 1997). Thus, loss of sensation in adult diabetics has significant impact on postural control and normal sensory integration.

Three commonly used instruments for measuring sensory integration in older adults in a clinical setting that do not have the potential problem of a ceiling effect are the Sensory Organization Test (SOT), the modified Clinical Test of Sensory Integration in Balance (m-CTSIB)(Shumway-Cook and Horak, 1986, Cohen, 1993) and the Sensory-oriented Mobility Assessment Instrument (SOMAI)(Tang, Moore, and Woollacott, 1998). These tests assess a

person's ability to maintain balance under altered sensory conditions, though the SOMAI places greater demand on using balance senses during mobility tasks. The SOT can be performed using a force platform to measure root mean square calculations of postural sway to differentiate between different types of sensory impairment while the m-CTSIB uses four different sensory conditions using the floor and foam to assess sensory integration. The SOMAI score is based on a 4-point scale for quality of movement during increasingly demanding mobility tasks. These tasks included performing maneuvers in a continuous fashion while adapting to a changing environment, walking across uneven floors, walking across cushions placed under carpet, and pulling tape off of a wall. The SOT and SOMAI were not found to correlate during inaccurate sensory conditions in community-dwelling older adults and can not be performed easily in the home (Tang et al, 1998). The SOT protocol may be beneficial for balance assessment during later stages of diabetes when deficits are more prevalent in the visual and somatosensory systems, but would not be indicated in newly diagnosed diabetic cohorts who may only exhibit minimal deficits in these systems. The SOT protocol was not found to differentiate between patients suffering from whiplash syndrome, Meniere's disease, and vestibular dysfunction (El-Kahky, Kingma, and Dolmans, 2000). Utilizing the SOT in diabetic subjects is an area in need of research.

The m-CTSIB allows the investigator to note differences in performance between conditions that are indicative of visual preference, somatosensory preference, and vestibular function, without the use of a force plate or long testing times that homebound older adults could not reasonably perform. The m-CTSIB is more appropriate for homebound adults as it involves placing the adult in the standing position of feet together with eyes open and then closed with the arms crossed for a target of 30 seconds in each position. Then the adult stands on a 3-inch piece of dense foam in the same positions for 30 seconds each, for a total of four positions. Poor

performance while standing on the floor with eyes open can indicate somatosensory deficits, while poor performance during standing on the foam may indicate vestibular hypofunction (Cohen, Blatchyly, and Gombash,1993, Whitney, Marchetti, and Schade, 2006).

Postural Control and Diabetes: Hypothesis IV

It was hypothesized that balance, as measured by the Dynamic Gait Index, is significantly different between homebound Type 2 diabetic adults, 47 years of age and older, and non-diabetic homebound adults because diabetics in general have a higher incidence of falling.

Measuring Balance

When determining the most appropriate method for measuring the variability in postural reactions that may result from diabetes, a logical approach may be to decide which aspects of balance are influenced the most by loss of normal peripheral sensory input. Horak and Nashner have shown that somatosensory losses result in the increased use of the hip strategy for postural correction (Horak et al, 1990). Thus, one method of measuring postural stability in this population would be to use kinematic devices to monitor activation of balance strategies. Loss of peripheral sensory input results in greater body sway, indicating that another method for assessing balance could include velocity of body sway and standard deviation. Uccioli and colleagues found a direct correlation between presence of peripheral neuropathy and postural instability as measured by the posturographic parameters of trace length, trace surface and body sway (Uccioli et al, 1997). Postural stability has been measured in diabetic adults with peripheral neuropathy during various fingertip touch conditions using anterior-posterior and medial-lateral root mean square of center of pressure (Dickstein, Shupert, and Horak, 2001). Again, this type of instrumentation is not feasible with a cohort of homebound older adults, leaving the investigator with clinical assessments that do not require laboratory methods.

Identifying differences in postural stability between diabetics and control groups without using a force plate may require a more challenging task than quiet stance, such as head turning during walking, (Oppenheim et al, 1999). The Sharpened Romberg test (feet in tandem with eyes open and then closed for 30 seconds) has been used with and without a force plate to assess balance. The Sharpened Romberg was challenging enough to detect vestibular problems in cohorts with and without vestibular pathology (Horn, 1997), but has not been used with an adult diabetic population. Semi-tandem stance was used as a condition for determining differences in postural control between healthy subjects and those with bilateral vestibular hypofunction with eyes open and eyes closed (Riley, Benda, Gill-Body, and Krebs, 1995), but not with diabetics.

Several methods have been used to assess postural control and balance reactions in older adults. The most common methods include degree of postural sway during quiet stance, postural platform systems that can alter sensory feedback, measuring limits of stability, calculating center of pressure and anteroposterior torque exerted on a support surface, the one-leg stance test, and numerous functional assessment tools such as the Functional Reach Test (Duncan, Studenski, and Chandler,1990) Berg Balance Scale (Berg, Wood-Daphinee, and Williams, 1989), Tinetti Score (Tinetti, Williams, and Mayewski, 1986), Dynamic Gait Index (Whitney, Hudak, and Marchetti, 2000, Whitney, Marchetti, Schade, and Wrisley, 2004) and the Timed Up and Go Test (DiFabio and Seay, 1997, Mathias, Nayak, and Issacs, 1986).

In the laboratory, electromyography has also been useful in determining stereotypical muscle response patterns activated during balance tasks, including sequence of muscle firing and timing of activation of hip and ankle strategies for balance. This type of kinematic study identified a number of differences in postural stability between young and old adults. Older adults have been found to have more variability in muscle activation during platform testing, including slower ankle muscle activation, more cervical muscle activity and less trunk flexor

muscle activation, and occasionally reverse the normal distal-to-proximal sequence of muscle activation (Hu and Woollacott, 1990, Manchester, Woollacott, and Zederbauer-Hylton, 1989, Woollacott, Shumway-Cook, and Nashner, 1986). Another example of increased variability was found in greater joint angle rotation excursions and more variable initial rotation during external pertubations to balance (Alexander, Shepard, and Gu, 1992). This increase in variability is compounded by the presence of multiple pathology in older adults, especially those that impact the person's ability to adapt ankle and hip strategies to external forces, such as stroke, Parkinson's disease, or peripheral vascular disease (Black, Shupert, and Horak, 1988). This increased variability exhibited by older adults must be considered when choosing a method of testing postural stability. Unfortunately, the typical homebound older adult does not have access to a force plate for this type of sensitive testing for postural control.

A clinical approach to assessing postural stability could include the one-leg stance test, Functional Reach Test, Berg Balance Scale, Tinetti Scale, Dynamic Gait Index, or Timed Up and Go Test. These more clinical assessments have been proven reliable and valid and most have predictive validity for risk for falls for community-dwelling older adults. While these tools may be very appropriate for the clinic, the potential for ceiling effects in those tests using a qualitative scale may prove ineffective in identifying early changes in postural control in adults with recently diagnosed Type 2 diabetes. The Dynamic Gait Index has less potential for a ceiling effect based on the greater degree of difficulty with head turning activities that the other tests do not include. Inclusion of one or more of these functional assessment tools would be indicated in a repeated measures study that required follow-up assessment of the effectiveness of an intervention to impact postural stability in a more functional environment, though some would argue that specific conditions of some of these tests are not always functional.

As mentioned earlier, the Berg Balance Scale is a reliable and valid clinical measure for balance and fall risk in older adult populations, but has not been applied specifically in diabetic research (Shumway-Cook, Brauer, and Woollacott, 2000). The Berg test does encompass more challenging balance tasks, such as single-limb stance, which could be useful in detecting early changes in postural control due to diabetes, but has the limitation of a potential ceiling effect due to the 4-point scale used for scoring. To avoid this potential ceiling effect, the Dynamic Gait Index is also a reliable and valid test of balance and fall risk and incorporates the more challenging tasks of walking with vertical and horizontal head turns, stepping over objects, and negotiating stairs. It has been validated in community-dwelling older adults (Whitney, Hudak, and Marchetti, 2000, Chiu, Fritz, Light, and Velozo, 2006) and found reliable with adults with multiple sclerosis (McConvey and Bennett, 2005) and vestibular dysfunction (Whitney, Wrisley, and Furman, 2003).

Fear of Falling: Hypothesis V

It was hypothesized that fear of falling as measured by the Modified Falls Efficacy Scale (MFES) is more significant in homebound diabetic adults, 47 years of age and older, than in homebound non-diabetic adults because the higher incidence of falls in diabetics is associated with an increase in fear of falling.

The psychological consequences of experiencing a fall or fall injury can sometimes be as limiting as the physical injuries resulting from falls. Studies have shown that a fall injury may trigger the fear of additional falls (Tinetti, Mendes de Leon, Doucette, and Baker, 1994, Maki, Holiday, and Topper, 1991). Fear of falling may lead to increased depressive symptoms and fear of institutionalization (Scaf-Clomp, Sanderman, Ormel, and Kempen, 2003). The fear of another fall may lead to decreases in quality of life due to restricting usual activities in hopes of avoiding a future fall (Schiller et al, 2007). Fear of falling has been identified as an intrinsic factor

associated with recent falls in women with osteoporosis (Arnold, Busch, and Schachter, 2005) and older adults transitioning to frailty (Kressig, Wolf, and Sattin, 2001). Older adults afraid of falling reduce their physical activity to prevent outdoor falls (Wijihuizen, de Jong, and Hopman-Rock, 2007). Fear of falling has also been associated with decreased satisfaction with life, increased frailty, depressed mood, recent falls, and decreased mobility (Arfken, Lach, and Birge, 1994). Individuals who develop either fear of falling or experience a fall are at risk for developing the other, with a resulting spiraling risk of falls, fear of falling, and functional decline (Friedman, Munoz, and West, 2002). Even adults who have never experienced a fall can have a higher fear of falling than is justified by their physical condition (Scheffer, Schuurmans, and van Dijk, 2008). An estimated one third of adults who fall develop a fear of falling (Vellas et al, 1997) and it is suggested that rehabilitation programs address balance confidence as well and the physical skills needed for postural control (Tinetti et al, 1994). One study reports the main risk factors for developing a fear of falling are as simple as being female, being older, and experiencing at least one fall (Scheffer et al, 2008).

Fear of falling, which can impact postural stability, can be assessed using a self-efficacy survey asking situation-specific questions, such as the Activities-specific Balance Confidence (ABC) Scale (Powell and Myers, 1995) or the Modified Falls Efficacy Scale (MFES) (Tinetti, Richman, and Powell, 1990, Hill, Schwarz, Kalogeropoulos, and Gibson, 1996). The ABC survey and MFES provide comparable data and are reliable and valid measures of activity-related fear of falling (Kressig et al, 2001). The MFES contains questions regarding activities that can be performed in the home, while the ABC survey contains some activities that would be performed in the community, which a homebound adult would not be able to assess based on performance. Older adults with low MFES scores (<75) have been identified as having an increased risk for falls (Cumming, Salkeid, and Thomas, 2000). While some researchers promote

the study of fall-related self-efficacy and fear of falling as separate constructs (Legters, 2002, Moore and Ellis, 2008), these terms will be used interchangeably fro the purposes of this study.

CHAPTER III

METHODS

This research investigation involved identification of differences in risk factors for falling among homebound diabetic older adults as compared to a control group of non-diabetic homebound older adults. Study methods are described in this chapter.

Participants

This retrospective study involved analysis of data collected over the past four years for older adults who have received homecare from Gentiva Health Services in the Triad area of North Carolina. All participants were referred to the Safe Strides balance and fall prevention program. The Safe Strides program received referrals from physicians, hospital discharge planners, and assisted living facilities for physical therapy intervention to reduce falls and improve balance for older homebound adults. The program was available in the Triad area from September, 2004, to the present time. Approval to conduct this study was obtained from the Gentiva Clinical Compliance Board and from the Institutional Review Board at the University of North Carolina at Greensboro following an expedited review.

Study participants were grouped into two cohorts (one diabetic homebound cohort and one control cohort of non-diabetic homebound adults). One cohort consisted of homebound diabetic adults between 47 and 98 years of age. The other group consisted of non-diabetic control adults. Diabetic classification guidelines were followed using the American Diabetes Association fasting plasma glucose (FPG) recommendations for glucose level-based classifications for Type II diagnosed participants. An FPG scale rating of less than 110 mg/dL

was considered normal, 110-125 mg/dL was the impaired range, and a reading of more than 125 mg/dL was classified as diabetic (Mayfield,1998).

The American Diabetes Association recommends that the FPG show elevated plasma glucose twice before establishing a diagnosis for diabetes (Halter, 2002). For the oral glucose tolerance test (OGTT), a reading less than 140 mg/dL was considered normal, 140-199 mg/dL was in the impaired range, and over 200 mg/dL was classified as diabetes. The current standard of practice was the FPG screening using the ADA ranges listed (Halter, 2002). Participants were recruited from a cohort of homebound older adults seen for health services by Gentiva Home Health in the local Piedmont Triad community, specifically in Guilford, Forsyth, Alamance, Davie, Davidson, and Surry counties. All participants were asked to provide informed consent using the Gentiva form for Authorization for Release of Information (Appendix A).

Participants were tested in their homes and were informed verbally and in writing of the goals and risks involved in the physical therapy assessment prior to initiation of treatment and data collection (approved consent form by Gentiva Health Services, Appendix B). The data collection was part of the standard physical therapy home health evaluation and did not impact the length of treatment, assessment or outcomes of such treatment in any way. Any participant could refuse release of information at any time without impact on their delivery of prescribed skilled health care. Participation in the collection of data, or withdrawal from the collection, did not affect the participant's overall treatment in any way. All participants signed a Consent for Treatment form approved by Gentiva and Medicare (Appendix B). No participants were financially compensated for their participation as all participants were Medicare eligible for home health services which were covered 100% by Medicare or Medicaid. Participation in this study did not alter the normal delivery, billing, or process of physical therapy services in any way

associated with delivery of home health care. No modifications were made to the testing environment.

Inclusion Criteria

Participants included men and women 47 years of age and older (to 98 years of age) who met the definition of Type II homebound diabetic adult and non-diabetic homebound adult. Homebound was defined by the Medicare definition of community activity restricted due to taxing effort, safety, or need for supervision when leaving the home. This is the standard used by the home health industry. Participants with co-morbidities that did not alter the peripheral autonomic nervous system, such as hypertension, were included. Diabetic participants required written documentation that they were diagnosed with Type 2 diabetes mellitus, which was obtained from the referring physician. Participants were allowed to wear glasses to correct their vision. Participants in the control cohort were determined to be non-diabetic by their referring physician using the accepted medical criteria based on diabetic risk factors: 1) normal glucose tolerance testing within the past six months, or 2) no familial history of diabetes, 3) normal blood pressure, 4) no evidence of abdominal obesity as defined by waist measurements of more than 40 inches for men and more than 36 inches for women, and 5) no subjective reports of numbness or tingling in the lower extremities, and 6) no history of hyperlipidemia. If glucose tolerance testing had not been previously performed on a participant, but they met fewer than 3 out of the inclusion criteria 2-6, they were categorized as having minimal risk for diabetes. This is the medical standard of practice in the United States.

Exclusion Criteria

Participants and controls who were under age 47 or over age 98 were not included because they were generally not homebound at the younger end of the range and had higher chance of exclusionary co-morbidities at the upper end of the age range It was unlikely that

female volunteers were pregnant, but they were not included in the study if pregnant because pregnancy alters the extremity microcirculation and could alter normal balance strategies typically used as a result of the weight gain related to pregnancy. Persons with connective tissue diseases such as scleroderma were not included. All participants were able to walk with minimal assistance, contact guard (minimal manual support from the therapist), supervision, or independently with or without an assistive device and were free from wounds or amputations involving the lower extremities. Participants were free from skin ulceration on the feet. Participants did not have significant medical problems involving the visual or vestibular systems, with the exception of eyeglasses. Participants were excluded from the control group if they displayed more than three of the previously mentioned risk factors for diabetes, specifically hypertension, lower extremity cardiovascular disease, foot ulceration, or abdominal obesity. This information was obtained using the Gentiva OASIS form required by Medicare for all homebound Medicare-eligible adults (Appendix B). All consent forms, authorization forms, medical history, evaluations, and testing results were kept in the participant's medical record in each Gentiva branch. These records were locked in a file room and were assigned a case number by the computerized referral system in each Gentiva office.

Procedures

Each participant completed the Gentiva authorization form, Medicare OASIS form and Medicare-specific consent form during the initial home visit following a referral from a licensed physician. A licensed physical therapist employed by Gentiva Health Services interviewed each participant to obtain the required information contained in the participant evaluation. All Gentiva therapists were trained to complete the OASIS through an on-line course in Gentiva University that requires an 85% passing rate on a comprehensive online exam. Gentiva University is an on-line collection of a variety of educational self-paced workbooks designed to assist Gentiva

employees in providing home care services. When the physical therapist completed the OASIS they began their assessment, including the study measures, on the initial assessment day or over two sessions, depending on the participant's endurance and tolerance for testing. The OASIS information was available for any caregiver involved in direct care of a participant through the medical record housed in a locked file room in the Gentiva branch responsible for the county in which the participant lived.

After completion of the OASIS and physical therapy assessment, an outcome data sheet was provided to the principal research investigator by each assessing therapist (Appendix D). This form was a standard part of the medical record and contained the data under investigation and indication of patient authorization for release of information. The principal investigator was a Gentiva employee and physical therapist in charge of the Safe Strides Balance program in the surrounding counties of Guilford, Forsyth, Alamance, Davie, Davidson, and Surry.

Training of Testers

The principal investigator has 24 years of experience as a physical therapist with a specialization in neurology from the American Physical Therapy Association, as well as 8 years of physical therapy instruction at a local university. The principal investigator personally trained every Gentiva physical therapist in the Triad area in performance of the study measures and the Safe Strides balance program. The principal investigator completed a rigorous regional trainer program in order to become qualified to train all Triad area physical therapists. All Gentiva therapists also completed a 2-day course on balance assessment and treatment taught by the principal investigator, who performed skills competency check-offs on every therapist caring for Gentiva patients with balance issues. All therapists who completed the balance course were required to complete eight mandatory lab sessions at their home branch on topics including monofilament testing, balance testing, oculomotor testing, etc. The therapists also practiced these

testing skills in monthly labs held in each home branch. Lab attendance was recorded electronically through Gentiva University. All study participants were evaluated and treated by a Safe Strides trained therapist at Gentiva who completed all necessary steps to be Safe Strides credentialed by Gentiva.

Tests and Instrumentation

Sensory testing for protective sensation and pain

Somatosensory testing of the feet was performed by a physical therapist on all participants as part of the testing protocol described by Mueller (Mueller, 1996, Mueller, Minor, and Sahrmann, 1994). Somatosensory testing of both feet was performed using Semmes-Weinstein monofilaments calibrated at 5.07g (purchased through the Anodyne Company, Tampa, FL), which was the size used as the threshold for protective sensation (Mueller, 1996). Each nylon monofilament was calibrated by the manufacturer to deliver its targeted force of 5.07 grams when applying sufficient force to produce a 45 degree bend in the shaft, within a 5% standard deviation, per manufacturer's documentation. The monofilaments were placed in a protected box when not in use in order to maintain the integrity of the nylon filament. After each use the monofilament was immediately returned to its protective cover by the therapist. Bent or kinked monofilaments were not used for testing and were replaced. The monofilament was discarded after use with one participant. Both feet were assessed for each participant by testing 5 locations on each foot using the same monofilament. A perfect score was the sum of 5 normal detections of the monofilament on each foot, or a score of 10.

Each participant was seated comfortably in a chair with a supportive backrest and was asked to remove their socks and shoes. Each foot was tested using the standard method of applying a monofilament to each of five areas on the sole of the foot (great toe, first metatarsal head, third metatarsal head, fifth metatarsal head, and fourth toe). The foot was supported during

sensory testing by the therapist or by furniture available in each home. Each application of monofilament involved 1-1.5 seconds of pressure at an angle perpendicular to the skin surface (enough to result in a 45 degree bend in the filament). Testing did not occur over callused tissue. If skin abnormalities were present the therapist moved to the nearest normal skin adjacent to the testing spot. Testing order was randomized, and each therapist varied the speed of application to improve reliability and prevent participants from guessing based on a rhythm of application. Each area was tested one time, with an assessment of normal sensibility given using a "yes-no" method. Sensory loss was documented at a site if the monofilament was not sensed correctly. Results were recorded on a sensory foot form developed by Gentiva (Appendix E). Application was repeated at a location if the therapist was unsure of a participant's response. Only one additional repetition was permitted for any location. The procedure was repeated for the other foot, with random order of right versus left foot to be tested first. Participants were considered at risk for peripheral sensory neuropathy if they received 6 (of 10 possible) or fewer correct responses to the monofilament applications. Participants were considered at risk for loss of protective sensation if any portion of the foot was insensitive to the monofilament (Mueller, 1996), which is a conservative criterion for sensory assessment. Participants at risk were informed of this assessment following completion of all testing and were referred to their physician for consultation. A summary of the Semmes-Weinstein scores was provided for the physician of any participant at the participant's request.

Pain in the feet or lower extremities was assessed by the therapist using a verbal analog scale with 0 equating to no pain and 10 equating to the worst pain imaginable. Participants were instructed to rate only the pain, if present, in their feet or lower legs that could be described as burning, tingling, or stabbing, which are terms typically used to describe neuropathic pain. This pain score was recorded on the outcome form and on the OASIS assessment.

Postural stability testing for sensory integration

Postural stability and sensory integration were assessed using the m-CTSIB test. This test was performed by the physical therapist using a Gentiva digital stopwatch and a 3-inch thick piece of dense foam purchased through Gentiva. The high density foam used for the m-CTSIB testing was purchased from the AIREX Company who manufactured this product with the dimensions of 50 x 41 x 6 cm or 19 x 16 x 2.5 inches (Alcan Airex AG, CH-5643 Sins/Switzerland). AIREX mats consist of closed-cell foam designed to prevent "bottoming out" under rigorous conditions and do not absorb water. The foam was covered by a protective coating that allowed removal of dirt or germs using anti-bacterial wipes between testing. The same type of foam was used by each tester and is a standard product used in the physical therapy industry. All timing for the m-CTSIB was completed using a Gentiva digital stopwatch supplied to each therapist at the Safe Strides training session. Times were recorded for each position from 0 to 30 whole seconds. All times were recorded on the participant outcome form.

The participant was asked to stand on the floor, with shoes on or off, with their feet as close together as possible, while crossing their arms at their chest or waist with their eyes open. If a participant could not achieve feet touching due to joint position or soft tissue, the therapist recorded the distance between the feet. Any participant with a distance between feet greater than 2 inches was excluded from the study, but not from continued therapy. It the participant could not accomplish feet touching due to poor balance, then a score of zero seconds was recorded for all positions. The therapist asked the participant to maintain this position for 30 seconds while they timed them using their stopwatch. Timing stopped if the participant required assistance for balance, uncrossed their arms, or exhibited excessive sway that indicated an impending fall. They were then asked to repeat this task with their eyes closed. The third position involved standing in the same manner, but on a 3-inch piece of foam with eyes open, then with eyes

closed. Timing was stopped if the participant uncrossed their arms, lifted their toes off of the foam, opened their eyes, or required assistance to prevent loss of balance. The score in seconds for each of four positions was recorded on the outcome form previously mentioned. A perfect score was successful stance in four out of four positions for 30 seconds, or 4/4. The participants were allowed to rest in between positions if necessary, but not for longer than 2-3 minutes. The therapists did not coach the participant in any way during the timing of each position.

Fall risk and balance testing

Fall risk and balance were tested using the Dynamic Gait Index (DGI). The DGI is an 8-item assessment involving gait while performing challenging dynamic activities, including walking 20 feet with or without an assistive device, changing gait speed, pivot turning, gait with horizontal and vertical head turns, stepping over objects, stepping around objects, and negotiation of steps. Each activity is rated on a 0-3 scale using quality statements printed on the DGI form (Appendix F). A higher score indicated more independence and better balance during the required tasks. Participants were allowed to rest between the 8 DGI activities for at least 1-3 minutes, depending on their endurance. The walking path was the space available in each home that best matched 20 feet (or as close to 20 feet as possible) of smooth walking surface, which could include tile, carpet, hardwood floors, or concrete. A higher score indicated lesser risk for falls. The highest score was a 24 out of 24 total quality points. A score of 20/24 or less indicated a high fall risk (Whitney et al, 2000). The DGI score for each participant was recorded on the outcome form.

Fear of falling assessment

Fear of falling (or lack of balance confidence) was measured using the Modified Falls Efficacy Scale (Powell and Myers, 1995, Appendix G). The assessing therapist asked the participant to give a subjective assessment of their confidence in completing 14 household tasks

without losing their balance. The possible choices were very confident, fairly confident, and not confident at all. The therapist recorded the participant's responses. The total points awarded out of 140 possible were recorded on the outcome form. A score of 60 or fewer indicated a fear of falling (poor confidence in balance).

Primary Data Analysis

To test each hypothesis, a univariate analysis of variance (ANOVA), alpha level of .05, was utilized to compare diabetic to non-diabetic groups for all fall risk factors.

Secondary Data Analysis

Because of the richness of the data set, additional analyses were performed to examine possible interaction of gender and age, though these factors were not included in the original hypotheses. To examine the influence of age on differences in mean scores of fall risk factors, both cohorts were divided into age categories, defined as 0) 45-54 years, 1) 55- 64 years, 2) 65-74 years, 3) 75 -84 years, and 4) 85 years and older. An ANOVA, alpha level .05, was performed to identify significant differences by age category and was repeated to examine potential differences based on gender.

CHAPTER IV

RESULTS

This retrospective study focused on a challenging population of homebound older adults identified as appropriate for a physical therapy balance program. The total cohort was divided into two groups, diabetic and non-diabetic, which were compared using five fall risk factors. The risk factors included lower extremity sensation on the plantar surface of the feet, lower extremity pain, sensory integration, balance, and fear of falling. It was hypothesized that the group of diabetic older adults would display a greater degree of deficit in each of the five risk factors than the non-diabetic group. The results of this study are described in the following chapter.

Primary Analysis Results: Difference in Fall Risk Factors

Participants included in this study totaled 284 homebound older adults (N = 74, diabetics and N = 210, non-diabetic adults). Characteristics and demographic data for both diabetic and non-diabetic groups are in Table 1. The average age in years and standard deviation for both cohorts was similar (76.7 yoa $\pm$ 9.8 years for diabetics and 81.5 yoa $\pm$ 8.2 years for non-diabetics). An independent samples t-test confirmed that there was no significant difference in age ($t = 4.14$, $p = .06$). The majority of participants for both cohorts were female and Caucasian, though the diabetic group was divided more equally by gender than the non-diabetic group (56.8 % female and 43.24 % male versus 75.7 % female and 24.3 % male for non-diabetics). The mean scores for both cohorts for each fall risk factor are in Table 2.

Table 1. Demographic and Mean Test Data

Characteristic	Diabetic Homebound (n=74)	Non-Diabetic Homebound (n=210)
Age (years, mean ± Standard Deviation (SD)	76.7 (9.8) Range = 47 – 95	81.5 (8.2) Range = 47 - 98
Gender (% Female)	56.76	75.71
Race (% Caucasian)	74.32	85.24

Table 2. Data for Fall Risk Factors

Fall Risk Factor	Diabetic	Non-Diabetic	Skewness	Kurtosis
Pain score (0-10)(SD)	1.89 (3.25)	1.25 (2.62)	1.723	1.448
Sensory score (0-10)(SD)	6.15 (4.07)	7.59 (3.36)	-.919	-.734
Modified Falls Efficacy Scale (0-140)(SD)	61.94 (28.81)	63.15 (32.65)	.257	-.586
Clinical Test for Sensory Integration in Balance (CTSIB) 0-120 s (SD)	39.10 (30.82)	42.72 (32.38)	.332	-.960
Dynamic Gait Index score (0-24)(SD)	9.81 (4.03)	10.01 (4.08)	-.049	.170

To test each hypothesis, univariate analyses of variance (ANOVA) were performed to examine group differences. All statistics were performed using SPSS version 16.0 with an alpha level set at 0.05. Effect sizes (partial eta squared) also were examined. Effect sizes of .2 -.3 are considered small, .4 - .5 is a medium effect size, and .8-1.0 is a large effect size (Cohen, 1988).

Fall Risk Factor: Sensory Score

Table 3 contains the results of the ANOVA for sensation. Mean sensory scores differed significantly between diabetic and non-diabetic groups (p =.003), but the effect size of .031

(partial eta squared) was very low. Even though the observed power of .85 did reach the threshold for ideal power, this effect size was too small to suggest a clinically meaningful difference. The diabetic group displayed slightly less sensation in the soles of the feet than the non-diabetic group (mean = 6.15 versus 7.59).

Table 3. ANOVA for Sensory Scores

Dependent Variable: Semmes-Weinstein Score (0-10)

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Observed Power[b]
Diabetic/Non-DM	113.302	1	113.302	8.938	.003	.031	.846
Error	3561.977	281	12.676				
Corrected Total	3675.279	282					

Fall Risk Factor: Pain

There was no significant difference between groups in reported pain perceived in the lower extremities. Table 4 contains the results of the ANOVA for pain.

Table 4. ANOVA for Pain

Dependent Variable :Analog Pain (0-10)

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Observed Power[b]
Diabetic/nonDM	22.713	1	22.713	2.903	.090	.010	.397
Error	2206.259	282	7.824				
Corrected Total	2228.972	283					

Fall Risk Factor: Sensory Integration

Mean scores and standard deviations for the modified Clinical Test for Sensory Integration in Balance (m-CTSIB) are in Table 2. These means were not statistically different. Results for the ANOVA for the m-CTSIB scores can be found in Table 5.

Table 5. ANOVA for Modified CTSIB

Dependent Variable :Modified CTSIB Total Seconds 0-120

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Observed Power[b]
Diabetic/Non-DM	701.029	1	701.029	.685	.409	.002	.131
Error	283460.068	277	1023.322				
Corrected Total	284161.097	278					

Fall Risk Factor: Balance

Mean scores and standard deviations for the Dynamic Gait Index (DGI) are in Table 2. DGI mean scores were not statistically different (p=.712) between groups. Table 6 contains results of the ANOVA for DGI scores.

Table 6. ANOVA for DGI

Dependent Variable :Balance Tests Dynamic Gait (0-24)

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Observed Power[b]
Diabetic/Non-DM	2.263	1	2.263	.137	.712	.000	.066
Error	4626.308	280	16.523				
Corrected Total	4628.571	281					

Fall Risk Factor: Fear of Falling

To test differences in fear of falling between groups the Modified Falls Efficacy Scale (MFES) scores were analyzed. Descriptive values for means and standard deviations are in Table 2. Table 7 contains results of the ANOVA for MFES. The mean MFES scores were not statistically different between diabetic and non-diabetic groups (p =.789). Both groups displayed means that approached the threshold of 60 points, indicating a fear of falling.

Table 7. ANOVA for MFES

Dependent Variable: Modified Falls Efficacy Scale
0-140

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Observed Power[b]
Diabetic/Non-DM	72.164	1	72.164	.072	.789	.000	.058
Error	255249.613	254	1004.920				
Corrected Total	255321.777	255					

Secondary Analysis: Impact of Age and Gender

Impact of Age on Fall Risk Factors

Keeping in mind that age influences activity level and fall incidence in community-dwelling and institutionalized older adults (Horgas, Wims, and Bataes, 1998), each cohort was divided into age categories, defined as 0 = 47-54, 1 = 55-64, 2 = 65-74, 3 = 75-84, and 4 = 85 and older. Table 8 contains frequency information for each age category and diagnostic group. There were no non-diabetic participants in the youngest age group and the cell sizes for the 55-64 year olds contained very few participants. These two youngest age categories were excluded from analysis due to the small cell size.

Table 8. Frequencies for Age Categories

Age Category	Non-Diabetic	Diabetic	Total
0 (47- 54)	0	3	3
1 (55-64)	7	5	12
2 (65-74)	33	17	50
3 (75-84)	90	32	122
4 (85 plus)	80	17	97
Totals	**210**	**74**	**284**

A univariate analysis of variance was performed for each of the five fall risk factors to identify the impact of increasing age. No significant differences or interactions were identified between the three oldest age categories, with the exception of significant interaction for age, diagnosis, and pain (p = .048). Tables 9 - 13 contain ANOVA results.

Table 9. ANOVA for Sensory Scores by Age and Interaction

Dependent Variable: Semmes-Weinstein Score 0-10

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Observed Power[b]
Corrected Model	9465.038[a]	5	1893.008	.511	.768	.010	.189
Intercept	14232.868	1	14232.868	3.844	.051	.014	.497
Age category	1513.552	2	756.776	.204	.815	.002	.082
Diabetic or Not	1442.733	1	1442.733	.390	.533	.001	.095
Age category * Diabetic or Not	1601.807	2	800.904	.216	.806	.002	.084
Error	973704.724	263	3702.299				
Corrected Total	983169.762	268					

a. R Squared = .010 (Adjusted R Squared = -.009)

Table 10. ANOVA for Pain by Age and Interaction

Dependent Variable: Analog Pain Scale 0-10

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Observed Power[b]
Corrected Model	62.141[a]	5	12.428	1.727	.129	.032	.592
Intercept	292.525	1	292.525	40.653	.000	.134	1.000
Age category	27.495	2	13.748	1.911	.150	.014	.395
Diabetic or Not	6.568	1	6.568	.913	.340	.003	.159
Age category * Diabetic or Not	44.316	2	22.158	3.079	.048	.023	.591
Error	1892.469	263	7.196				
Corrected Total	1954.610	268					

a. R Squared = .032 (Adjusted R Squared = .013)

Table 11. ANOVA for m-CTSIB by Age and Interaction

Dependent Variable: Modified CTSIB Total Seconds 0-120

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Observed Power[b]
Corrected Model	72199.911[a]	5	14439.982	1.297	.265	.024	.457
Intercept	382067.540	1	382067.540	34.322	.000	.116	1.000
Age category	11964.108	2	5982.054	.537	.585	.004	.138
Diabetic or Not	5325.847	1	5325.847	.478	.490	.002	.106
Age category * Diabetic or Not	19403.913	2	9701.956	.872	.420	.007	.199
Error	2905396.156	261	11131.786				
Corrected Total	2977596.067	266					

a. R Squared = .024 (Adjusted R Squared = .006)

Table 12. ANOVA for DGI by Age and Interaction

Dependent Variable: Balance Tests Dynamic Gait 0-24

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Observed Power[b]
Corrected Model	4.374[a]	5	.875	.053	.998	.001	.062
Intercept	17618.750	1	17618.750	1074.303	.000	.805	1.000
Age category	1.499	2	.749	.046	.955	.000	.057
Diabetic or Not	.006	1	.006	.000	.985	.000	.050
Age category * Diabetic or Not	2.839	2	1.420	.087	.917	.001	.063
Error	4280.442	261	16.400				
Corrected Total	4284.816	266					

a. R Squared = .001 (Adjusted R Squared = -.018)

Table 13. ANOVA for MFES by Age and Interaction

Dependent Variable: Modified Falls Efficacy Scale 0-140

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Observed Power[b]
Corrected Model	256220.817[a]	5	51244.163	.614	.689	.012	.223
Intercept	4934300.002	1	4934300.002	59.120	.000	.184	1.000
Age category	231537.801	2	115768.900	1.387	.252	.010	.297
Diabetic or Not	13593.196	1	13593.196	.163	.687	.001	.069
Age category * Diabetic or Not	46134.701	2	23067.351	.276	.759	.002	.093
Error	2.195E7	263	83462.214				
Corrected Total	2.221E7	268					

a. R Squared = .012 (Adjusted R Squared = -.007)

Impact of Gender on Fall Risk Factors

A univariate analysis of variance was performed for each of the five fall risk factors to identify the impact of gender on performance. This analysis compared cohorts with the following cell size: diabetic females (N = 42), non-diabetic females (N = 159), diabetic males (N = 32), and non-diabetic males (N = 51). Tables 14-18 contain ANOVA data for each fall risk factor and gender comparisons. There was no significant impact of gender on any of the five fall risk factors, with the exception of pain. The percentage of women in the diabetic group in this study was 56.76%, but was higher in the non-diabetic cohort (75.71 % female). Despite this difference in gender proportion, the only significant interaction identified in fall risk factors was for pain.

Table 14. ANOVA for Sensory Score and Gender

Dependent Variable: Semmes-Weinstein Score 0-10

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Observed Power[b]
Corrected Model	160.744[a]	3	53.581	4.254	.006	.044	.859
Intercept	8964.621	1	8964.621	711.653	.000	.718	1.000
Gender	47.122	1	47.122	3.741	.054	.013	.487
Diabetic or Not	89.361	1	89.361	7.094	.008	.025	.756
Gender * Diabetic or Not	3.766	1	3.766	.299	.585	.001	.085
Error	3514.535	279	12.597				
Corrected Total	3675.279	282					

Table 15. ANOVA for Pain and Gender

Dependent Variable : Analog Pain Scale 0-10

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Observed Power[b]
Corrected Model	59.280[a]	3	19.760	2.550	.056	.027	.626
Intercept	421.861	1	421.861	54.441	.000	.163	1.000
Gender	36.553	1	36.553	4.717	.031	.017	.581
Diabetic or Not	24.315	1	24.315	3.138	.078	.011	.423
Gender * Diabetic or Not	5.248	1	5.248	.677	.411	.002	.130
Error	2169.691	280	7.749				
Corrected Total	2228.972	283					

Table 16. ANOVA for m-CTSIB and Gender

Dependent Variable: Modified CTSIB Total Seconds 0-120

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Observed Power[b]
Corrected Model	1992.536[a]	3	664.179	.647	.585	.007	.185
Intercept	327343.535	1	327343.535	319.027	.000	.537	1.000
Gender	892.159	1	892.159	.869	.352	.003	.153
Diabetic or Not	445.962	1	445.962	.435	.510	.002	.101
Gender * Diabetic or Not	870.319	1	870.319	.848	.358	.003	.151
Error	282168.561	275	1026.067				
Corrected Total	284161.097	278					

Table 17. ANOVA for DGI and Gender

Dependent Variable: Balance Tests Dynamic Gait 0-24

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Observed Power[b]
Corrected Model	18.779[a]	3	6.260	.377	.769	.004	.124
Intercept	19312.098	1	19312.098	1164.643	.000	.807	1.000
Gender	1.887	1	1.887	.114	.736	.000	.063
Diabetic or Not	.143	1	.143	.009	.926	.000	.051
Gender * Diabetic or Not	16.508	1	16.508	.996	.319	.004	.169
Error	4609.792	278	16.582				
Corrected Total	4628.571	281					

Table 18. ANOVA for MFES and Gender

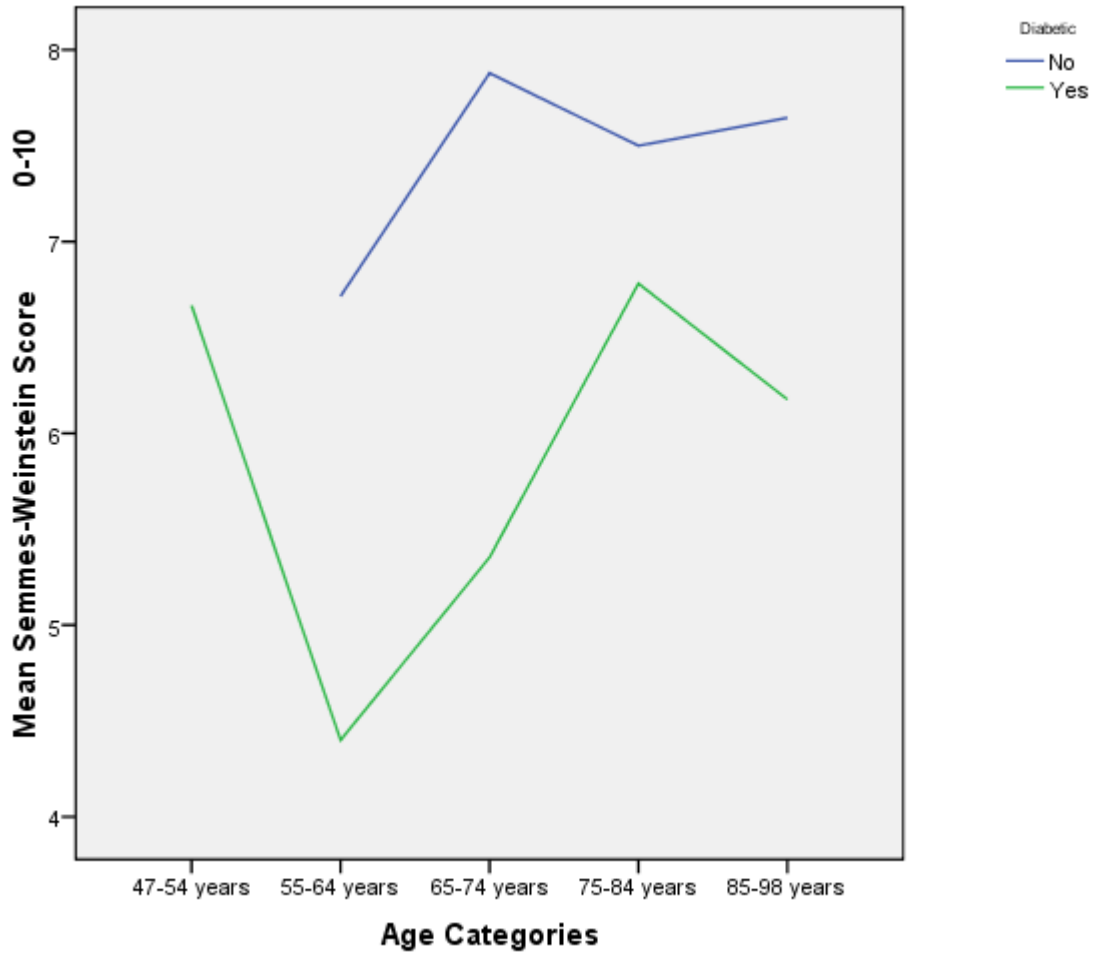
Dependent Variable: Modified Falls Efficacy Scale 0-140

Source	Type III Sum of Squares	df	Mean Square	F	Sig.	Partial Eta Squared	Observed Power[b]
Corrected Model	1701.560[a]	3	567.187	.564	.640	.007	.166
Intercept	707221.283	1	707221.283	702.703	.000	.736	1.000
Gender	1239.430	1	1239.430	1.232	.268	.005	.198
Diabetic or Not	289.212	1	289.212	.287	.592	.001	.083
Gender * Diabetic or Not	42.642	1	42.642	.042	.837	.000	.055
Error	253620.218	252	1006.429				
Corrected Total	255321.777	255					

Visual Data Patterns

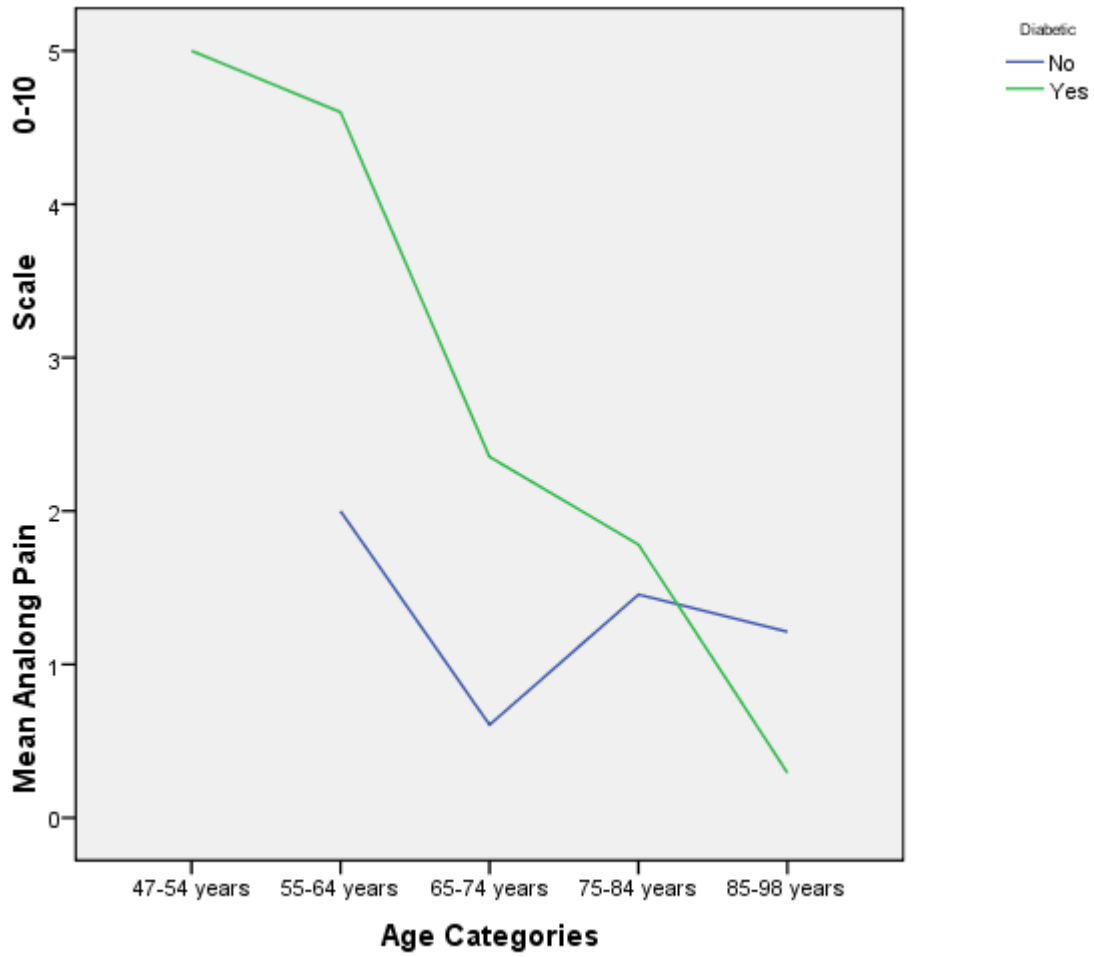
Visual comparison of the means for each risk factor by diagnostic group and age category revealed some interesting patterns. Non-diabetic cohorts are represented by the blue line and diabetic cohorts are represented by the green line in each figure. In Figure 1, the mean diabetic sensation score was lower in every age category than the mean score of the non-diabetic age groups. This was the only fall risk factor that showed a consistent pattern in every age group.

Figure 1. Line Plot for Mean Sensation Scores



The mean lower extremity pain score for diabetics was higher for every age category with the exception of the oldest cohort (age 85 – 98 years). The sensation line plot can be found in Figure 2.

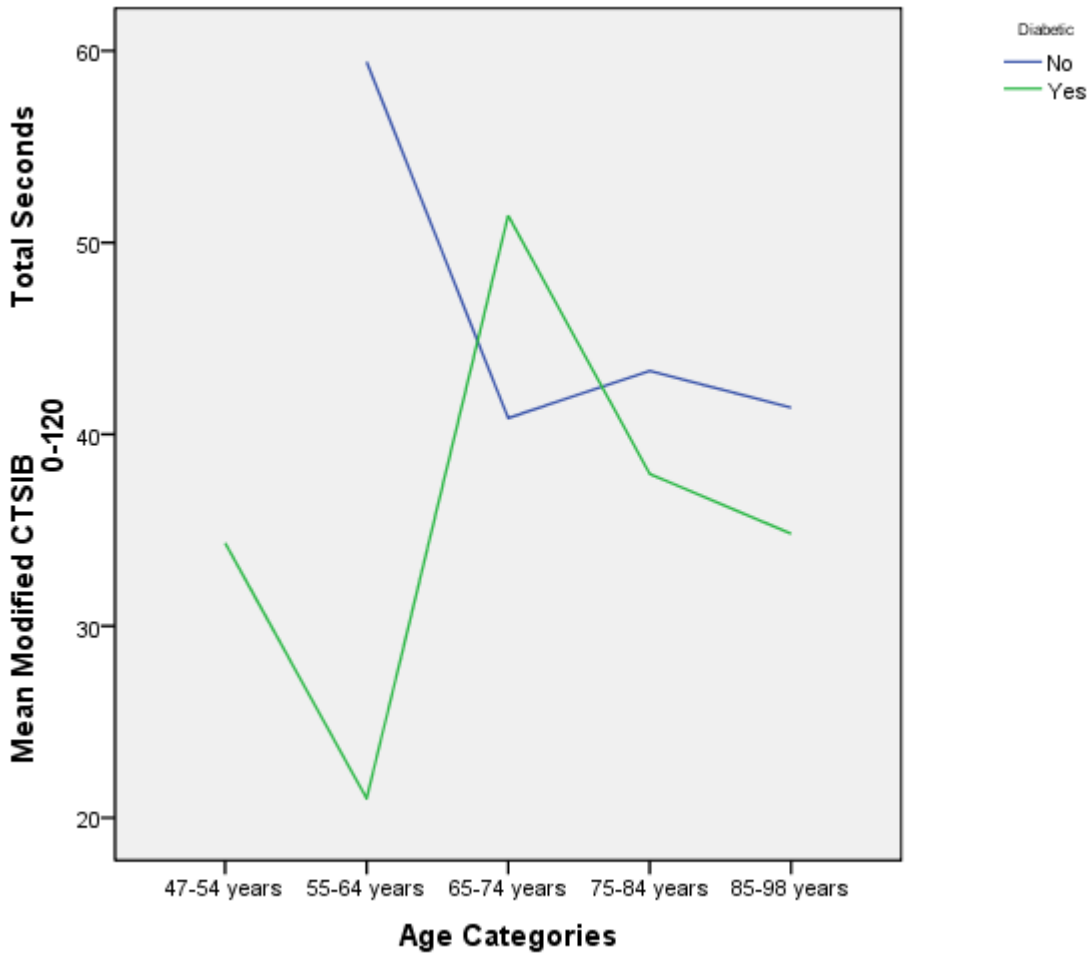
Figure 2. Line Plot for Mean Pain Scores



No interaction was found between age category and diagnosis and the factor of pain. No significant interaction was revealed (p = .052), though the visual analysis of the mean pain scores for both groups suggests that non-diabetics reported more pain with increased age with diabetics reporting less.

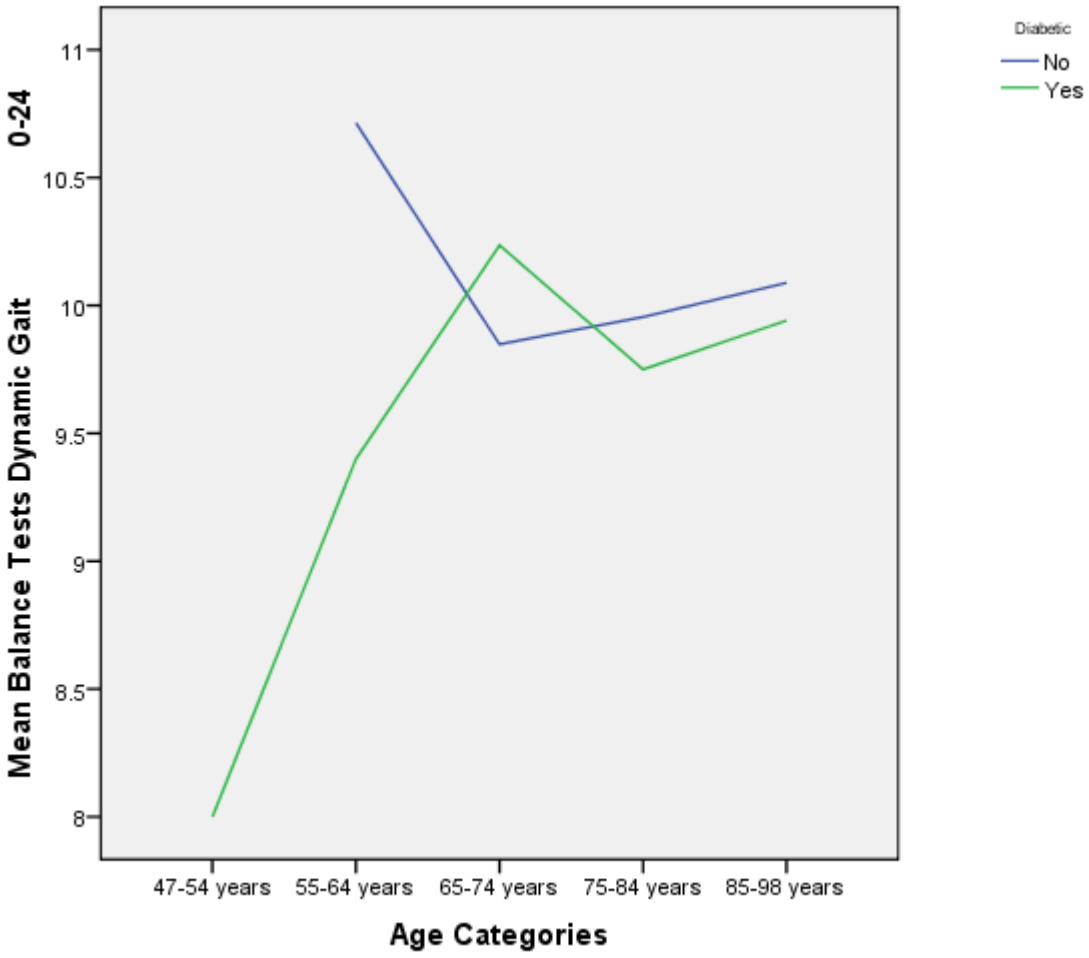
Mean sensory integration scores were lower for all diabetic age categories than that of non-diabetics, with the exception of the 65-74 year old group. The m-CTSIB line plot can be found in Figure 3.

Figure 3. Line Plot for m-CTSIB Scores



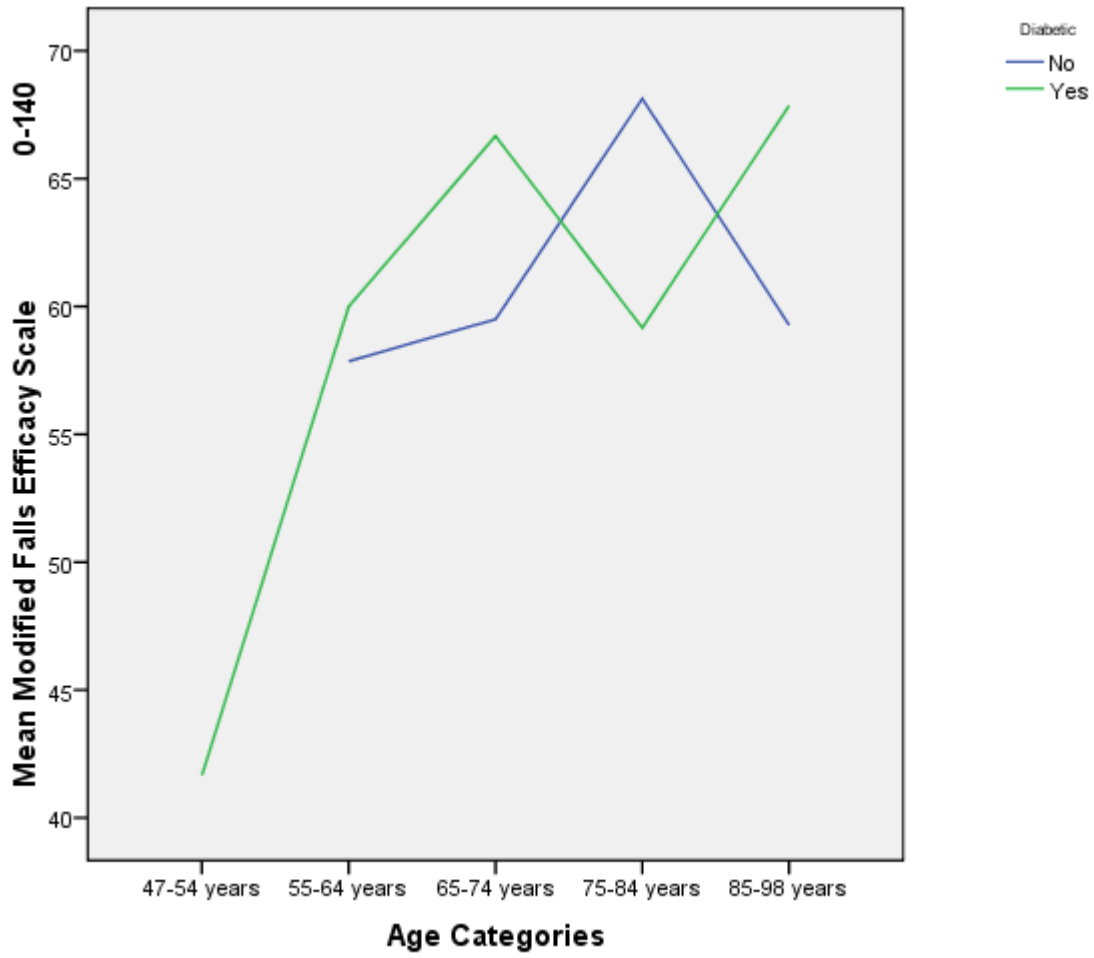
Comparison of Dynamic Gait Index scores revealed lower balance scores for every diabetic age group, except the 65-74 year olds. The DGI line plot can be found in Figure 4.

Figure 4. Line Plot for Dynamic Gait Index Scores



Mean scores for the Modified Falls Efficacy Scale were higher for all diabetic age groups when compared to non-diabetic groups, with the exception of the 75-84 years of age cohort. This one diabetic age group reported less fear of falling when compared to same aged non-diabetic adults. Figure 5 contains the line plot for MFES mean scores.

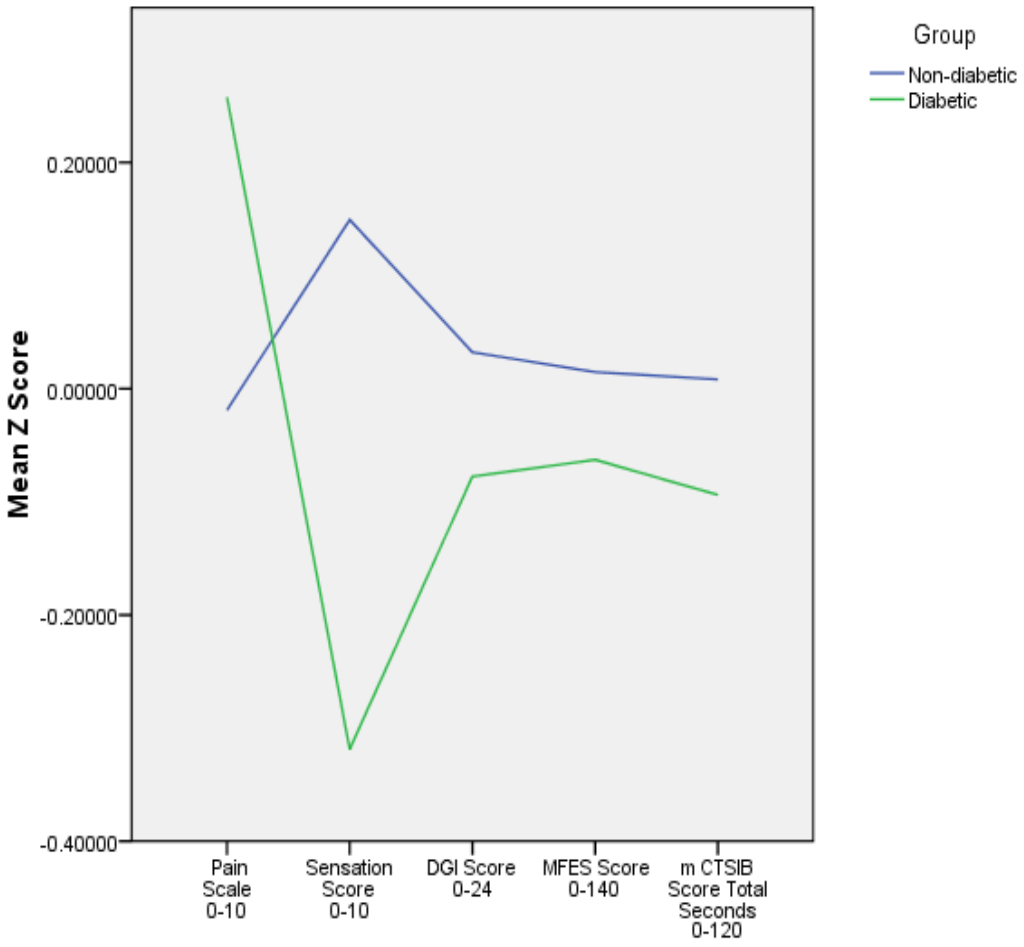
Figure 5. Line Plot for MFES Mean Scores



To visually compare mean values across all variables, the raw data were converted to standardized scores. The non-transformed data were converted to z scores by finding the difference between each data point and the mean for that variable and then dividing this difference by the standard deviation. This score identifies how many standard deviation units a data point is above or below the mean. A z score of 1 represents a data point one standard deviation above the mean, while -1 represents a value one standard deviation below the mean.

This allows a meaningful comparison of the variables with different units of measurement, different means, and different standard deviations. The mean z score for the data points for each factor was plotted for comparison. Figure 6 contains the line plot comparing z score means between diagnostic groups. Pain and lower extremity sensation showed the greatest differences in z score means (diabetic pain z score -.06 compared to .17 non-diabetic pain z score; diabetic sensation z score mean -.30 compared to .10 non-diabetic z score mean). Overall, differences for all five factors were very small.

Figure 6. Line Plot for Z Scores for all Variables



CHAPTER V

DISCUSSION

Summary of Primary Findings

After comparison of each fall risk factor for diabetic and non-diabetic adults, only one of the proposed hypotheses was supported. Semmes-Weinstein sensory scores were significantly different between diagnostic groups indicating that these diabetic adults experience a greater loss of normal sensation in the feet than do non-diabetic adults. The small effect size limits external validity of these results, however. Secondary analysis showed that sensory scores were lower for diabetics at each age compared with non-diabetics. Other studies exploring why diabetics are more likely to fall also identified reduced peripheral nerve function, responsible for sensory and motor activity, as a predictor for falls (Barclay and Lie, 2008, Schwartz et al, 2008). The American Diabetes Association, in their 2007 Standards of Medical Care in Diabetes, recommended annual screenings for diabetic peripheral neuropathy (DPN) for patients with diabetes. They recommend using a minimum of one clinical test such as monofilament testing, pinprick sensation, temperature, or vibration perception (ADA, 2007). The ADA described the association of sensory loss and DPN pain with higher rates of several common geriatric syndromes in older adults with diabetes, including polypharmacy, depression, cognitive impairment, urinary incontinence, injurious falls, and persistent pain (ADA, 2007). Though the sensory score effect size was too small to be considered clinically meaningful, the results support inclusion of monofilament testing in the homebound population because of the severe

consequences of the progression of sensory loss if undetected. This type of sensory screening should be part of a comprehensive foot examination designed to recognize common diabetic complications that can lead to ulcers or amputations if left untreated.

The homebound non-diabetic cohort in the present study may have had a level of sensory impairment and pain close to that of the diabetic group due to nerve dysfunction resulting from normal aging or other pathology. The loss of normal sensation in diabetic neuropathy predisposes joints to repeated trauma and progressive joint destruction and pain, which can be similar to complaints of pain due to osteoarthritis or other age-related joint disease. The lack of a clinically meaningful difference in sensation or pain in the two diagnostic cohorts can be explained in part by the clinical and functional heterogeneity of older adults with diabetes (ADA, 2007). While some older adults acquire diabetes in middle age and face years of co-morbidity and the possible transition to frailty, others may experience few complications or have gone undiagnosed for years. Other diabetics enjoy an active life with few co-morbidities. The extreme variation in diabetic medical care also influences the severity of complications and functional disability experienced by older adults with this disease. Variations exist in the medical treatment of critical areas in diabetic care, such as glycemic control, blood pressure, and lipid control (ADA, 2007). These variations influence results of any study involving homebound older adults with diabetes.

The factors of sensory integration and balance were not significantly different between these diabetic and non-diabetic cohorts. The presence of co-morbidities in homebound adults, such as visual disorders, orthostatic hypotension, or cognitive impairment, may have influenced balance and/or sensory integration in all of the participants. The presence of these co-morbidities was not controlled in this study. Risk factors for falling have been identified as history of falling, use of assistive devices for ambulation, muscle weakness, gait and balance impairments, visual disorders, polypharmacy, cognitive and sensory impairments, orthostatic hypotension, and

environmental hazards (Peel et al, 2008). The non-diabetic cohort may have experienced at least one, if not several, of these risk factors, making it difficult to distinguish between diabetics and non-diabetics.

Though unexpected, the diagnosis of diabetes did not influence fear of falling in our homebound cohort, with both diagnostic groups reporting low self-efficacy. Our results were unexpected in light of statistics that indicate increasing incidence of falls in diabetic older adults versus non-diabetics (ADA, 2007). Fear of falling develops for multiple reasons, most commonly a history of falls, being an older non-faller, being female, and reporting poorer health and functional decline, all common in homebound adults (Legters, 2002). An increased incidence of falls in diabetics would logically result in an increased fear of falling, but our results did not substantiate this relationship and we did not record fall history. A relationship between fear of falling and other neurologic diagnosis has been found in conditions such as Parkinson's disease, multiple sclerosis and stroke (Andersson, Kamwendo, and Appelros, 2008, Mak and Pang, 2009, Peterson, Cho, von Koch, and Finlayson, 2008). The reality that older, homebound, non-diabetic adults also have an increased fear of falling when compared to homebound diabetic adults may help explain our results. Fear of falling is considered the most common fear of older adults (Sharaf and Ibrahim, 2008). A survey of over 3,400 community-dwelling older Americans reported a 22% incidence of fear of falling (Bertera and Bertera, 2008), while others report the prevalence as high as 36.2% of all older adults (Boyd and Stevens, 2009). Fear of falling increases after age 65 years (Legters, 2002, Scheffer et al, 2008) and as age approaches 80 years and beyond (CDC [fatalities and falls], 2006, Stevens et al, 2008). Though we did not record fall history, the majority of the population included in our study was referred to home health because of a fall. Recurrent falls are more likely to happen with increased age, being female, being nonwhite, reporting fair to poor health, and increased number of limitations in personal activities

of daily living and instrumental activities of daily living and co-morbidities (Shumway-Cook, Ciol, and Hoffman, 2009). Older women have been shown to have a 48.4% higher fall rate than men (Stalenhoef, Diedriks, and Knottnerus, 2002) and tend to have more serious injuries as a result of falling than do men (CDC [fatalities and falls], 2006, Stevens, 2006). Thus, the combination of these factors that can lead to fear of falling in homebound older adults, whether or not they are fallers or have diabetes.

The differences in means for the five fall risk factors, while not statistically significant, may be clinically significant when combined to impact health and overall fall risk in an older homebound population, whether they are diabetic or whether they are diagnosed with other co-morbidities. A diabetic older adult with deficits in multiple areas of balance performance and confounding co-morbidities could benefit from earlier interventions designed to address subtle changes before they progress to a significant level that renders a person as homebound. These interventions could begin when diabetic adults are first referred for out-patient physical therapy. While diabetes is typically not the primary treatment diagnosis for this population, it is a common secondary diagnosis (Kirkness, Marcus, and LaStayo, 2008). A recent study based on primary physician records included 52,667 adults and identified 80% of them as having diabetes, pre-diabetes, or risk factors associated with diabetes, including hypertension, elevated body mass index, and elevated triglycerides, resulting in an overall incidence of 13.2 % of diabetes in this population (Kirkness et al, 2008). While estimates vary, the prevalence of those diagnosed with diabetes is believed by some to have increased 61% from 1990 to 2001, resulting in 6.9 million men and 9.8 million women being diagnosed (Mokdad, Ford, and Bowman, 2008). The prevalence of diabetes in the current study was 26.1 % of the total population of 284 participants. This is higher than the national averages of diabetes for several age categories (11.2 % for adults between 50-59 years of age, 15.1 % for adults between 60-69 years of age, and 15.5 % average

for adults over 70 years of age)(Mokdad et al, 2008). The prevalence of adult-onset diabetes in North Carolina has been reported at 7.6 % of the total adult population (Mokdad et al, 2008), which is lower than the 26.1 % prevalence found in this study with homebound residents. While diabetes is typically not a primary diagnostic code for adults receiving out-patient therapy, it is one of the top ten diagnostic codes for homebound older adults receiving home care in the Triad, which helps explain the high incidence in our study (CMS, 2002). As the prevalence of this condition increases in the general population, it is crucial for healthcare providers to recognize deficits that can impact balance and fall risk, especially in the Medicare population, preferably before the diabetic becomes homebound.

Summary of Secondary Findings

Further analysis of the data included exploration of the influence of gender and age on fall risk. Comparisons by gender failed to uncover significant effects for any of the five fall risk factors for either diagnostic group. The percentage of women in the diabetic group in this study was 56.76%, but was higher in the non-diabetic cohort (75.71 % female). Despite this difference in gender proportion, no significant differences in fall risk factors were identified for the two groups. This does not mimic findings in previous research that reported a higher fall rate for community dwelling older females than males (Stalenhoef et al, 2002). Being homebound may blur gender differences for fall risk due to co-morbidities, as previously mentioned.

Noting that the two youngest age categories contained a small number of participants, statistical analyses were repeated using only the three oldest age groups, but no statistical significance was identified. Converting the raw data into standardized z scores allowed comparison of all factors on a common scale, using units of standard deviation from the mean. Sensation and pain revealed the greatest differences between diagnostic groups, though small,

supporting the need for further research to identify the contribution of these factors in assessment of overall fall risk for diabetic homebound older adults.

Visual analysis of the means for the fall risk factors appeared to indicate interaction of age and diagnosis for all factors, excluding somatosensation. No statistically significant interaction was detected for any factor when comparing the three oldest age categories and diagnosis. While the sensory means for each diabetic age group revealed poorer somatosensation than the non-diabetics, no clear patterns emerged for the other factors. For pain, the oldest diabetic group reported the least amount of pain, while the youngest diabetic group reported the highest pain levels of any age group. The youngest diabetic age category (55-64 years of age) contained only 5 participants, but collectively displayed the poorest sensory scores, most pain, and lowest DGI and CTSIB scores of any diagnostic group in any age category. Only the 75-84 diabetic age group reported more fear of falling than this youngest group. The small sample size for the two youngest diabetic groups makes comparisons difficult. The 65-74 year old diabetic group (n = 17) performed much better than the youngest diabetic group, with the second highest scores for any group for the DGI and CTSIB and third highest for the MFES. The 75-84 year old diabetics (n = 32) showed variable performance with the best diabetic mean sensory score, but the second worst DGI and MFES scores of any group. The oldest diabetic group (n = 17), ages 85-98 years, also lacked a clear pattern with the least pain, second best MFES scores, and second poorest CTSIB performance.

Impact on Therapy Practices

Diabetic homebound older adults were hypothesized to be at a heightened fall risk when compared to the non-diabetic population in this study, but instead, the groups were equally impaired for most risk factors. Accurate identification and testing for fall risk factors for all homebound adults, including diabetics, are important steps toward improving the health and

decreasing fall risk, but should also be followed by effective treatment. A recent survey of fall prevention knowledge and practice patterns in home health physical therapists found that the majority of therapists actively seek to identify risk factors for falls among older patients (Peel et al, 2008). Areas identified that needed enhancements included: understanding the importance of certain key risk factors like strength and balance deficits, addressing identified risk factors with evidence based interventions, and recognizing when referral to other healthcare professionals is warranted (Peel et al, 2008). Therapists surveyed in this study did not list fear of falling or pain as identifiable risk factors for falls, which should be addressed in an effective treatment plan. Physical therapists are ideally positioned to provide thorough assessment and effective treatment for homebound Medicare population. In 2002, estimates of falls in Medicare beneficiaries were estimated at 3.7 million (single fall) to 3.1 million (recurrent falls), with 2.2 million people experiencing a medically injurious fall (Shumway-Cook et al, 2009). The prevalence of injurious falls is sure to increase as more of our adult population reaches Medicare age, making identification of fall risk factors essential for physical therapists working with older adults. Accurate identification of the impaired systems or components of systems may assist therapists in deciding how to treat the underlying disorders that lead to falls (Horak et al, 2009).

Including each risk factor within a multi-factoral approach to determining overall fall risk can help drive specific rehabilitation approaches that are more effective at improving overall postural control and decreasing falls (Horak et al, 2009). This type of 'systems model of motor control' would evaluate interacting components separately to identify differences and impairments that impact overall postural control (Horak, Shupert, and Mirka, 1989). Horak et al (2009) proposed that balance is comprised of biomechanical constraints, stability limits/verticality, anticipatory postural adjustments, postural responses, sensory orientation, and stability in gait. This conceptual framework that balance function can be divided into separate

underlying systems prompted the recent development of the BESTest (Balance Evaluation Systems Test, Horak et al, 2009). This evaluation system contains six sections that correspond with to a conceptual framework and test older adults using various tasks contributing to each category. For example, ankle and hip strength are two of the five items that test for Biomechanical Constraints (Section 1 of the BESTest). Early studies using the BESTest show excellent interrater reliability and strong agreement with balance confidence (r = .64) (Horak et al, 2009), though continued research is necessary to establish validity, sensitivity, and specificity, as well as shorten the test. The BESTest does not include measurement of pain, sensation, or fear of falling, but does include the m-CTSIB (Section V: Sensory Orientation) and items from the DGI (Section VI: Stability in Gait). BESTest scores did identify poorer performance in different subcategories when comparing healthy elderly (n=3) to those with Parkinson's disease (n=3), bilateral vestibular loss (n=3), unilateral vestibular loss (n=2), and peripheral neuropathy (n=1). The one participant with peripheral neuropathy in the BESTest study, a common diabetic complication, had higher scores overall than adults with Parkinson's or unilateral vestibular loss. This person also performed better than the control group on the m-CTSIB, which demonstrates that variability in balance performance in older adults. Dibble recently provided evidence that the collective interpretation of multiple clinical balance tests resulted in fewer false-negative results when examining fall risk in adults with Parkinson's disease (Dibble, Christensen, Ballard, and Foreman, 2008). Continued research aimed at identifying specific components of balance and fall risk for diabetic adults could be modeled similar to the BESTest and should include, at a minimum, the additional factor of sensory scores. This type of comprehensive assessment could be applied in all types of homebound adults, despite diagnosis.

Further research is needed to determine if pain and fear of falling are part of a "systems approach" to fall risk assessment for diabetic older adults. This type of assessment model could

also be helpful to the therapist in identifying the transition from vitality to frailty in homebound older adults, who are at risk for losing their independence due to falls, diseases such as diabetes or cancer, or disabilities (Hanke and Levi, 2009). The presence of frailty and co-morbidities that exist in homebound older adults could not be controlled in this study. Some of these co-morbidities that lead to frailty can also impact the vascular supply to the lower extremities, potentially influencing sensory nerve function and impairing sensation. Examples of these co-morbidities are cardiovascular disease and atherosclerosis. Several participants reported no pain (0 on a scale of 0-10) and displayed normal sensation (10 on a scale of 0-10), which could indicate a lack of sensitivity in the methods used to assess these areas. Improving the sensitivity of the pain examination could help clarify differences between diagnostic groups and is an area that home health agencies should explore. The addition of a pain questionnaire such as in the Leeds Assessment of Neuropathic Symptoms and Signs scale (Bennett, Smith, Torrance, and Potter, 2005, Cruccu and Truini, 2009) could be a more sensitive tool. The Leeds assessment is designed to identify neuropathic pain without the need for clinical examination and has correctly assessed pain in 80% of the cases (Bennett et al, 2005). The Neuropathic Pain Symptom Inventory has been tested with patients reporting diabetic neuropathy and includes descriptive terms for neuropathic pain such as burning, electric shocks and pins and needles (Crawford, Bouhassira, Wong, and Dukes, 2008). The Brief Pain Inventory has been described as a promising instrument for diabetics with neuropathic pain, dividing the 0-10 scale into mild, moderate, and severe categories of pain ratings (Zelman, Dukes, Brandenburg, Bostrom, and Gore, 2005, Backonja and Stacey, 2004). The ADA promotes a multifaceted approach to screening for neuropathy, utilizing pinprick testing, temperature and vibration perception, along with monofilament testing. They report a combination of more than one test with >87% sensitivity for detecting diabetic peripheral neuropathy (ADA, 2007).

Limitations

Several limitations impact the results of this study, many of which are inherent to studying homebound adults. The testing environment may have added variability to the results due to differences in the environment, time of day of testing, lighting, distractibility, or support surfaces. Some participants resided in assisted living facilities while others lived in individual homes, apartments, or temporary living arrangements with family members. Age-related differences have been found in children and the elderly in the ability to inhibit sensory stimuli by cortical structures in the brain, thus making it more difficult to discriminate between visual stimuli (Dustman, Emmerson, and Shearer, 1996). This lack of central control could impact balance if an older adult is trying to integrate varying levels of visual, sensory, and auditory stimulation. Homebound older adults must integrate stimulation from a wide range of sources, including low lighting, busy wallpaper, uneven walking surfaces, clutter on the floor, noisy traffic or phones. Falls may results from poor integration of these environmental challenges. While the variability in environment represented a challenge to the gathering of data, it was the ideal place for therapeutic interventions designed to prevent falls and was considered an acceptable limitation.

The home health referral process for Gentiva could have contributed to a lack of differences between groups. All participants were identified at the referral process as having Medicare coverage for services and as benefiting from physical therapy in the home, specifically the Safe Strides balance program. Homebound older adults identified for Safe Strides had one or more health indicators that qualified them for this balance program (history of falls, lower extremity weakness, recent hospitalization, etc.). Inclusion of all participants in this program could explain the lack of significant differences between fall risk factors in diabetic and non-diabetic older adults in the Safe Strides program, as all participants were at a high fall risk based

on their referral to home health. The additional diagnosis of diabetes, in combination with other co-morbidities and being homebound, did not differentiate the diabetic from non-diabetic potential fallers.

Testing reliability may have also contributed to the homogeneity of results for the two cohorts. Several different physical therapists performed testing on participants and though they received training from the same investigator, the nature of this retrospective design did not allow for reliability testing to be conducted with this group of therapists using these specific participants.

Methods of this study did not control for the length of time since diagnosis with diabetes. Some participants may have been newly diagnosed, while others may have been suffering from this disease for several years. This time factor may have significantly impacted sensory and pain scores due to the progression of neuropathy, which typically begins after at least 5 years of onset of diabetes. The prevalence of undiagnosed diabetes has been reported at 6.2 million cases in the United States, or almost 30% of all diabetes cases, in 2005 by the National Health and Nutrition Examination Surveys (NHANES, 2005). This alarmingly high percentage could mean that participants included in the non-diabetic group could actually have undiagnosed diabetes, which is more common in older adults over the age of 65 years of age. The presence of undiagnosed diabetics in the non-diabetic cohort could help explain the lack of significant difference between fall risk factors in these two groups. Diabetic risk factors were screened for participants in an attempt to avoid this type of misclassification. Other confounding variables, such as body mass index, types and number of medications, glucose control in the diabetic group, and psychological issues such as depression, were not controlled in this study, thus resulting in a more potentially homogeneous cohort.

Future studies involving homebound older adults may find significant differences in fall risk factors if the diabetic cohort and non-diabetic cohorts are both referred to general physical therapy, versus a specific balance program that already categorizes participants at a higher risk for falls. Including participants with all types of insurance coverage could also be a more accurate picture of all homebound older adults, not just those with Medicare Part A. Testing for undiagnosed pre-diabetes prior to data collection could also improve correct grouping of participants. Diabetic participants could also be categorized by length of time since diagnosis (0-5 years, 6-10 years, 11-15 years, etc.), which could be helpful in tracking the sensory changes that occur as this disease progresses and how those changes impact fall risk. Performing inter-rater and intra-rater reliability testing during data gathering in future studies could also be beneficial for prospective studies, though difficult for retrospective analysis. Despite the difficulties that accompany research in homebound populations, overcoming these challenges is an important step in understanding how to improve and maintain the health of our aging communities.

Conclusion

Identifying fall risk factors in homebound diabetic older adults presents a challenge to healthcare professionals, including physical therapists. Of the five risk factors studied, sensation on the soles of the feet represents the best differentiator between diabetics and non-diabetics who are homebound, supporting the use of monofilament testing in a comprehensive assessment of fall risk. Inclusion of this type of assessment early on in the progression of diabetes may help prevent the debilitating complications of ulceration, amputations, and injurious falls. Further research is needed to determine if pain, sensory integration, fear of falling, and balance can be measured with enough sensitivity to differentiate diabetics from non-diabetics in a homecare setting. The presence of multiple co-morbidities and advanced age in the homebound population may make it difficult to develop sensitive fall risk assessments that are disease-specific.

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APPENDIX A

AUTHORIZATION FOR RELEASE OF INFORMATION

I hereby authorize the use or disclosure of my individually identifiable health information as described below. I understand this authorization is voluntary. I understand if the organization authorized to receive the information is not a health plan or health care provider, the released information may no longer be protected by federal privacy regulations.

Patient name: _____ Patient number: _____

Persons/organizations providing this information: Gentiva Health Services

Persons/organizations receiving the information: Gentiva Local, Corporate staff or company agent responsible for post-discharge survey completion.

Specific description of information being released and purpose:
Patient name and medical record number, contact numbers, diagnosis, gender, age for the purpose of making post-discharge survey contacts. The survey purpose is to improve the quality of the Safe Strides Program by determining post-discharge clinical outcomes.

The health care provider must complete the following:

1. Will the health care provider requesting the authorization receive financial or in-kind compensation in exchange for using or disclosing the health information described above?
   YES _____ NO __X

The patient or the patient's representative must read and initial the following statements:

1. I understand that my health care treatment will not be affected if I do not sign this form. Initials: _____
2. I understand that I may view and copy the information described on this form at my request, and a copy of this form will be provided to me. Initials: _____

The patient or the patient's representative must read and initial the following statements:

1. I understand that this authorization will expire two years from the date below. Initials: _____
2. I understand that I may revoke this authorization at any time by notifying Gentiva Health Services in writing. The revocation will be effective upon receipt by Gentiva Health Services. Initials: _____

_____ _____
Signature of patient or patient's representative Date

Printed name of patient's representative: _____

Relationship to the patient: _____

*** YOU MAY REFUSE TO SIGN THIS AUTHORIZATION ***

APPENDIX B

CONSENT FOR TREATMENT

A photocopy of this authorization shall be as valid as the original.

GENTIVA®

Patient Name:_____ Patient #_____ Location #_____

Patient's Rights and Responsibilities

I have received, reviewed and understand my patient rights and responsibilities as provided to me by a Gentiva Health Services Representative.

Consent for Treatment

I consent to treatment from Gentiva Health Services consistent with my established plan of care. I confirm that I have been informed and have participated in planning the care and procedure (s) to be carried out by Gentiva Health Services and sign this consent willingly and voluntarily. I understand that this consent is valid from the date of the initial visit by Gentiva Health Services personnel and that I may withdraw my consent at any time by notice to Gentiva Health Services, and, if I do so, the services will not thereafter be provided. I understand that admission to and continuation of services are subject to Gentiva Health Services policies and procedures.

Notice of Services/Charges

Gentiva Health Services available from this provider include the following (check as appropriate):

- ☐ RN
- ☐ LPN/LVN
- ☐ Physical Therapy
- ☐ Medical Social Services
- ☐ Transportation
- ☐ Housekeeping (or Homemaker)
- ☐ Speech/Language Pathology
- ☐ Other_____
- ☐ Home Health Aide
- ☐ Nutritional Services
- ☐ Occupational Therapy
- ☐ Hospice Services

The services which Gentiva Health Services will provide for me are indicated below.

Services/Supplies	Expected Frequency & Duration	Payer	Expected Charge(s)	Expected* Patient Financial Responsibility**
			$ _____ per ____	$ _____ per ____
			$ _____ per ____	$ _____ per ____
			$ _____ per ____	$ _____ per ____
			$ _____ per ____	$ _____ per ____
			$ _____ per ____	$ _____ per ____
			$ _____ per ____	$ _____ per ____

*or financially responsible party, if other than patient.

** financial information is the best information available at this time and may change as more specific information becomes available from the patient or payer(s).

I understand that I am responsible to Gentiva Health Services for any/all charges not paid by a third party including any co-payments, deductibles, coinsurance, lifetime maximums, or charges for non covered services except where program requirements or contractual agreements hold me harmless (for example, Home Health Services billed to Medicare)unless prohibited by law.

I further understand that I will be held liable for payment if I fail to notify Gentiva if I disenroll from or become ineligible for coverage under my current payer(s).

If this presents a financial hardship, or if you have any questions or concerns, please do not hesitate to call us.

Authorization for Payment/Assignment of Insurance Benefits

I certify that the information provided by me is correct. I authorize my insurance company (ies) including as appropriate Medicare, Medicaid, TriCare and other governmental programs to furnish any agent of Gentiva Health Services any and all information pertaining to my insurance benefits and status of claims submitted by Gentiva Health Services.

I,_____ the insured, authorize payment directly to Gentiva Health Services for Medicare, Medicaid or other
PRINT NAME
government program benefits (as applicable) and other insurance benefits otherwise payable to me under Policy#_____.
In the event that my insurance carrier does not accept 'assignment of benefits', or any other payments are sent directly to me, I will hold them in trust for Gentiva Health Services for payment of my bill. I understand that I must promptly make payment for services by either personal check or by endorsing the insurance payment by writing " Pay to the order of Gentiva Health Services" and my signature.

Insured Signature ►_____ ☐ **Self Insured** ☐ **Relationship to Patient**_____

WHITE—CLINICAL RECORD
YELLOW—FINANCIAL FILE
PINK—PATIENT

HOME CARE CONSENT
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A photocopy of this authorization shall be as valid as the original.

GENTIVA®

Patient Name:_____ Patient #_____ Location #_____

Charges: This section ❒ **Does** ❒ **Does not apply in this case**

Holiday/Overtime

All charges for services rendered on holidays or rendered by the same individual, at my request, in excess of 40 hours during any work week will be one and one-half times the applicable weekday or weekend rate. In some states there are different wage and hour laws that may be applicable. Where state wages and hour law differs from federal law, state law (which provides for a richer benefit) shall be applicable. An example would be in the state of Arkansas, Nevada, and California, where charges for services rendered in excess of eight (8) hours in any workday (including holidays) will be paid at one and one half times the applicable rate.

Holidays are Thanksgiving Day, Christmas Day, New Year's Eve, New Year's Day, Fourth of July, Labor Day, Memorial Day and other local holidays as follows:

_____

All rates are subject to change with at least 2 weeks (or as required by applicable law) prior notice to me.

Mileage. Mileage ❒ will ❒ will not be billed at the rate of_____ per mile as recorded on employee time slips signed by the patient or patient's designee.

Deposit. I agree to pay simultaneously with the signing of the Agreement $_____ in the form of check number _____/ cash / credit card type_____card number_____
Expiration date_____ a deposit for services to be rendered. This deposit will be applied to Gentiva Health Service's first invoice of service.

Unanticipated Service Interruption. I understand Gentiva Health Services uses reasonable efforts to provide uninterrupted services, however, sometimes interruptions in service are unavoidable including but not limited to inclement weather or other natural disasters. During such unanticipated interruption of essential services, I agree to provide or arrange for backup care, or I agree that Gentiva Health Services may assist in arranging for transfer to an appropriate emergency facility.

Time Documents. I agree and acknowledge that time slips record the services provided and constitute the basis of billing. I authorize_____to sign time slips on my behalf.

Equipment. I agree that any leased, loaned or rented equipment received by me from Gentiva Health Services for my treatment remains the property of Gentiva Health Services. I agree to use and maintain the equipment as taught, and per the manufacturers guidelines and to return the equipment in good condition no later than ten days upon completion of therapy or when I am no longer receiving services from Gentiva. I understand that I will be responsible for the replacement cost of this equipment should this equipment be lost or not returned to Gentiva Health Services.

Hiring of Gentiva Health Services Employees. I understand that if I hire a Gentiva Health Services employee, I must give notice or pay a fee. I also understand I must give sixty (60) days notice prior to hiring the individual or pay 15% of the employee's annualized billing rate to Gentiva Health Services.

Termination. I understand I may terminate this Agreement by giving at least four (4) hours notice or as specified by regulation, whichever is greater. Additionally, Gentiva Health Services may terminate this Agreement by providing at least seventy-two (72) hours or such other minimum notice required by applicable state law, except for emergency terminations by either party for any reason. The obligations contained in sections/paragraphs related to the following shall survive such termination: Services/Charges, Authorization for Payment, Payment, Late Charges, and Overtime, Deposit, Hiring of Gentiva Health Services Employees, Equipment, and Authorization to Release Information.

Property Damages

In consideration for the health treatment being provided to me by Gentiva Health Services, I hereby release Gentiva Health Services, Inc., it subsidiaries and affiliates from any and all claims, demand, and causes of action involving any and all damages to my property except that caused solely by the negligence of Gentiva Health Services agents or employees acting within the scope of their employment.

Home Care Consent Addenda:

I have read, understand, and consent to services as described in the Home Care Consent Addendum (a) provided to me in conjunction with this Home Care Consent, as checked below:

- ☐ Patient Bill of Rights Addendum specific to the state of _____
- ☐ OASIS Statement of Patient Privacy Rights for Medicare/Medicaid patients (CMS form)
- ☐ Privacy Act Statement - Health Care Records
- ☐ OASIS Notice About Privacy for Patients Who Do Not Have Medicare/Medicaid Coverage (CMS form for non- Medicare/Medicaid patients whose services are subject to OASIS data collection through a Medicare certified/certifiable agency)
- ☐ Notice of Medicare Bundled Services
- ☐ Other State Notices (specify):_____
- ☐ Notice of Information and Privacy Practices

A photocopy of this authorization shall be as valid as the original.

GENTIVA®

Patient Name:_____ Patient #_____ Location #_____

Advance Directives

I have received and reviewed Advance Directives information specific to the state of _____.
I certify that I have read and received a copy of the Patient Rights and Advance Directives information specific to my state of residence and that I am the patient, or I am acting in the patient's behalf, and accept their terms.

❒ I have prepared an Advance directive regarding my healthcare Specify: _____

❒ I have not prepared an Advance Directive regarding my health care.

Authorization to Release Information

I consent to the release of information and/or disclosure to Gentiva Health Services of all or any part of my medical record by any physician, hospital, or other facility of which I have been a patient (except when services provided by Gentiva are not health related services, e.g., housekeeper or homemaker services), checking of my credit and financial rating and history with any person, firm or credit bureau if I may have any self-pay responsibility; and release of information by Gentiva Health Services to individuals acting in official capacities as my advocate, representing governmental or third party payers, governmental agencies, accrediting bodies or other health care providers involved in my care including any successors of Gentiva Health Services.

I hereby authorize the staff of Gentiva Health Services to disclose information related to my care to the following persons upon request:

Name and Relationship: _____ Name and Relationship_____

Name and Relationship: _____ Name and Relationship_____

Choice of Agency: Patient/Authorized Representative must select on of the following:

❒ I understand the services I will receive will be provided by an agency that DOES participate in the Medicare home health program and that services paid by Medicare (and some other payers) must be provided by this agency.

❒ I understand that the services I will receive will be provided by an agency that DOES NOT participate in the Medicare home health program and that any service I receive from this agency CANNOT be billed to Medicare now or at any time in the future. I am aware that a bill cannot be submitted to Medicare requesting a decision on coverage now or at any time in the future for services provided by the non-certified agency.

Signature: _____ Date: _____ Patient Name: _____ _____

(Patient or Authorized Representative Signature) **√If ❒ Power of Attorney** **(Applicable only if Authorized Representative signs for Patient)** **Relationship to Patient**

Gentiva Health Services
Representative Print Name (as witness):_____ Signature _____ Date:_____

If patient did not sign, please state the reason including patient's understanding that representative is signing.

_____

_____

Financially Responsible Party if other than Patient

I understand and agree that as the financially responsible party I am responsible to Gentiva Health Services for any/all charges not paid for by this patient or third parties including, but not limited to, any co-payments, deductibles, coinsurance, or any amount which exceeds but is not limited to lifetime maximums or for any charges for non-covered services. I also consent to the release of information and/or disclosure to Gentiva Health Services for checking of my credit and financial rating through a credit bureau.

Printed Name _____ Signature _____ SS#_____

Party Accepting Responsibility for Payment

Address_____ Phone # _____ Relationship to Patient _____

Signing in the capacity of: ❒ Parent ❒ Court appointed legal guardianship ❒ Health Care Proxy
❒ Other _____ *** A copy of proof to be provided and attached to form if available(except for Parent capacity)**

For Translations:

❒ This document was translated to patient/authorized representative into _____prior to signature.
(Language/Sign Language)

❒ This document was read to the patient verbatim/provided on an audio cassette and questions, if any were answered prior to signature.

Translated By (Signature/Title): _____Date:_____

Note: this document shall not be valid if altered in any way.

WHITE—CLINICAL RECORD
YELLOW—FINANCIAL FILE

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APPENDIX C

OASIS FORM

Comprehensive Adult Assessment,
485 P.O.C. Worksheet and Outcome and
Assessment Information Set (OASIS-B1, 1/2008)

COLOR KEY: GREEN Ink = OASIS Items; = PPS Indicators; T RED Ink = Specific 485 Items (completed per agency policy); BLACK Ink = Additional Comprehensive Assessment Items

START OF CARE VERSION - PHYSICAL THERAPY
Resumption of Care

Items to be used at this Time Point: M0080-M0826

EMPLOYEE TIME SLIP

☐ Cert. ☐ Non-Cert. | Location Name | Location No. | Client No.

Employee No. | Employee Name (Last, First) | T Patient Name (Last, First)

Pay/Bill Code | Shift | Date of Service (Month Day Year) | Service Time (Start / Stop) | Travel Time (Start / Stop) | Travel Duration | Mileage (Mileage / Bill Mileage ☐Yes ☐No)

Patient Time (Hrs Min) | Non-Billable Visit Duration (NBD) (Hrs Min) | Chart Time (Hrs Min) | Total Time (Hrs Min)

☐ Bill/Pay ☐ Bill ☐ Pay ☐ No Pay/No Bill ☐ Overtime
Override Bill Rates ☐ Yes ☐ No
Override Pay Rates ☐ Yes ☐ No

Payor Code	Bill Units	Pay Units	Bill Rate	Pay Rate	Product Category	Product Code

Supplies: Code / Quantity

Patient Signature: X _____ | Employee Signature | Approved by Initials/Date

CLINICAL RECORD ITEMS

2 Start of Care Date: month day year ___ ___ / ___ ___ / ___ ___ ___ ___

3 Certification Period: From: To:

24 Primary Referring Physician/Phone No.

(M0032) Resumption of Care Date: ☐ NA - Not Applicable — month day year ___ ___ / ___ ___ / ___ ___ ___ ___

Prior Admission this year? ☐ Yes ☐ No

(M0080) Discipline of Person Completing Assessment: ☐ 1-RN ☐ 3-SLP/ST ☐ 2-PT ☐ 4-OT

Secondary Physician's Name/Phone No.

Emergency Contact Name/Phone No.

DM (M0090) Date Assessment Completed: month day year ___ ___ / ___ ___ / ___ ___ ___ ___

DM (M0100) This Assessment is Currently Being Completed for the Following Reason: START/RESUMPTION OF CARE
☐ 1 - Start of care - further visits planned ☐ 3 - Resumption of care (after inpatient stay)

(M0110) Episode Timing: Is the Medicare home health payment episode for which this assessment will define a case mix group an "early" episode or a "later" episode in the patient's current sequence of adjacent Medicare home health payment episodes?
☐ 1 - Early ☐ 2 - Later ☐ UK - Unknown ☐ NA - Not Applicable: No Medicare case mix group to be defined by this assessment.

(M0150) Current Payment Sources for Home Care: (Mark all that apply)
☐ 0 - None; no charge for current services
☐ 1 - Medicare (traditional fee-for-service)
☐ 2 - Medicare (HMO/managed care)
☐ 3 - Medicaid (traditional fee-for-service)
☐ 4 - Medicaid (HMO/managed care)
☐ 5 - Workers' compensation
☐ 6 - Title programs (e.g., Title III, V, or XX)
☐ 7 - Other government (e.g., CHAMPUS, VA, etc.)
☐ 8 - Private insurance
☐ 9 - Private HMO/managed care
☐ 10 - Self-pay
☐ 11 - Other (specify) _____
☐ UK - Unknown

DEMOGRAPHICS AND PATIENT HISTORY

Ability of Patient to handle personal finances
☐ Independent ☐ Needs Assistance ☐ Totally Dependent

Comments

(M0175) From which of the following Inpatient Facilities was the patient discharged during the past 14 days? (Mark all that apply.)
☐ 1 - Hospital
☐ 2 - Rehabilitation facility
☐ 3 - Skilled nursing facility
☐ 4 - Other nursing home
☐ 5 - Other (specify) _____
☐ NA - Patient was not discharged from an inpatient facility [If NA, go to M0200]

Name of Hospital/Facility:

Comments

(M0180) Inpatient Discharge Date: (most recent): month day year ___ ___ / ___ ___ / ___ ___ ___ ___ ☐ UK - Unknown

(M0190) List each Inpatient Diagnosis and ICD-9-CM code at the level of highest specificity for only those conditions treated during an inpatient stay within the last 14 days (no surgical, E-codes, or V-codes):

Inpatient Facility Diagnosis	ICD-9-CM	Inpatient Facility Diagnosis	ICD-9-CM
a.	(___ ___ . ___)	b.	(___ ___ . ___)

(M0200) Medical or Treatment Regimen Change Within Past 14 Days: Has this patient experienced a change in medical or treatment regimen (e.g., medication, treatment, or service change due to new or additional diagnosis, etc.) within the last 14 days?
☐ 0 - No [If No, go to M0220] ☐ 1 - Yes

WHITE - Clinical YELLOW - Billing PINK - Employee

DM = Outcome Measure Indicator

SOC - Physical Therapy

Form# GCL1363 (Rev. 04/09)

Patient Name (First, MI, Last) | Client No.

DEMOGRAPHICS AND PATIENT HISTORY (continued)

(M0210) List the patient's **Medical Diagnoses** and ICD-9-CM codes at the level of highest specificity for those conditions requiring changed medical or treatment regimen (no surgical, E-codes, or V-codes):

Changed Medical Regimen Diagnosis	ICD-9-CM	Changed Medical Regimen Diagnosis	ICD-9-CM
a.	(____.__)	c.	(____.__)
b.	(____.__)	d.	(____.__)

(M0220) Conditions Prior to Medical or Treatment Regimen Change or Inpatient Stay Within Past 14 Days: If this patient experienced an inpatient facility discharge or change in medical or treatment regimen within the past 14 days, indicate any conditions which existed prior to the inpatient stay or change in medical or treatment regimen. **(Mark all that apply.)**

- ☐ 1 - Urinary incontinence
- ☐ 2 - Indwelling/suprapubic catheter
- ☐ 3 - Intractable pain
- ☐ 4 - Impaired decision-making
- ☐ 5 - Disruptive or socially inappropriate behavior
- ☐ 6 - Memory loss to the extent that supervision required
- ☐ 7 - None of the above
- ☐ NA - No inpatient facility discharge and no change in medical or treatment regimen in past 14 days
- ☐ UK - Unknown

Significant Past Health History/Surgical Procedures

(M0230/240/246) Diagnoses, Severity Index, and Payment Diagnoses: List each diagnosis for which the patient is receiving home care (Column 1) and enter its ICD-9-CM code at the level of highest specificity (no surgical/procedure codes) (Column 2). Rate each condition (Column 2) using the severity index. (Choose one value that represents the most severe rating appropriate for each diagnosis.) V codes (for M0230 or M0240) or E codes (for M0240 only) may be used. ICD-9-CM sequencing requirements must be followed if multiple coding is indicated for any diagnoses. If a V code is reported in place of a case mix diagnosis, then optional item M0246 Payment Diagnoses (Columns 3 and 4) may be completed. A case mix diagnosis is a diagnosis that determines the Medicare PPS case mix group.

Code each row as follows:

(Column 1): Enter the description of the diagnosis.

(Column 2): Enter the ICD-9-CM code for the diagnosis described in Column 1; Rate the severity of the condition listed in Column 1 using the following scale:
- 0 - Asymptomatic, no treatment needed at this time
- 1 - Symptoms well controlled with current therapy
- 2 - Symptoms controlled with difficulty, affecting daily functioning; patient needs ongoing monitoring
- 3 - Symptoms poorly controlled; patient needs frequent adjustment in treatment and dose monitoring
- 4 - Symptoms poorly controlled; history of re-hospitalizations

(Column 3): *(OPTIONAL)* If a V code reported in any row in Column 2 is reported in place of a case mix diagnosis, list the appropriate case mix diagnosis (the description and the ICD-9-CM code) in the same row in Column 3. Otherwise, leave Column 3 blank in that row.

(Column 4): *(OPTIONAL)* If a V code in Column 2 is reported in place of a case mix diagnosis that requires multiple diagnosis codes under ICD-9-CM coding guidelines, enter the diagnosis descriptions and the ICD-9-CM codes in the same row in Columns 3 and 4. For example, if the case mix diagnosis is a manifestation code, record the diagnosis description and ICD-9-CM code for the underlying condition in Column 3 of that row and the diagnosis description and ICD-9-CM code for the manifestation in Column 4 of that row. Otherwise, leave Column 4 blank in that row.

(M0230) Primary Diagnosis & (M0240) Other Diagnoses		(M0246) Case Mix Diagnoses (OPTIONAL)	
Column 1	**Column 2**	**Column 3**	**Column 4**
	ICD-9-CM and severity rating for each condition	Complete only if a V code in Column 2 is reported in place of a case mix diagnosis.	Complete only if the V code in Column 2 is reported in place of a case mix diagnosis that is a multiple coding situation (e.g., a manifestation code).
Description	ICD-9-CM/Severity Rating	Description/ICD-9-CM	Description/ICD-9-CM
11 (M0230) Primary Diagnosis	**(V codes are allowed)**	**(V or E codes NOT allowed)**	**(V or E codes NOT allowed)**
a. Date: O/E	a. (____.__) ☐0 ☐1 ☐2 ☐3 ☐4	a. (____.__)	a. (____.__)
13 (M0240) Other Diagnoses	**(V or E codes are allowed)**	**(V or E codes NOT allowed)**	**(V or E codes NOT allowed)**
b. Date: O/E	b. (____.__) ☐0 ☐1 ☐2 ☐3 ☐4	b. (____.__)	b. (____.__)
c. Date: O/E	c. (____.__) ☐0 ☐1 ☐2 ☐3 ☐4	c. (____.__)	c. (____.__)
d. Date: O/E	d. (____.__) ☐0 ☐1 ☐2 ☐3 ☐4	d. (____.__)	d. (____.__)
e. Date: O/E	e. (____.__) ☐0 ☐1 ☐2 ☐3 ☐4	e. (____.__)	e. (____.__)
f. Date: O/E	f. (____.__) ☐0 ☐1 ☐2 ☐3 ☐4	f. (____.__)	f. (____.__)
12 Surgical Diagnosis			
a. Date: O/E		a. (____.__)	☐0 ☐1 ☐2 ☐3 ☐4
b. Date: O/E		b. (____.__)	☐0 ☐1 ☐2 ☐3 ☐4

(M0250) Therapies the patient receives at home: **(Mark all that apply.)**
- ☐ 1 - **Intravenous or infusion therapy (excludes TPN)**
- ☐ 2 - **Parenteral nutrition (TPN or lipids)**
- ☐ 3 - **Enteral nutrition (nasogastric, gastrostomy, jejunostomy, or any other artificial entry into the alimentary canal)**
- ☐ 4 - None of the above

Comments / Interventions

(M0260) Overall Prognosis: BEST description of patient's overall prognosis for recovery from this episode of illness
- ☐ 0 - Poor: little or no recovery is expected and/or further decline is imminent
- ☐ 1 - Good/Fair: partial to full recovery is expected
- ☐ UK - Unknown

Comments

28 PROGNOSIS: ☐ Poor ☐ Guarded ☐ Fair ☐ Good ☐ Excellent

(M0270) Rehabilitative Prognosis: BEST description of patient's prognosis for functional status
- ☐ 0 - Guarded: minimal improvement in functional status is expected; decline is possible
- ☐ 1 - Good: marked improvement in functional status is expected
- ☐ UK - Unknown

Comments

NSS - Non Routine Supply Indicator

SOC - Physical Therapy

DEMOGRAPHICS AND PATIENT HISTORY (continued)

(M0290) Life Expectancy: (Physician documentation is not required.)
☐ 0 - Life expectancy is greater than 6 months
☐ 1 - Life expectancy is 6 months or fewer

Advance Directives: ☐ Yes ☐ No
Specify: _____

(M0290) High Risk Factors characterizing this patient: **(Mark all that apply.)**
☐ 1 - Heavy smoking ☐ 3 - Alcohol dependency ☐ 5 - None of the above
☐ 2 - Obesity ☐ 4 - Drug dependency ☐ UK - Unknown

Comments

LIVING ARRANGEMENTS

(M0330) Current Residence:
☐ 1 - Patient's owned or rented residence (house, apartment, or mobile home owned or rented by patient/couple/significant other)
☐ 2 - Family member's residence
☐ 3 - Boarding home or rented room
☐ 4 - Board and care or assisted living facility
☐ 5 - Other (specify) _____

Comments

21 **HOME ENVIRONMENT/SAFETY INTERVENTIONS:**

Assess:
☐ Architectural Barriers
☐ Patient Safety Awareness

Instruct:
☐ Home Safety Measures ☐ Other _____
☐ Fall Prevention

Additional Orders (Specify): _____

19 **SAFETY MEASURES:** ☐ Bathroom ☐ Electrical ☐ Medication ☐ Fire ☐ Environmental ☐ HME Other: (specify) _____

HOME ENVIRONMENT:				SAFETY AWARENESS:	
Steps/Stairs	☐ N/A	☐ Inside	☐ Outside	☐ Yes	☐ No
Railing	☐ N/A	☐ Inside	☐ Outside	☐ Yes	☐ No
Chair Lift	☐ N/A	☐ Inside	☐ Outside	☐ Yes	☐ No
Ramps	☐ N/A	☐ Inside	☐ Outside	☐ Yes	☐ No
Elevator	☐ N/A	☐ Inside	☐ Outside	☐ Yes	☐ No
Scatter Rugs	☐ N/A	☐ Yes	☐ No	☐ Yes	☐ No
Cords	☐ N/A	☐ Yes	☐ No	☐ Yes	☐ No
Doorways	☐ N/A	☐ Yes	☐ No	☐ Yes	☐ No
Furniture	☐ N/A	☐ Yes	☐ No	☐ Yes	☐ No

Oxygen related fire risk? ☐ Yes ☐ No Oxygen fire prevention measures? ☐ Yes ☐ No
Tub room _____ Fall risk? ☐ Yes ☐ No Fall prevention measures? ☐ Yes ☐ No
Pressure ulcer risk? ☐ Yes ☐ No Pressure ulcer prevention measures? ☐ Yes ☐ No

Is home safe/appropriate for home care? ☐ Yes ☐ No If no, explain and notify Clinical Manager (including follow-up) _____

Comments

EMERGENCY / DISASTER PLAN: **Disaster Priority Code** _____

Comments

I. Patients who require skilled interventions that must be provided as scheduled.
II. Patients requiring a moderate level of skilled care that should be provided the day scheduled, if possible, but the patient would not be at risk or in discomfort.
III. Patients who can safely miss scheduled visits

Has an effective **Home Escape Route** been established? ☐ Yes ☐ No Explain: _____

Does the Pt/Cg have an **Evacuation Plan?** ☐ Yes ☐ No Explain: _____

(M0340) Patient Lives With: (Mark all that apply.)
☐ 1 - Lives alone
☐ 2 - With spouse or significant other
☐ 3 - With other family member
☐ 4 - With a friend
☐ 5 - With paid help (other than home care agency staff)
☐ 6 - With other than above

Marital Status: ☐ Single ☐ Married ☐ Divorced ☐ Widowed

Religious/Cultural Issues and Significance _____

Suspected Abuse/Neglect, i.e.: *(Please circle)*
unexplained bruises, inadequate food, fearful of family member, c/g exploitation of funds, sexual abuse, neglect, left unattended if needs constant supervision. Other: _____

Comments

SUPPORTIVE ASSISTANCE

(M0350) Assisting Person(s) Other than Home Care Agency Staff: (Mark all that apply.)
☐ 1 - Relatives, friends, or neighbors living outside the home
☐ 2 - Person residing in the home (EXCLUDING paid help)
☐ 3 - Paid help
☐ 4 - None of the above **(If None of the above, go to M0390)**
☐ UK - Unknown **(If Unknown, go to M0390)**

Comments

(M0360) Primary Caregiver taking lead responsibility for providing or managing the patient's care, providing the most frequent assistance, etc. (other than home care agency staff):
☐ 0 - No one person **(If No one person, go to M0390)**
☐ 1 - Spouse or significant other
☐ 2 - Daughter or son
☐ 3 - Other family member
☐ 4 - Friend or neighbor or community or church member
☐ 5 - Paid help
☐ UK - Unknown **(If Unknown, go to M0390)**

Comments

(M0370) How Often does the patient receive assistance from the primary caregiver?
☐ 1 - Several times during day and night
☐ 2 - Several times during day
☐ 3 - Once daily
☐ 4 - Three or more times per week
☐ 5 - One to two times per week
☐ 6 - Less often than weekly
☐ UK - Unknown

Comments

3
113

Patient Name (First, M, Last) | Client No.

SUPPORTIVE ASSISTANCE (continued)

(M0380) Type of Primary Caregiver Assistance: (Mark all that apply.)

- ☐ 1 - ADL assistance (e.g., bathing, dressing, toileting, bowel/bladder, eating/feeding)
- ☐ 2 - IADL assistance (e.g., meds, meals, housekeeping, laundry, telephone, shopping, finances)
- ☐ 3 - Environmental support (housing, home maintenance)
- ☐ 4 - Psychosocial support (socialization, companionship, recreation)
- ☐ 5 - Advocates or facilitates patient's participation in appropriate medical care
- ☐ 6 - Financial agent, power of attorney, or conservator of finance
- ☐ 7 - Health care agent, conservator of person, or medical power of attorney
- ☐ UK - Unknown

Caregiver: ☐ Willing ☐ Able ☐ Available

Primary Caregiver Name: ____________

Relationship: ☐ Spouse ☐ Other ____________

Phone (if different than patient) ____________

Comments ____________

SENSORY STATUS

(M0390) Vision with corrective lenses if the patient usually wears them:

- ☐ 0 - Normal vision: sees adequately in most situations; can see medication labels, newsprint.
- ☐ 1 - **Partially impaired: cannot see medication labels or newsprint, but can see obstacles in path, and the surrounding layout; can count fingers at arm's length.**
- ☐ 2 - **Severely impaired: cannot locate objects without hearing or touching them or patient nonresponsive.**

☐ Glasses ☐ Glaucoma ☐ Cataracts ☐ Contacts: R L ☐ Blurred/Double Vision ☐ Other ____________

Comments ____________

(M0400) Hearing and Ability to Understand Spoken Language in patient's own language (with hearing aids if the patient usually uses them):

- ☐ 0 - No observable impairment. Able to hear and understand complex or detailed instructions and extended or abstract conversation.
- ☐ 1 - With minimal difficulty, able to hear and understand most multi-step instructions and ordinary conversation. May need occasional repetition, extra time, or louder voice.
- ☐ 2 - Has moderate difficulty hearing and understanding simple, one-step instructions and brief conversation; needs frequent prompting or assistance.
- ☐ 3 - Has severe difficulty hearing and understanding simple greetings and short comments. Requires multiple repetitions, restatements, demonstrations, additional time.
- ☐ 4 - Unable to hear and understand familiar words or common expressions consistently, or patient nonresponsive.

Comments ____________

EARS / NOSE / THROAT Hearing Loss? ☐ L ☐ R Ear Pain? ☐ L ☐ R Tinnitus? ☐ L ☐ R Aid Used? ☐ L ☐ R

Other ____________

OM **(M0410) Speech and Oral (Verbal) Expression of Language** (in patient's own language):

- ☐ 0 - Expresses complex ideas, feelings, and needs clearly, completely, and easily in all situations with no observable impairment.
- ☐ 1 - Minimal difficulty in expressing ideas and needs (may take extra time; makes occasional errors in word choice, grammar or speech intelligibility; needs minimal prompting or assistance).
- ☐ 2 - Expresses simple ideas or needs with moderate difficulty (needs prompting or assistance, errors in word choice, organization or speech intelligibility). Speaks in phrases or short sentences.
- ☐ 3 - Has severe difficulty expressing basic ideas or needs and requires maximal assistance or guessing by listener. Speech limited to single words or short phrases.
- ☐ 4 - Unable to express basic needs even with maximal prompting or assistance but is not comatose or unresponsive (e.g., speech is nonsensical or unintelligible).
- ☐ 5 - Patient nonresponsive or unable to speak.

Comments ____________

MUSCULOSKELETAL STATUS / PHYSICAL THERAPY ASSESSMENT

STRENGTH GRADES: N (5) = NORMAL G (4) = GOOD F (3) = FAIR P (2) = POOR T (1) = TRACE 0 = ZERO ROM GRADES or WNL/WFL

MUSCLE STRENGTH & ROM			PROM		AROM		STRENGTH		Comments
			Right	Left	Right	Left	Right	Left	
SHOULDER:	Flexion	0-180							
	Extension	0-50							
	Abduction	0-180							
	Adduction	0-45							
	Int. Rot.	0-70							
	Ext. Rot.	0-90							
ELBOW:	Flexion	0-145							
	Extension	0-0							
HIP:	SLR	0-90							
	Flexion	0-120							
	Extension	0-25							
	Abduction	0-45							
	Adduction	0-30							
	Int. Rot.	0-45							
	Ext. Rot.	0-45							
KNEE:	Flexion	0-135							
	Extension	0-0							
ANKLE:	Dorsiflex	0-20							
	Plantarflex	0-50							
	Inversion	0-35							
	Eversion	0-20							

MUSCULOSKELETAL STATUS / PHYSICAL THERAPY ASSESSMENT (continued)

FUNCTIONAL BALANCE

☐ WNL Describe: (Static, Dynamic-Sitting, Standing) Comments

POSTURE & COORDINATION

☐ WNL Describe: Comments

SYMMETRY AND DEFORMITIES

☐ WNL Describe: Comments

TONE

☐ WNL Describe: Comments

ENDURANCE/TOLERANCE TO ACTIVITIES

☐ WNL ☐ Good ☐ Fair ☐ Poor Comments

JOINTS

☐ No Deficit ☐ Enlarged ☐ Warm/Red ☐ Painful ☐ Stiff Comments

SENSATION/PERCEPTION/PROPRIOCEPTION

☐ WNL Describe: Comments

21 MUSCULOSKELETAL INTERVENTIONS:

Assess:
- ☐ Balance/Posture/Coordination
- ☐ Tone/Spasticity of
- ☐ Endurance/Tolerance to activity

Perform:
- ☐ Muscle retraining/body mechanics
- ☐ Balance and coordination training/retraining

Instruct:
- ☐ Posture/body mechanics
- ☐ HEP

Additional Orders (Specify):

Observation and assessment related to recent changes:

22 EQUIPMENT INTERVENTIONS:

Assess:
- ☐ Equipment Needs
- ☐ Adaptive Equipment

Perform:
- ☐ W/C Measurements/Fittings
- ☐ Prosthetic/Orthotic training
- ☐ Request HME

Instruct:
- ☐ Use of assistive devices/orthotics
- ☐ Home use of HME:
- ☐ Home use of CPM

Additional Orders (Specify):

KEY: IND = Independent SB/CG = Stand-by/Contact Guard MIN A = Minimum Assist MOD A = Moderate Assist MAX A = Maximum Assist NT = Not Tested

FUNCTIONAL ABILITIES: Assistive Device Distance NUMBER OF STAIRS RAILS: ☐ Yes ☐ No

	IND	SB/CG	MIN A	MOD A	MAX A	DEPENDENT	NT	ASSISTIVE DEVICE	Comments
Transfer:									
bed mobility									
in/out of bed									
bed to chair									
in/out chair									
toilet/commode									
bath/shower									
in/out of car									
sit to stand									
other									
Propels W/C On:									
level surface									
uneven surface									
ramps									
W/C Management:									
brakes									
foot/leg rests									
Ambulation On:									
level/smooth									
carpet									
uneven surfaces									
ramps									
steps/curbs									
stairs with rails									
stairs without rails									

Gait Analysis Comments: (Distances, Assistive Device, Weight-Bearing, Pattern, Deviations, Posture, Orthotics, Prosthetics)

23A FUNCTIONAL LIMITATIONS:
- ☐ Amputation
- ☐ Bowel/Bladder Incontinence
- ☐ Contracture
- ☐ Hearing
- ☐ Pain
- ☐ Paralysis
- ☐ Dyspnea with exertion
- ☐ Endurance
- ☐ Ambulation
- ☐ Vision
- ☐ Speech
- ☐ Legally Blind
- ☐ Other (specify):

Comments

SOC - Physical Therapy

Patient Name (First, MI, Last) | Client No.

MUSCULOSKELETAL STATUS / PHYSICAL THERAPY ASSESSMENT (continued)

[GG] ACTIVITIES PERMITTED:

☐ Complete Bed Rest ☐ Bed Rest with BRP ☐ Transfer Bed/Chair ☐ Up as Tolerated ☐ Exercises Prescribed
☐ Partial Weight Bearing ☐ Wheelchair ☐ Walker ☐ Cane ☐ Crutches
☐ Independent at Home ☐ No Restrictions ☐ Other: _____

[O] MUSCULOSKELETAL INTERVENTIONS:

Assess:	Perform:	Instruct:	
☐ Bed Mobility	☐ Functional Mobility Training	☐ Positioning	☐ WBAT on _____ extremity
☐ Transfers	☐ Bed Mobility	☐ Energy Conservation	☐ FWB on _____ extremity
☐ Wheelchair use	☐ Transfer Training	☐ NWB on _____ extremity	Additional Orders (Specify): _____
☐ Gait on Level Surfaces	☐ Wheelchair Training	☐ TDWB on _____ extremity	
☐ Gait on Stairs/Uneven Surfaces	☐ Gait Training	☐ PWB on _____ extremity	
☐ Weight Bearing Status	☐ Gait on Stairs/Uneven Surfaces		

Observation and assessment related to recent changes: _____

[GG] **(M0430) Frequency of Pain** interfering with patient's activity or movement:

☐ 0 - Patient has no pain or pain does not interfere with activity or movement ☐ 1 - Less often than daily ☐ 2 - Daily, but not constantly ☐ 3 - All of the time

Location: _____
Onset Date: _____
Pain precipitated by: _____
Pain duration: _____
Pain relieved by: _____
History of pain management: _____
Current pain management & effectiveness: _____
Pain site assessment: _____

PAIN PROFILE _____

Intensity: 0 (LOW) 1 2 3 4 5 6 7 8 9 10 (WORST)

[O] Pain Management Interventions: Assess/Perform/Instruct P/I/C

	A	P	I
☐ _____	☐	☐	☐
☐ _____	☐	☐	☐
☐ _____	☐	☐	☐
☐ Heat/Ice to _____	☐	☐	☐
☐ TENS to _____	☐	☐	☐
☐ Ultrasound to _____ at _____ for _____	☐	☐	☐

Additional Orders (Specify): _____

Comments: _____

(M0433) Intractable Pain: Is the patient experiencing pain that is not easily relieved, occurs at least daily, and affects the patient's sleep, appetite, physical or emotional energy, concentration, personal relationships, emotions, or ability or desire to perform physical activity?

☐ 0 - No ☐ 1 - Yes

Comments: _____

INTEGUMENTARY STATUS

OPEN WOUNDS ARE DOCUMENTED ON WOUND ASSESSMENT ADDENDUM ☐ See Wound Assessment Addendum

Additional Assessment Findings: _____

[O] **(M0440)** Does this patient have a **Skin Lesion** or an **Open Wound**? This excludes "DISTURBED."

☐ 0 - No **(If No, go to M0460)** ☐ 1 - Yes

Comments: _____

(M0445) Does this patient have a **Pressure Ulcer**?

☐ 0 - No **(If No, go to M0465)** ☐ 1 - Yes

Comments: _____

[GG] **(M0450) Current Number of Pressure Ulcers at Each Stage:** (Circle one response for each stage.)

Pressure Ulcer Stages	Number of Pressure Ulcers				
a) Stage 1: Nonblanchable erythema of intact skin; the heralding of skin ulceration. In darker-pigmented skin, warmth, edema, hardness, or discolored skin may be indicators.	0	1	2	3	4 or more
b) Stage 2: Partial thickness skin loss involving epidermis and/or dermis. The ulcer is superficial and presents clinically as an abrasion, blister, or shallow crater.	0	1	2	3	4 or more
c) Stage 3: Full-thickness skin loss involving damage or necrosis of subcutaneous tissue which may extend down to, but not through, underlying fascia. The ulcer presents clinically as a deep crater with or without undermining of adjacent tissue.	0	1	2	3	4 or more
d) Stage 4: Full-thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures (e.g., tendon, joint capsule, etc.)	0	1	2	3	4 or more
e) In addition to the above, is there at least one pressure ulcer that cannot be observed due to the presence of eschar or a nonremovable dressing, including casts? ☐ 0 - No ☐ 1 - Yes					

Comments: _____

(M0460) Stage of Most Problematic (Observable) Pressure Ulcer:

☐ 1 - Stage 1 ☐ 2 - Stage 2 ☐ 3 - Stage 3 ☐ 4 - Stage 4
☐ NA - No observable pressure ulcer

Comments: _____

(M0464) Status of Most Problematic (Observable) Pressure Ulcer:

☐ 1 - Fully granulating ☐ 3 - Not healing
☐ 2 - Early/partial granulation ☐ NA - No observable pressure ulcer

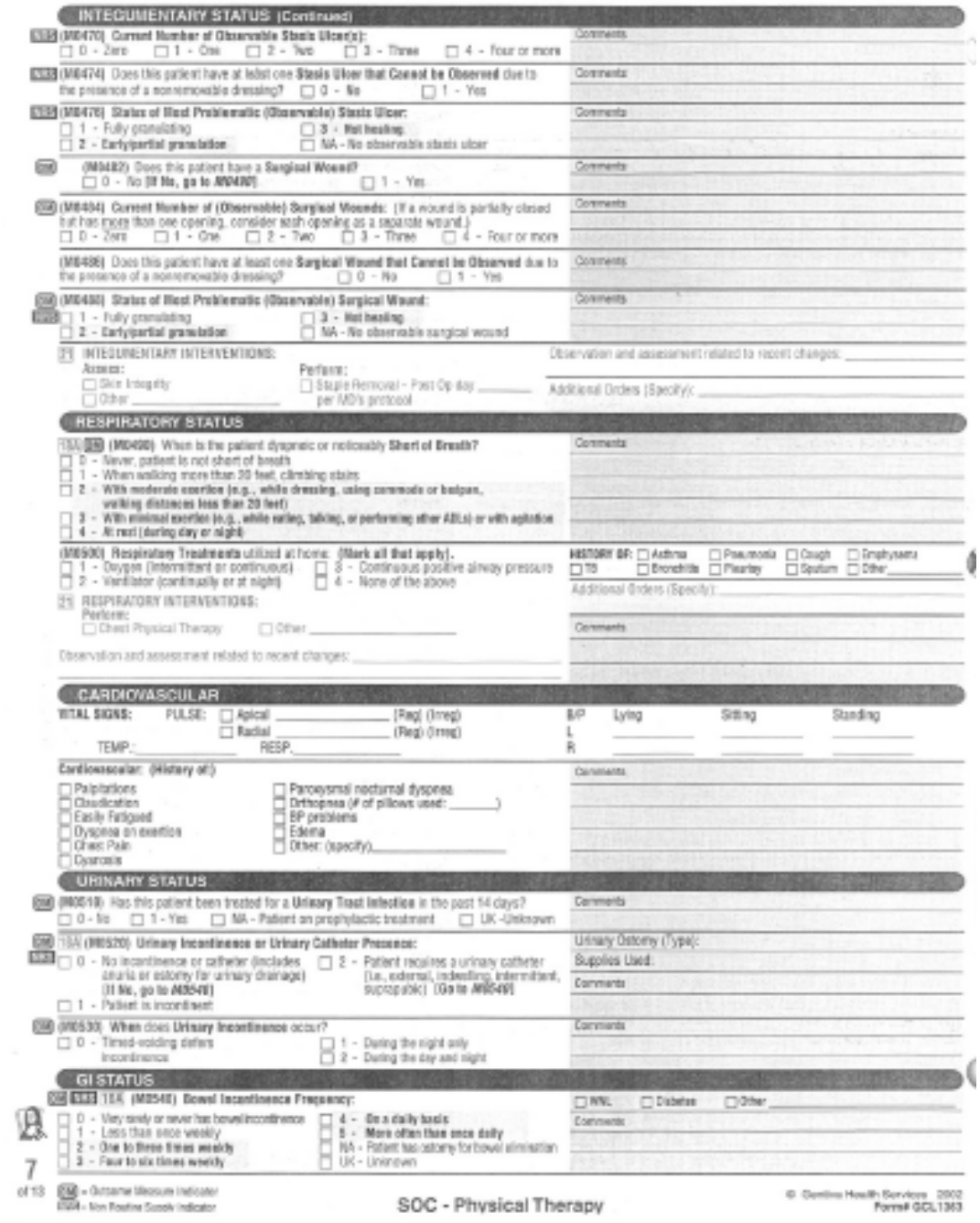
Comments: _____

(M0468) Does this patient have a **Stasis Ulcer**?

☐ 0 - No **(If No, go to M0482)** ☐ 1 - Yes

Comments: _____

[GG] – Outcome Measure Indicator
[O] – Non Routine Supply Indicator



INTEGUMENTARY STATUS (Continued)

(M0470) Current Number of Observable Stasis Ulcer(s): ☐ 0 - Zero ☐ 1 - One ☐ 2 - Two ☐ 3 - Three ☐ 4 - Four or more

(M0474) Does this patient have at least one Stasis Ulcer that Cannot be Observed due to the presence of a non-removable dressing? ☐ 0 - No ☐ 1 - Yes

(M0476) Status of Most Problematic (Observable) Stasis Ulcer: ☐ 1 - Fully granulating ☐ 2 - Early/partial granulation ☐ 3 - Not healing ☐ NA - No observable stasis ulcer

(M0482) Does this patient have a Surgical Wound? ☐ 0 - No (If No, go to M0490) ☐ 1 - Yes

(M0484) Current Number of (Observable) Surgical Wounds: (If a wound is partially closed but has more than one opening, consider each opening as a separate wound.) ☐ 0 - Zero ☐ 1 - One ☐ 2 - Two ☐ 3 - Three ☐ 4 - Four or more

(M0486) Does this patient have at least one Surgical Wound that Cannot be Observed due to the presence of a non-removable dressing? ☐ 0 - No ☐ 1 - Yes

(M0488) Status of Most Problematic (Observable) Surgical Wound: ☐ 1 - Fully granulating ☐ 2 - Early/partial granulation ☐ 3 - Not healing ☐ NA - No observable surgical wound

Comments

21 INTEGUMENTARY INTERVENTIONS: Assess: ☐ Skin Integrity ☐ Other _____ Perform: ☐ Staple Removal - Post Op day _____ per MD's protocol

Observation and assessment related to recent changes: _____

Additional Orders (Specify): _____

RESPIRATORY STATUS

(M0490) When is the patient dyspneic or noticeably Short of Breath? ☐ 0 - Never, patient is not short of breath ☐ 1 - When walking more than 20 feet, climbing stairs ☐ 2 - With moderate exertion (e.g., while dressing, using commode or bedpan, walking distances less than 20 feet) ☐ 3 - With minimal exertion (e.g., while eating, talking, or performing other ADLs) or with agitation ☐ 4 - At rest (during day or night)

(M0500) Respiratory Treatments utilized at home: (Mark all that apply). ☐ 1 - Oxygen (intermittent or continuous) ☐ 2 - Ventilator (continually or at night) ☐ 3 - Continuous positive airway pressure ☐ 4 - None of the above

HISTORY OF: ☐ Asthma ☐ Pneumonia ☐ Cough ☐ Emphysema ☐ TB ☐ Bronchitis ☐ Pleurisy ☐ Sputum ☐ Other: _____

Additional Orders (Specify): _____

21 RESPIRATORY INTERVENTIONS: Perform: ☐ Chest Physical Therapy ☐ Other _____

Observation and assessment related to recent changes: _____

Comments

CARDIOVASCULAR

VITAL SIGNS: PULSE: ☐ Apical _____ (Reg) (Irreg) ☐ Radial _____ (Reg) (Irreg) TEMP.: _____ RESP.: _____

B/P	Lying	Sitting	Standing
L			
R			

Cardiovascular: (History of:) ☐ Palpitations ☐ Claudication ☐ Easily Fatigued ☐ Dyspnea on exertion ☐ Chest Pain ☐ Cyanosis ☐ Paroxysmal nocturnal dyspnea ☐ Orthopnea (# of pillows used: _____) ☐ BP problems ☐ Edema ☐ Other: (specify) _____

Comments

URINARY STATUS

(M0510) Has this patient been treated for a Urinary Tract Infection in the past 14 days? ☐ 0 - No ☐ 1 - Yes ☐ NA - Patient on prophylactic treatment ☐ UK -Unknown

(M0520) Urinary Incontinence or Urinary Catheter Presence: ☐ 0 - No incontinence or catheter (includes ostomy for urinary drainage) (If No, go to M0540) ☐ 1 - Patient is incontinent ☐ 2 - Patient requires a urinary catheter (i.e., external, indwelling, intermittent, suprapubic) (Go to M0490)

Urinary Ostomy (Type): _____

Supplies Used: _____

Comments

(M0530) When does Urinary Incontinence occur? ☐ 0 - Timed-voiding defers incontinence ☐ 1 - During the night only ☐ 2 - During the day and night

Comments

GI STATUS

(M0540) Bowel Incontinence Frequency: ☐ 0 - Very rarely or never has bowel incontinence ☐ 1 - Less than once weekly ☐ 2 - One to three times weekly ☐ 3 - Four to six times weekly ☐ 4 - On a daily basis ☐ 5 - More often than once daily ☐ NA - Patient has ostomy for bowel elimination ☐ UK - Unknown

☐ IVNL ☐ Diabetes ☐ Other _____

Comments

M = Outcome Measure Indicator; NQI = Non Routine Quality Indicator

SOC - Physical Therapy

Form# GCL1363

GI STATUS (continued)

(M0560) **Ostomy for Bowel Elimination:** Does this patient have an ostomy for bowel elimination that (within the last 14 days): a) was related to an inpatient facility stay, or b) necessitated a change in medical or treatment regimen?

- 0 - Patient does not have an ostomy for bevel elimination.
- 1 - **Patient's ostomy was not related to an inpatient stay and did not necessitate change in medical or treatment regimen.**
- 2 - **The ostomy was related to an inpatient stay or did necessitate change in medical or treatment regimen.**

Ostomy (Type):

Equipment Used (Size, Type):

Comments

NEURO/EMOTIONAL/BEHAVIORAL STATUS

(19) MENTAL STATUS:

☐ Oriented ☐ Comatose ☐ Forgetful ☐ Depressed ☐ Disoriented ☐ Lethargic ☐ Agitated ☐ Other:

(CM) (M0560) **Cognitive Functioning:** (Patient's current level of alertness, orientation, comprehension, concentration, and immediate memory for simple commands.)

- ☐ 0 - Alert/oriented, able to focus and shift attention, comprehends and recalls task directions independently.
- ☐ 1 - Requires prompting (cuing, repetition, reminders) only under stressful or unfamiliar conditions.
- ☐ 2 - Requires assistance and some direction in specific situations (e.g., on all tasks involving shifting of attention), or consistently requires low stimulus environment due to distractibility.
- ☐ 3 - Requires considerable assistance in routine situations. Is not alert and oriented or is unable to shift attention and recall directions more than half the time.
- ☐ 4 - Totally dependent due to disturbances such as constant disorientation, coma, persistent vegetative state, or delirium.

Comments

(BM) (M0570) **When Confused (Reported or Observed):**

- ☐ 0 - Never
- ☐ 1 - In new or complex situations only
- ☐ 2 - On awakening or at night only
- ☐ 3 - During the day and evening, but not constantly
- ☐ 4 - Constantly
- ☐ NA - Patient nonresponsive

Comments

(BM) (M0580) **When Anxious (Reported or Observed):**

- ☐ 0 - None of the time
- ☐ 1 - Less often than daily
- ☐ 2 - Daily, but not constantly
- ☐ 3 - All of the time
- ☐ NA - Patient nonresponsive

Comments

(BM) (M0590) **Depressive Feelings Reported or Observed in Patient: (Mark all that apply.)**

- ☐ 1 - Expressed mood (e.g., feels sad, tearful)
- ☐ 2 - Sense of failure or self reproach
- ☐ 3 - Hopelessness
- ☐ 4 - Recurrent thoughts of death
- ☐ 5 - Thoughts of suicide
- ☐ 6 - None of the above feelings observed or reported

Comments

(BM) (M0610) **Behaviors Demonstrated at Least Once a Week (Reported or Observed): (Mark all that apply.)**

- ☐ 1 - Memory deficit: failure to recognize familiar persons/places, inability to recall events of past 24 hours, significant memory loss so that supervision is required
- ☐ 2 - Impaired decision-making: failure to perform usual ADLs or IADLs, inability to appropriately stop activities, jeopardizes safety through actions
- ☐ 3 - Verbal disruption: yelling, threatening, excessive profanity, sexual references, etc.
- ☐ 4 - Physical aggression: aggressive or combative to self and others (e.g., hits self, throws objects, punches, dangerous maneuvers with wheelchair or other objects)
- ☐ 5 - Disruptive, infantile, or socially inappropriate behavior (excludes verbal actions)
- ☐ 6 - Delusional, hallucinatory, or paranoid behavior
- ☐ 7 - None of the above behaviors demonstrated

Comments

(BM) (M0620) **Frequency of Behavior Problems (Reported or Observed)** (e.g., wandering episodes, self abuse, verbal disruption, physical aggression, etc.):

- ☐ 0 - Never
- ☐ 1 - Less than once a month
- ☐ 2 - Once a month
- ☐ 3 - Several times each month
- ☐ 4 - Several times a week
- ☐ 5 - At least daily

Comments

(M0630) Is this patient receiving **Psychiatric Nursing Services** at home provided by a qualified psychiatric nurse?

- ☐ 0 - No
- ☐ 1 - Yes

Comments

ADL / IADLs

PRIOR FUNCTIONAL LEVEL:	N/A	INDEPENDENT	ADAPTED INDEPENDENT	DEPENDENT	Comments
ADLs					
IADLs					
Home Ambulation					
Community Ambulation					
Wheelchair Mobility					
Functional Communication					

For M0640-M0690, complete the "Current" column for all patients. For these same items, complete the "Prior" column only at start of care and at resumption of care; mark the level that corresponds to the patient's condition 14 days prior to start of care date (M0030) or resumption of care date (M0032). In all cases, record what the patient is able to do.

(BM) (M0640) **Grooming:** Ability to tend to personal hygiene needs (i.e., washing face and hands, hair care, shaving or make up, teeth or denture care, fingernail care).

Prior	Current	
☐	☐	0 - Able to groom self unaided, with or without the use of assistive devices or adapted methods.
☐	☐	1 - Grooming utensils must be placed within reach before able to complete grooming activities.
☐	☐	2 - Someone must assist the patient to groom self.
☐	☐	3 - Patient depends entirely upon someone else for grooming needs.
☐		UK - Unknown

* Evaluate the level of assistance required to allow the patient to safely groom.

Comments

(BM) = Outcome Measure Indicator
(CM) = Plan Provides Supply Indicator

ADL / IADLs (continued)

SOC (M0650) Ability to Dress Upper Body (with or without dressing aids) including undergarments, pullovers, front-opening shirts and blouses, managing zippers, buttons, and snaps:

Prior Current

- ☐ ☐ 0 - Able to get clothes out of closets and drawers, put them on and remove them from the upper body without assistance.
- ☐ ☐ 1 - **Able to dress upper body without assistance if clothing is laid out or handed to the patient.**
- ☐ ☐ 2 - **Someone must help the patient put on upper body clothing.**
- ☐ ☐ 3 - **Patient depends entirely upon another person to dress the upper body.**
- ☐ UK - Unknown

* Evaluate the level of assistance required to allow the patient to safely dress the upper body.

Comments

SOC (M0660) Ability to Dress Lower Body (with or without dressing aids) including undergarments, slacks, socks or nylons, shoes:

Prior Current

- ☐ ☐ 0 - Able to obtain, put on, and remove clothing and shoes without assistance.
- ☐ ☐ 1 - **Able to dress lower body without assistance if clothing and shoes are laid out or handed to the patient.**
- ☐ ☐ 2 - **Someone must help the patient put on undergarments, slacks, socks or nylons, and shoes.**
- ☐ ☐ 3 - **Patient depends entirely upon another person to dress lower body.**
- ☐ UK - Unknown

* Evaluate the level of assistance required to allow the patient to safely dress the lower body.

Comments

SOC (M0670) Bathing: Ability to wash entire body. Excludes grooming (washing face and hands only).

Prior Current

- ☐ ☐ 0 - Able to bathe self in shower or tub independently.
- ☐ ☐ 1 - With the use of devices, is able to bathe self in shower or tub independently.
- ☐ ☐ 2 - **Able to bathe in shower or tub with the assistance of another person:**
  - **(a) for intermittent supervision or encouragement or reminders, OR**
  - **(b) to get in and out of the shower or tub, OR**
  - **(c) for washing difficult to reach areas.**
- ☐ ☐ 3 - **Participates in bathing self in shower or tub, but requires presence of another person throughout the bath for assistance or supervision.**
- ☐ ☐ 4 - **Unable to use the shower or tub and is bathed in bed or bedside chair.**
- ☐ ☐ 5 - **Unable to effectively participate in bathing and is totally bathed by another person.**
- ☐ UK - Unknown

* Evaluate the level of assistance required to allow the patient to safely bathe in the tub or shower.

Comments

SOC (M0680) Toileting: Ability to get to and from the toilet or bedside commode.

Prior Current

- ☐ ☐ 0 - Able to get to and from the toilet independently with or without a device.
- ☐ ☐ 1 - When reminded, assisted, or supervised by another person, able to get to and from the toilet.
- ☐ ☐ 2 - **Unable to get to and from the toilet but is able to use a bedside commode (with or without assistance).**
- ☐ ☐ 3 - **Unable to get to and from the toilet or bedside commode but is able to use a bedpan/urinal independently.**
- ☐ ☐ 4 - **Is totally dependent in toileting.**
- ☐ UK - Unknown

* Evaluate the level of assistance required to allow the patient to safely get to the toilet or bedside commode.

Comments

SOC (M0640) Transferring: Ability to move from bed to chair, on and off toilet or commode, into and out of tub or shower, and ability to turn and position self in bed if patient is bedfast.

Prior Current

- ☐ ☐ 0 - Able to independently transfer.
- ☐ ☐ 1 - Transfers with minimal human assistance or with use of an assistive device.
- ☐ ☐ 2 - **Unable to transfer self but is able to bear weight and pivot during the transfer process.**
- ☐ ☐ 3 - **Unable to transfer self and is unable to bear weight or pivot when transferred by another person.**
- ☐ ☐ 4 - **Bedfast, unable to transfer but is able to turn and position self in bed.**
- ☐ ☐ 5 - **Bedfast, unable to transfer and is unable to turn and position self.**
- ☐ UK - Unknown

* Evaluate the level of assistance required to allow the patient to safely transfer.

Comments

SOC (M0700) Ambulation/Locomotion: Ability to SAFELY walk, once in a standing position, or use a wheelchair, once in a seated position, on a variety of surfaces.

Prior Current

- ☐ ☐ 0 - Able to independently walk on even and uneven surfaces and climb stairs with or without railings (i.e., needs no human assistance or assistive device).
- ☐ ☐ 1 - **Requires use of a device (e.g., cane, walker) to walk alone or requires human supervision or assistance to negotiate stairs or steps or uneven surfaces.**
- ☐ ☐ 2 - **Able to walk only with the supervision or assistance of another person at all times.**
- ☐ ☐ 3 - **Chairfast, unable to ambulate but is able to wheel self independently.**
- ☐ ☐ 4 - **Chairfast, unable to ambulate and is unable to wheel self.**
- ☐ ☐ 5 - **Bedfast, unable to ambulate or be up in a chair.**
- ☐ UK - Unknown

* Evaluate the level of assistance required to allow the patient to safely ambulate.

Comments

SOC = Outcome Measure Indicator

SOC - Physical Therapy

Patient Name (First, MI, Last) | Client No.

ADL / IADLs (continued)

OM (M0710) **Feeding or Eating:** Ability to feed self meals and snacks. **Note: This refers only to the process of eating, chewing, and swallowing, not preparing the food to be eaten.**

Prior Current

- ☐ ☐ 0 - Able to independently feed self.
- ☐ ☐ 1 - Able to feed self independently but requires:
  - (a) meal set-up; OR
  - (b) intermittent assistance or supervision from another person; OR
  - (c) a liquid, pureed or ground meat diet.
- ☐ ☐ 2 - Unable to feed self and must be assisted or supervised throughout the meal/snack.
- ☐ ☐ 3 - Able to take in nutrients orally and receives supplemental nutrients through a nasogastric tube or gastrostomy.
- ☐ ☐ 4 - Unable to take in nutrients orally and is fed nutrients through a nasogastric tube or gastrostomy.
- ☐ ☐ 5 - Unable to take in nutrients orally or by tube feeding.
- ☐ UK - Unknown

Comments

OM (M0720) **Planning and Preparing Light Meals** (e.g., cereal, sandwich) or reheat delivered meals:

Prior Current

- ☐ ☐ 0 - (a) Able to independently plan and prepare all light meals for self or reheat delivered meals; OR
  - (b) Is physically, cognitively, and mentally able to prepare light meals on a regular basis but has not routinely performed light meal preparation in the past (i.e., prior to this home care admission).
- ☐ ☐ 1 - Unable to prepare light meals on a regular basis due to physical, cognitive, or mental limitations.
- ☐ ☐ 2 - Unable to prepare any light meals or reheat any delivered meals.
- ☐ UK - Unknown

Comments

(M0730) **Transportation:** Physical and mental ability to safely use a car, taxi, or public transportation (bus, train, subway).

Prior Current

- ☐ ☐ 0 - Able to independently drive a regular or adapted car; OR uses a regular or handicap-accessible public bus.
- ☐ ☐ 1 - Able to ride in a car only when driven by another person; OR able to use a bus or handicap van only when assisted or accompanied by another person.
- ☐ ☐ 2 - Unable to ride in a car, taxi, bus, or van, and requires transportation by ambulance.
- ☐ UK - Unknown

Comments

OM (M0740) **Laundry:** Ability to do own laundry — to carry laundry to and from washing machine, to use washer and dryer, to wash small items by hand.

Prior Current

- ☐ ☐ 0 - (a) Able to independently take care of all laundry tasks; OR
  - (b) Physically, cognitively, and mentally able to do laundry and access facilities, but has not routinely performed laundry tasks in the past (i.e., prior to this home-care admission).
- ☐ ☐ 1 - Able to do only light laundry, such as minor hand wash or light washer loads. Due to physical, cognitive, or mental limitations, needs assistance with heavy laundry such as carrying large loads of laundry.
- ☐ ☐ 2 - Unable to do any laundry due to physical limitation or needs continual supervision and assistance due to cognitive or mental limitation.
- ☐ UK - Unknown

Comments

OM (M0750) **Housekeeping:** Ability to safely and effectively perform light housekeeping and heavier cleaning tasks.

Prior Current

- ☐ ☐ 0 - (a) Able to independently perform all housekeeping tasks; OR
  - (b) Physically, cognitively, and mentally able to perform all housekeeping tasks but has not routinely participated in housekeeping tasks in the past (i.e., prior to this home care admission).
- ☐ ☐ 1 - Able to perform only light housekeeping (e.g., dusting, wiping kitchen counters) tasks independently.
- ☐ ☐ 2 - Able to perform housekeeping tasks with intermittent assistance or supervision from another person.
- ☐ ☐ 3 - Unable to consistently perform any housekeeping tasks unless assisted by another person throughout the process.
- ☐ ☐ 4 - Unable to effectively participate in any housekeeping tasks.
- ☐ UK - Unknown

Comments

OM (M0760) **Shopping:** Ability to plan for, select, and purchase items in a store and to carry them home or arrange delivery.

Prior Current

- ☐ ☐ 0 - (a) Able to plan for shopping needs and independently perform shopping tasks, including carrying packages; OR
  - (b) Physically, cognitively, and mentally able to take care of shopping, but has not done shopping in the past (i.e., prior to this home care admission).
- ☐ ☐ 1 - Able to go shopping, but needs some assistance:
  - (a) By self is able to do only light shopping and carry small packages, but needs someone to do occasional major shopping; OR
  - (b) Unable to go shopping alone, but can go with someone to assist.
- ☐ ☐ 2 - Unable to go shopping, but is able to identify items needed, place orders, and arrange home delivery.
- ☐ ☐ 3 - Needs someone to do all shopping and errands.
- ☐ UK - Unknown

Comments

ADL / IADLs (continued)

(M0770) **Ability to Use Telephone:** Ability to answer the phone, dial numbers, and effectively use the telephone to communicate.

Comments

Prior Current

- ☐ ☐ 0 - Able to dial numbers and answer calls appropriately and as desired.
- ☐ ☐ 1 - Able to use a specially adapted telephone (i.e., large numbers on the dial, teletype phone for the deaf) and call essential numbers.
- ☐ ☐ 2 - Able to answer the telephone and carry on a normal conversation but has difficulty with placing calls.
- ☐ ☐ 3 - Able to answer the telephone only some of the time or is able to carry on only a limited conversation.
- ☐ ☐ 4 - Unable to answer the telephone at all but can listen if assisted with equipment.
- ☐ ☐ 5 - Totally unable to use the telephone.
- ☐ ☐ NA - Patient does not have a telephone.
- ☐ UK - Unknown

15A Homebound Status

Comments

Based on above information, is this patient homebound? ☐ Yes ☐ No

Check all that apply and provide brief example/explanation

- ☐ Considerable and taxing effort to leave home ______
- ☐ Illness/injury restricts ability to leave home ______
- ☐ Cognitive impairments (specify) ______
- ☐ Psychiatric illness manifested in refusal to leave home ______
- ☐ Psychiatric illness manifested in unsafe to leave home ______

Patient able to leave home using:

- ☐ Supportive devices (specify) ______
- ☐ Special transportation (specify) ______
- ☐ Assistance of another person (specify) ______

- ☐ Requires constant supervision to leave home ______
- ☐ How frequently does the patient leave home? ______
- ☐ For what purpose does the patient leave home? ______

NUTRITIONAL SCREENING	Yes
Patient has illness or condition that requires a change in the kind/amount of food eaten	2
Patient has fewer than 2 meals/day	2
Patient eats few fruits and vegetables or milk products	2
Patient consumes 3 or more drinks of alcohol almost every day	2
Patient has teeth or mouth problems that make it hard to eat	2
Patient does not have the resources to purchase needed food	3
Patient takes 3 or more medications per day	1
Patient has lost or gained > 10 lbs. in the past 6 months without dieting	1
There is no reliable caregiver to shop, cook, and/or feed patient if unable to do independently	1
Patient has inadequate/improper food storage/cooking facilities	2
Patient has significant memory loss and/or depression	2
Patient has been receiving enteral or parenteral nutrition	3
Patient has open wounds	3
Total Nutritional Score	

Nutritional Screening:
(9) or more = high risk; potential referral to MSW or dietitian
(6-8) = moderate risk; provide education/further assessment

Patient's Height ______ ☐ Actual ☐ Reported Weight ______ ☐ Actual ☐ Reported

Comments

16 NUTRITIONAL REQUIREMENTS NEW OR CHANGED: ☐ Regular

- ☐ ______ Sodium Diet ☐ ______ Calorie ADA Diet ☐ Bland Diet
- ☐ ______ Protein Hi Diet ______ / Low Diet ______
- ☐ ______ Carbohydrate Hi Diet ______ / Low Diet ______
- ☐ Enteral Feeding

______ Amount ______ ml/day Pump Type: ______

- ☐ Mechanical (Soft, Hi-Fiber, etc.) ☐ NG Tube
- ☐ Supplement ☐ PEG Tube
- ☐ Other (Specify) ☐ ______ Tube

MEDICATIONS

(M0780) **Management of Oral Medications:** Patient's ability to prepare and take all prescribed oral medications reliably and safely, including administration of the correct dosage at the appropriate times/intervals. Excludes **injectable and IV medications. (NOTE: This refers to ability, not compliance or willingness.)**

Comments ☐ "✓" if caregiver willing/able to assist w/administration of oral medications

Prior Current

- ☐ ☐ 0 - Able to independently take the correct oral medication(s) and proper dosage(s) at the correct times.
- ☐ ☐ 1 - Able to take medication(s) at the correct times if:
  - (a) individual dosages are prepared in advance by another person; OR
  - (b) given daily reminders; OR
  - (c) someone develops a drug diary or chart.
- ☐ ☐ 2 - Unable to take medication unless administered by someone else.
- ☐ ☐ NA - No oral medications prescribed.
- ☐ UK - Unknown

Patient Name (First, MI, Last) | Client No.

ADL / IADLs (continued)

OMI **(M0780) Management of Inhalant/Mist Medications:** Patient's ability to prepare and take all prescribed inhalant/mist medications (nebulizers, metered dose devices) reliably and safely, including administration of the correct dosage at the appropriate times/intervals. Excludes all **other forms of medication (oral tablets, injectable and IV medications).**

Comments: ☐ "✓" if caregiver willing/able to assist with administration of inhalant/mist medications

Prior Current

- ☐ ☐ 0 - Able to independently take the correct medication and proper dosage at the correct times.
- ☐ ☐ 1 - Able to take medication at the correct times if:
  - (a) individual dosages are prepared in advance by another person, OR
  - (b) given daily reminders.
- ☐ ☐ 2 - Unable to take medication unless administered by someone else.
- ☐ ☐ NA - No inhalant/mist medications prescribed.
- ☐ UK - Unknown

(M0800) Management of Injectable Medications: Patient's ability to prepare and take all prescribed injectable medications reliably and safely, including administration of correct dosage at the appropriate times/intervals. **Excludes IV medications.**

Comments: ☐ "✓" if caregiver willing/able to assist with administration of injectable medications

Prior Current

- ☐ ☐ **0 - Able to independently take the correct medication and proper dosage at the correct times.**
- ☐ ☐ **1 - Able to take injectable medication at correct times if:**
  - **(a) individual syringes are prepared in advance by another person, OR**
  - **(b) given daily reminders.**
- ☐ ☐ **2 - Unable to take injectable medications unless administered by someone else.**
- ☐ ☐ NA - No injectable medications prescribed.
- ☐ UK - Unknown

EQUIPMENT MANAGEMENT

NRSI 14 **DME AND SUPPLIES:**

DME:

- ☐ Bedside Commode
- ☐ Cane
- ☐ Elevated Toilet Seat
- ☐ Grab Bars
- ☐ Shower Chair
- ☐ Hospital Bed
- ☐ Tub/Shower Bench
- ☐ Wheelchair
- ☐ Walker
- ☐ Other ____________

Safety measures/additional equipment recommended to protect patient from injury ____________

Specific safety issues discussed: ____________

Supply Specifics: ____________

Patient/Family able to use all equipment/supplies safely? ☐ Yes ☐ No If No, specify: ____________

(M0810) Patient Management of Equipment (includes ONLY oxygen, IV/infusion therapy, enteral/parenteral nutrition equipment or supplies): Patient's ability to set up, monitor and change equipment reliably and safely, add appropriate fluids or medication, clean/store/dispose of equipment or supplies using proper technique. **(NOTE: This refers to ability, not compliance or willingness.)**

Comments

- ☐ 0 - Patient manages all tasks related to equipment completely independently.
- ☐ 1 - If someone else sets up equipment (i.e., fills portable oxygen tank, provides patient with prepared solutions), patient is able to manage all other aspects of equipment.
- ☐ 2 - Patient requires considerable assistance from another person to manage equipment, but independently completes portions of the task.
- ☐ 3 - Patient is only able to monitor equipment (e.g., liter flow, fluid in bag) and must call someone else to manage the equipment.
- ☐ 4 - Patient is completely dependent on someone else to manage all equipment.
- ☐ NA - No equipment of this type used in care **[If NA, go to M0826]**

(M0820) Caregiver Management of Equipment (includes ONLY oxygen, IV/infusion equipment, enteral/parenteral nutrition, ventilator therapy equipment or supplies): Caregiver's ability to set up, monitor, and change equipment reliably and safely, add appropriate fluids or medication, clean/store/dispose of equipment or supplies using proper technique. **(NOTE: This refers to ability, not compliance or willingness.)**

Comments

- ☐ 0 - Caregiver manages all tasks related to equipment completely independently.
- ☐ 1 - If someone else sets up equipment, caregiver is able to manage all other aspects.
- ☐ 2 - Caregiver requires considerable assistance from another person to manage equipment, but independently completes significant portions of task.
- ☐ 3 - Caregiver is only able to complete small portions of task (e.g., administer nebulizer treatment, clean/store/dispose of equipment or supplies).
- ☐ 4 - Caregiver is completely dependent on someone else to manage all equipment.
- ☐ NA - No caregiver
- ☐ UK - Unknown

THERAPY NEED

(M0826) Therapy Need: In the home health plan of care for the Medicare payment episode for which this assessment will define a case mix group, what is the indicated need for therapy visits (total of reasonable and necessary physical, occupational and speech-language pathology visits combined)? **(Enter zero ["000"] if no therapy visits indicated.)**

(______) Number of therapy visits indicated (total of physical, occupational and speech-language pathology combined).

☐ NA - Not Applicable: No case mix group defined by this assessment.

OMI = Outcome Measure Indicator
NRSI = Non Routine Supply Indicator

21 ORDERS FOR FREQUENCY/DURATION OF SERVICES

- ☐ Physical Therapy Visit Frequency/Duration _____
- ☐ _____
- ☐ HHA Visit Frequency/Duration _____ to assist w/personal care/ADLs/light housekeeping as needed
- ☐ Other _____
- ☐ Implement and Instruct Standard Precautions/Infection Control
- ☐ Dietitian evaluation *Refer to Page 11 Nutritional Screening to determine need for further Nutrition Assessment by qualified N.C. Professional.*
- ☐ May take orders from _____

22 REHABILITATION POTENTIAL/DISCHARGE PLANS

☐ Rehabilitation potential to achieve goals: ☐ Good ☐ Fair ☐ Poor Comments: _____

See Protocols, Specify: _____

Discharge Plans

- ☐ Patient to be discharged when skilled care no longer needed ☐ Other (specify) _____
- ☐ Patient to be discharged to the care of: ☐ Self ☐ Caregiver ☐ Other: _____
- ☐ Discharge plan initiated ☐ Discharge to Outpatient Physical Therapy
- ☐ No plans to discharge (patient requires ongoing care)

SKILLED SERVICES/SIGNIFICANT CLINICAL FINDINGS

SIGNIFICANT CLINICAL FINDINGS:

SKILLED SERVICES/TEACHING PROVIDED THIS VISIT: ☐ See Addendum

Conclusion/Impressions from Assessment:

☐ Changes in the POC discussed with Patient/Caregiver ☐ Patient/Caregiver agreed with plan: _____

Ordering Physician Name: Physician contacted and approved orders, discipline and frequency ☐ Yes ☐ No

Verbal Order Date: Specify:

☐ Gait Training ☐ HEP ☐ Safety Recommendation ☐ OTHER _____
☐ Transfer Training ☐ Therapeutic Exercise ☐ Equipment Recommendation

Therapist Name: (First, MI, Last) *Print*	HHA USE ONLY	Checked By	Entered By	Transmitted By
Therapist Signature and Date:		Date	Date	Date

SOC - Physical Therapy

Form# GOL1363

APPENDIX D

OUTCOME DATA SHEET

GENTIVA
safe strides

Patient: _____ Physician: _____

Patient #: _____ Location #: _____ Authorization: Yes: ____ No: ____

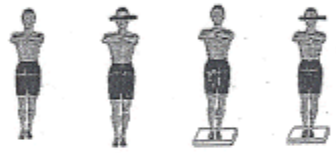
Standardized Tests	Initial Date	Mid-Point	D/C Date
Balance Tests: Tinetti #/28 Dynamic Gait #/24 Berg #/56			
Analog Pain Scale Score			
Semmes-Weinstein Score 5.07 Monofilament			
Modified Falls Efficacy Scale			
Modified CTSIB Clinical Test for Sensory Integration in Balance			
Occulomotor Testing Gaze Stabilization (VOR)			
BPPV (Benign Paroxysmal Positional Vertigo)			
Demographics	Age	Sex	# Visit

Modified CTSIB: Place time under each condition. Goal is 30 sec. If Patient: Opens eyes; Steps; Lifts toes; Uncrosses arms- Stop timing.

Initial: _____

_____ _____ _____ _____

Discharge: _____



_____ _____ _____ _____

Functional Progress:

We know that you have a choice in home health care providers and appreciate that you have chosen Gentiva's Safe Strides program. Our program's goal is to consistently exceed our customer's expectations for efficient, reliable, high quality rehabilitation services and setting industry standards for quality care and service delivery.

If we can be of any further assistance with you or your patients, please do not hesitate to contact us.

Therapist Initial Visit: _____ Date: _____

Therapist D/C Visit: _____ Date: _____

Patient Outcomes Chart

Great healthcare has come home

APPENDIX E

SENSORY FOOT FORM

GENTIVA®
safe strides™

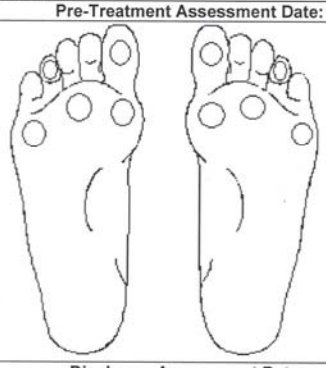
SAFE STRIDES℠ PROGRAM

Patient: _____ Client#: _____ Physician: _____

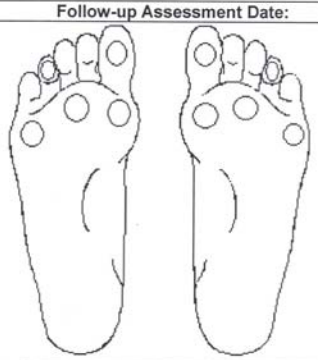
History: ☐ Diabetic ☐ Stroke ☐ Lumbar Spine Pathology ☐ Cancer/Chemo ☐ Other: _____

Directions: Note + or — in each of the five circled areas showing ability (+) or inability (—) to sense a 5.07 (10 gm) Semmes-Weinstein Monofilament.

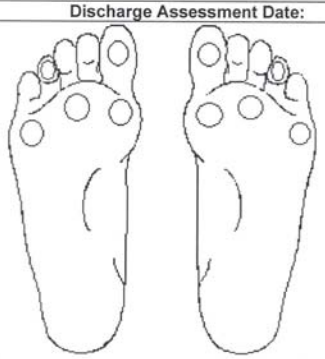
Pre-Treatment Assessment Date:



Follow-up Assessment Date:



Discharge Assessment Date:



Semmes Weinstein

Pre-Treatment Score	
Follow-Up Score	
Discharge Score	

Analog Pain Score

Pre-Treatment Score	
Follow-Up Score	
Discharge Score	

Notes:

AT DISCHARGE:

Pain Meds Reduced: ☐ Yes ☐ No Sleeping Meds Reduced: ☐ Yes ☐ No

Note details regarding effects of neuropathy on patient's quality of life (pain, inability to sleep, exercise, ambulate, wounds). After Infrared treatment, please note OBJECTIVE changes or improvements such as sensation/circulation changes, ability to ambulate, sleep, exercise, etc.

Signature: _____ Date: _____

Foot Sensation Evaluation Form

We know that you have a choice in home healthcare providers and appreciate that you have chosen Gentiva. As part of the Gentiva family of companies, we are pleased to offer our patients Safe Strides℠ a whole new way to deal with balance dysfunction. It's called Safe Strides. Developed by Gentiva, this innovative program has served more than 10,000 patients since its introduction in 2003. Our program's goal is to consistently exceed our customer's expectations for efficient, reliable, high quality rehabilitation services and setting industry standards for quality care and service delivery.

APPENDIX F

DYNAMIC GAIT INDEX FORM

Dynamic Gait Index

Patient Name: _____ Client #: _____ Adm. Date: _____ D/C Date: _____

	Adm Score	DC Score
1. **Gait on level surface.** *Instruction*: "Walk at your normal speed from here to the next mark (20')" (3) Normal: Walks 20', no assistive device, good speed, no evidence of imbalance, normal gait pattern (2) Mild Impairment: Walks 20', uses assistive device, slower speed, mild gait deviations. (1) Moderate Impairment: Walks 20', slow speed, abnormal gait pattern, evidence of imbalance (0) Severe Impairment: Cannot walk 20' without assistance, severe gait deviations or imbalance.		
2. **Change in gait speed.** *Instruction*: " Begin walking at your normal pace (for 5'). When I tell you "go", walk as fast as you can (for 5'). When I tell you "slow", walk as slowly as you can (for 5')." (3) Normal: Able to smoothly change walking speed without loss of balance or gait deviations. Shows a significant difference in walking speeds between normal, fast and slow speeds. (2) Mild Impairment: Is able to change speed but demonstrates mild gait deviations, or no gait deviations but unable to achieve a significant change in velocity, or uses an assistive device. (1) Moderate Impairment: Makes only minor adjustments to walking speed, or accomplishes a change in speed with significant gait deviations, or changes speed but loses balance but is able to recover and continue walking. (0) Severe impairment: Cannot change speeds or looses balance and has to reach for wall or be caught.		
3. **Gait with horizontal head turns.** *Instruction*: "Begin walking at your normal pace. When I tell you to look to the right, keep walking straight but turn your head to the right. Keep it there until I tell you to look to the left, then keep walking straight but turn your head to the left. Keep your head there until I tell you to look forward, then keep walking straight but turn your head to the center." (3) Normal: Performs head movements smoothly with no change in gait speed. (2) Mild Impairment: Performs head movements smoothly with slight change in gait speed, minor disruption in smooth gait path or uses walking aid. (1) Moderate Impairment: Performs head turns with moderate change in speed, slows down, staggers but recovers, can continue to walk. (0) Severe Impairment: Performs task with severe disruption in gait, staggers outside of 15" path, loses balance, stops, reaches for wall.		
4. **Gait with vertical head turns.** *Instruction*: "Begin walking at your normal pace. When I tell you to look up, keep walking straight but tip your head up toward the ceiling. Keep it there until I tell you to look down, then keep walking straight but turn your head down. Keep your head there until I tell you to look forward. Then keep walking straight but turn your head to the center." (3) Normal: Performs head movements smoothly with no change in gait speed. (2) Mild Impairment: Performs head movements smoothly with mild change in gait speed. Minor disruption in smooth gait path or uses walking aid. (1) Moderate Impairment: Performs head turns with moderate change in speed, slows down, staggers but recovers, can continue to walk. (0) Severe Impairment: Performs task with severe disruptions in gait, staggers outside of 15" path, loses balance, stops, reaches for wall.		
5. **Gait with pivot turns.** *Instruction*: "Begin walking at your normal pace. When I tell you to turn and stop, turn as quickly as you can to face the opposite direction and stop." (3) Normal: Pivot turns safely within 3 seconds and stops quickly with no loss of balance. (2) Mild Impairment: Pivot turns safely in >3 seconds and stops with no loss of balance. (1) Moderate Impairment: Turns slowly, requires verbal cueing and requires several steps to catch balance following turn and stop. (0) Severe Impairment: Cannot turn safely, requires assistance to turn and stop.		
6. **Step over obstacles.** *Instruction*: "Begin walking at your normal speed. When you come to the obstacle, step over it, not around it, and then keep walking." (3) Normal: Is able to step over obstacle without changing gait speed. (2) Mild Impairment: Is able to step over obstacle, but must slow down and adjust steps in order to clear safely. (1) Moderate Impairment: Is able to step over the box, but must stop and step over. May require verbal cueing. (0) Severe Impairment: Cannot perform without assistance.		
7. **Step around obstacles.** *Instruction*: "Begin walking at normal speed. When you come to the first cone (6"), walk around to the right side of it. When you come to the second cone (6" past the first cone", walk around to the left side of it. (3) Normal: Is able to walk around the cone safely without changing in gait speed. No evidence of imbalance. (2) Mild Impairment: Is able to step around both cones, but must slow down and adjust steps to clear cones. (1) Moderate Impairment: Is able to clear cones, but must significantly slow speed to accomplish task or requires verbal cueing. (0) Severe Impairment: Unable to clear cones, walks into one or both cones, or requires physical assistance.		
8. **Steps.** *Instruction*: "Walk up these stairs as you would at home (i.e. using rail if necessary). At the top, turn around and walk down." (3) Normal: Alternating feet, no rail. (2) Mild Impairment: Alternating feet, must use rail. (1) Moderate Impairment: Two feet to a stair, must use rail. (0) Severe Impairment: Cannot do safely.		
Total Score: Fall Risk (<20) ☐ Y ☐ N	/24	/24

_____ (Physical Therapist Signature)

APPENDIX G

MODIFIED FALLS EFFICACY SCALE FORM

The Modified Falls Efficacy Scale

(Hill KD, Schwarz JA, Kalogeropoulos AL, Gibson, SJ, Arch Phy Med Rehabil, 77:1025-1029, 1996)

	NOT CONFIDENTAT ALL (0)	FAIRLYCONFIDENT (5)	COMPLETELY CONFIDEN (10)
1.Get dressed and undressed			
2. Prepare a simple meal			
3. Take a bath or shower			
4. Get in & out of a chair			
5. Get in & out of bed			
6. Answer the door or telephone			
7. Walk around the inside of your house			
8. Reach into cabinets or closets			
9. Light housekeeping			
10. Simple shopping			
11. Using public transport			
12. Crossing roads			
13. Light gardening or hanging out laundry			
14. Using front or rear steps at home			

The items on the scale are scored from 0 to 10, with 0 meaning "not confident/ not sure at all", 5 being "fairly confident/fairly sure", and 10 being "completely confident/completely sure". Subjects are asked, "How confident/sure are you that you can do each of the activities without falling.

Test-retest reliability (ICC was .93)

High Internal Consistency (Cronbach's alpha .95)