# WHEELCHAIR RELATED FALL RISK AND FUNCTION IN NURSING HOME RESIDENTS: FACTORS RELATED TO WHEELCHAIR FIT

by

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**WHEELCHAIR RELATED FALL RISK AND FUNCTION IN NURSING HOME RESIDENTS: FACTORS RELATED TO WHEELCHAIR FIT**

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**Background:** Poor wheelchair fit may lead to increased pressure on bony prominences, reduced ability to propel the wheelchair and inability to reach, increasing pressure ulcer risk. Wheelchair fit impacts falls; the most frequently reported adverse event among nursing home residents.

**Purpose:** This research aimed to assess effect of individually-configured lightweight wheelchairs on wheelchair-related fall risk for nursing home residents. Secondary aims were to assess effect of wheelchair fit on the functional status of nursing home residents measured with the Functioning Everyday with a Wheelchair (FEW-C) and Nursing Home Life Space Diameter (NHLSD) measurements, and the relationship between FEW-C and pressure ulcer risk measured with the Braden Scale.

**Methods:** This study was a secondary analysis of data from a randomized clinical trial (RCT) on wheeled mobility for preventing pressure ulcers. A total of 258 residents were randomized into either a control group (n=131) provided a skin protection cushion with related adjustments to his/her nursing home wheelchair, or into a treatment group (n=127), receiving a wheelchair assessment and an individually configured manual lightweight wheelchair with skin protection cushion.

**Results:** The primary aim found in the treatment and control groups, 25/127 (19.69%) and 30/131 (22.90%) of individuals had a wheelchair-related fall (p=0.55), respectively. Significant

differences were found between groups for change in FEW-C independence between pre-randomization and endpoint ($p = 0.008$), and between groups for change in FEW-C safety between pre-randomization and endpoint ($p = 0.027$). Trends towards significance were found between groups for change in NHLSD between pre-randomization and endpoint ($p = 0.087$) and FEW-C independence between pre-randomization and day 14 ($p = 0.075$). Significant associations were observed for relationships between total Braden Scale and FEW-C independence ($p < 0.0001$), Braden activity-mobility sub-scale and FEW-C independence ($p = 0.021$), and total Braden and FEW-C safety scores ($p = 0.012$).

**Conclusion:** Wheelchair and seating assessments for manual wheelchair users is an important factor for improving functional outcomes. Even though not statistically significant, the incidence of wheelchair-related falls in the treatment group were lower than the control group. Improved function can be attained with provision of wheelchair technology without adversely affecting fall risk.

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# 1.0 INTRODUCTION

## 1.1 GENERAL INTRODUCTION

The Administration on Aging estimated that the population of individuals aged 65 years or older was at 44.7 million in 2013, representing 14.1 percent of the United States population. About 2 percent of individuals above the age of 65 years, and 10.2 percent of individuals above the age of 85 years reside in nursing homes (Medicare & Services, 2013). The Centers for Disease Control and Prevention reports that there are 15,700 nursing homes in the United States of America with a total of 1.7 million licensed beds (Medicare & Services, 2013).

Older adults can be independent, happy, socially active and contributors to the community (Grams & Albee, 1995). Personal, physical and /or environmental constraints may cause moderate or severe limitations, which lead to decreases in independence and quality of life. Physical limitations lead to an increased risk of falling (Masud & Morris, 2001). Falls are an important independent marker of frailty and a cause for injury (Mulrow et al., 1994; Ray et al., 1997). Falls increase the risk of premature or sudden deaths (Chen et al., 2011). Age has been identified as a risk factor causing at least one fall a year in individuals above 65 years of age (Masud & Morris, 2001).

In a study sample of elderly individuals with a mean age of 68 years, falls were shown to be the second most common mechanism of injury, with the first being motor vehicle accidents (Spaniolas et al., 2010). The proportion of people sustaining at least one fall varies and is summarized by various researchers based on age – 28-35% in the ≥65 years age group and 32-

42% in the ≥75 years age group (Blake et al., 1988; Campbell, Reinken, Allan, & Martinez, 1981; Downton & Andrews, 1991; Prudham & Evans, 1981; Tinetti, Speechley, & Ginter, 1988). The incidence of falls among institutionalized older adults is three times higher than community dwelling older adults (Rubenstein, Josephson, & Robbins, 1994). Each year, an estimated 1.64 million nursing home and community dwelling adults 65 years and older are treated in emergency departments due to injuries from falls (Masud & Morris, 2001). Among nursing home residents, falls are the most frequently reported adverse event (Mulrow et al., 1994). Twenty five percent of nursing home residents who fall die within a year (Chen et al., 2011). Furthermore, falls are an underestimated cause of mortality and morbidity due to ignorance towards dealing with the effects of falls (Medicare & Services, 2013). Falls are considered a major public health concern due to the morbidity, mortality and cost to health (Masud & Morris, 2001). Figure 1.1 is taken from Handfield-Jones (1989) who studied the effect of aging on falls. This study attempted to increase our understanding of falls from wheelchairs in nursing homes.

With the growing number of nursing home residents, falls and pressure ulcers represent a significant health problem affecting the safety and quality of life of individuals. It is important to be accountable and effective in the provision of services involving assistive technology and also for services associated with pressure ulcer prevention and treatment, to prove their value in improving the quality of life. One of the ways this can be achieved is through effective documentation, based on the use of appropriate outcome measures (R. O. Smith, 1996).

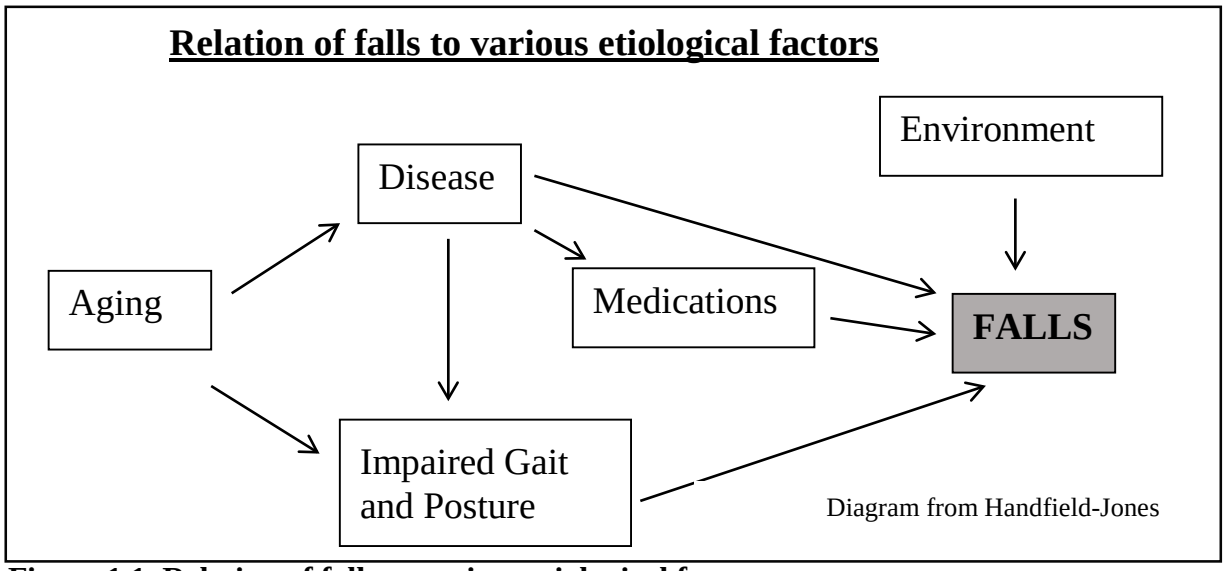



**Figure 1.1. Relation of falls to various etiological factors**

In rehabilitation for individuals with disability, wheelchairs are among the most important therapeutic assistive technology devices used to enhance mobility (Kirby, Swuste, Dupuis, MacLeod, & Monroe, 2002; Organization, 2008). Appropriate wheelchair prescriptions, adjustment for the user, and training the user for safety and function are important components of the rehabilitation process (Axelson, Minkel, Chesney, & Thomas, 1994). Pressure ulcer risk associated with wheelchair use is influenced by postural-related imbalances and also by inactivity and low functional capacity caused by poor wheelchair fit (Brienza et al., 2010). Wheelchair-related injuries appear to be due to failed attempts while transferring independently in or out of the chair, or while conducting functional activities while in the wheelchair, such as leaning forward (Gavin-Dreschnack et al., 2005).

The primary aim of this dissertation is to assess the effect of individually-configured lightweight manual wheelchairs and skin protection cushions on wheelchair-related fall risks for residents in nursing homes (NIH grant number: R01HD041490). The secondary aims are to

determine the association of the Braden Scale scores with the Functioning Everyday with a Wheelchair - Capacity (FEW-C) scores, and to assess the effect of individually configured lightweight manual wheelchairs with appropriately sized skin protection cushions on the functional status of residents in nursing homes.

These aims were addressed using the data set of the parent study, "An RCT on wheeled mobility for preventing pressure ulcers" (RCT-WC2 grant number: R01HD041490) funded by the National Institutes of Health. RCT-WC2 was conducted by the University of Pittsburgh at 17 nursing homes in the greater Pittsburgh area. Institutional Review Board (IRB) approval was obtained for this study.

### 1.1.1 Significance of this study

Injuries resulting from falls reduce a person's ability to function independently which in turn leads to decreased quality of life. In a study by Nelson et al (2010), the causes and resulting impacts of wheelchair-related falls in veterans with spinal cord injury were assessed. The researchers concluded that the most common factors associated with falling were wheelchair-related activities such as transfers (44%), riding in a vehicle (30%), propelling the chair (15%) and reaching (11%) (Nelson et al., 2010). The impact from falls included morbidity, mortality, functional deterioration, hospitalization, institutionalization and expenditures to health and social services (Masud & Morris, 2001; Nelson et al., 2010). Falls in the elderly, especially with altered mental status, are related to significant increases in mortality (Spaniolas et al., 2010). Researchers Calder & Kirby et al. found that 8.1% of the 770 wheelchair related-accidents between 1973 and 1987 were caused by falls during transfers (Calder & Kirby, 1990). The other cause of falls included tips (68.5%), environmental factors (9.8%), restraints (8.7%) and thermal-

caused by heat (5.9%) (Calder & Kirby, 1990). Calder & Kirby (1990) emphasized the importance of environmental hazards (Calder & Kirby, 1990; Handfield-Jones, 1989) contributing to falls and also to the patients' mental status as it is found to impact the degree of environmental awareness (Handfield-Jones, 1989).

It is important to identify the factors associated with falls so that these factors can be eliminated or reduced. Increased fall risk was found in a fall assessment in a sample of nursing home individuals and was correlated with wheelchair use (Fonad, Wahlin, Winblad, Emami, & Sandmark, 2008). Various factors increase the likelihood of a fall or contribute significantly to the fall-risk, but do not actually cause the fall (Handfield-Jones, 1989). For example, unassisted walking due to dementia or confusion could contribute to a fall. The Effective Health Care Bulletin classified the causes of falls as environmental, medication, medical conditions, nutritional and changes associated with aging (Masud & Morris, 2001). Various long-term complications arising from a fall often go unrecognized (Handfield-Jones, 1989). The factors that cause a fall need to be retrospectively identified and addressed to prevent a fall from reoccurring in the future due to the same condition or situation.

An understanding of the causes of wheelchair-related falls will help clinicians and users work together to reduce the risks. In addition, a better understanding of wheelchair fit and comfort in improving function and safety may help to improve independence and quality of life. Researchers have talked about the effect of nurse staffing on pressure ulcer incidence and stated that there isn't enough literature to conclude a direct association between staffing levels and the incidence of falls or pressure ulcers (Lake & Cheung, 2006). A multifactorial fall prevention program is more effective for older individuals with a previous history of falls (Costello & Edelstein, 2008). There is a need for practitioners to provide wheelchair users with better

education with respect to wheelchair fit and functioning to enhance safety (Mikołajewska, 2013). Lower effectiveness of rehabilitation, lower functional abilities of the wheelchair user, and fatal secondary changes (like pressure ulcers) may be a result of improper wheelchair selection (Mikołajewska, 2012). It is important to focus on enhancing function and safety to prevent increased dependence and improve quality of life.

## 1.2 OBJECTIVES AND SPECIFIC AIMS

The objective of this dissertation is to determine the factors associated with wheelchair related falls and function among nursing home residents using manual wheelchairs. The specific aims are to:

1. Determine the effect of individually-configured lightweight manual wheelchairs on fall risk,
2. Determine the association between the Braden Risk Assessment Scale and the Functioning Everyday in a Wheelchair – Capacity (FEW-C) scores, and
3. Determine the effect of individually-configured lightweight manual wheelchairs on users' mobility and function.

### 1.2.1 Rationale for Aim 1

**Determine the effect of individually-configured lightweight manual wheelchairs on fall risk**

This aim focuses on testing and understanding the role of individually-configured lightweight manual wheelchairs compared to nursing home provided wheelchairs on fall risk. The literature indicates an increase in future falls in individuals with a prior history of falls (Chen et al., 2011;

Davis et al., 2010; Fries et al., 2000; Hofmann, Bankes, Javed, & Selhat, 2003). This aim analyzes the fall data from the study with respect to the history of fall information obtained retrospectively from the Minimum Data Set (MDS).

We hypothesize that by providing an individually configured lightweight manual wheelchair we can achieve increased mobility and activity without increasing risk of falling because a wheelchair with proper fit will allow the user to operate in a safe manner. This aim is intended to investigate the question of whether or not wheelchairs can be provided to people at risk of falling without increasing such risks. Wheelchairs are intended to increase activity and mobility. For people with multiple risk factors for falling, increased activity and mobility may increase the risk of falling simply due to exposure to more potentially dangerous circumstances. The prevalence of falls is shown to decrease when appropriate changes are made to the environment, staffing and restorative activity programs in nursing homes (Hofmann et al., 2003).

Aizen et al. (2007) studied the characteristics of factors that lead to falls post-inpatient hospitalization. Falls during the first week of in-patient hospitalization are often due to frailty, physical dependence during routine ambulation and transfer tasks. During the second week of in-patient hospitalization, falls may occur due to the exposure of fall risks spreading over a wider range of physical environments and activities. Post-operative cognitive dysfunction is possibly related to the high incidence of falling while engaging in a risk-taking activity among patients hospitalized for hip surgery on an in-patient rehabilitation unit (Aizen, Shugaev, & Lenger, 2007).

Individuals who have had a fall are one and a half times more likely to experience a subsequent fall (Chen et al., 2011; Davis et al., 2010; Fries et al., 2000; Hofmann et al., 2003). A bidirectional relationship between fear of falling and actual falling has been identified (Fonad et

al., 2008; Fries et al., 2000; Hofmann et al., 2003). A study of a multifactorial fall prevention intervention considered the history of falls in the previous 12 months to be a risk factor for falling (Russell et al., 2010). There was a high incidence of falls in individuals in the stroke rehabilitation units, possibly due to cognitive impairment (Aizen et al., 2007). Precautionary measures should be taken to prevent the individual with a history of previous falls from falling again (Fries et al., 2000). A model by French et al. (2007) suggested that a multifaceted fall reduction program for the nursing home should include resident risk factor assessment and modification, staff education, gait assessment and intervention, assistive device assessment and optimization and environmental assessment and modification. A multifactorial fall prevention program has been shown to be more effective for older individuals with previous fall history (Costello & Edelstein, 2008).

Researchers have conducted detailed analyses to study the risk factors associated with falling, including those factors associated with individual characteristics, and factors associated with the individuals' environment. After the first week of the onset of a disease, the risk of falling moves from intrinsic factors to extrinsic environment and activity-related factors (Aizen et al., 2007). Falls may be caused by purely extrinsic factors, for example a tripping hazard in the environment or a slippery surface, or due to a combination of intrinsic factors, such as a condition that impairs postural control and an environmental factor (Masud & Morris, 2001). Unfortunately, wheelchairs have been considered to be an extrinsic factor increasing the risk of falls in the elderly (Handfield-Jones, 1989). It is contended that if the an individually configured lightweight manual wheelchair is prescribed, it can benefit the elderly user by increasing their mobility and activity without increasing their risk of falling.

Various aspects of the wheelchair and its interaction with the environment have been studied by some researchers to analyze the effect of a wheelchair on the risk of falling. According to a model for examining wheelchair-related falls in a study by Gavin-Dreschnack, et al. (2005), hazardous conditions give rise to adverse events as a result of the interaction among the following five variables: characteristics of the user, wheelchair type and features, healthcare practices by providers and patients, wheelchair activities and characteristics of the environment (Gavin-Dreschnack et al., 2005). Falls from wheelchairs can be due to mismanagement of the wheelchair by the user with respect to the environment (Kirby & Smith, 2001). It has been suggested that the prevalence of falls can be decreased via changes made to the environment, staffing and restorative activity programs in nursing homes which are cost-conscious environments (Hofmann et al., 2003). In the geriatric population, there is limited research that emphasizes the importance of individually configured lightweight manual wheelchairs in reducing fall risk. French et al. (2007) state that the resident's MDS assessment and care planning instrument is a key component in resident safety efforts (French et al., 2007). Wheelchair falls affect the function, activity, independence and quality of life (Gavin-Dreschnack et al., 2005). Various modifications to the wheelchair characteristics can possibly enhance wheelchair user safety (Gavin-Dreschnack et al., 2005). In the geriatric population, there is limited research that evaluates the role of wheelchair fit in reducing fall risk associated with wheelchair use. Thus, these hypotheses look at the relationships between wheelchair fit, wheelchair related falls and previous fall history.

In summary, individuals with a previous history of falls are at a greater risk of falling. Wheelchair characteristics have been proven to be an important environmental risk factor associated with falls. The data from the Randomized Clinical Trial – Wheelchair Phase 2 (RCT-

WC2) where participants were assigned to groups with and without individually-configured wheelchairs can be used to investigate this contention by analyzing wheelchair-related falls relative to the factors causing those falls. Some prior work has been done related to this question. Aizen et al. (2007) suggested that individually tailored and prescribed wheelchairs should be used for individuals who have had a fall as an intervention measure (Aizen et al., 2007). A need exists to provide a skin protection cushion together with a seating evaluation for an individually fit manual wheelchair by a clinician trained to conduct seating evaluations (Brienza et al., 2010; Friedman et al., 1995).

### 1.2.2 Rationale for Aim 2

**Determine the association between the Braden Risk Assessment Scale and the Functioning Everyday with a wheelchair (FEW-C)**

This aim focuses on assessing the association of the Braden scores with the FEW-C scores. It is a mandate for nursing homes to record MDS data regularly. The Braden scores are part of the MDS data reporting.

Wheelchair related falls and pressure ulcer risk are related due to the dependence of stable, efficient and safe wheelchair use on distribution of body weight for sitting and for other supportive surfaces. For example, ease of transfer into and out of a wheelchair depends on friction between the user and their seat cushion. Transfers will naturally be easier if there is less friction, yet risk of falling out of the wheelchair may be increased with less friction. The Braden scale measures pressure ulcer risk factors, including friction, and estimates a person's risk of developing a pressure ulcer. The FEW-C measures a person's ability to operate a wheelchair effectively and safely, including the ability to transfer. By evaluating the relationship between

Braden Scale scores and FEW-C scores, we will establish the association between a nursing home resident's pressure ulcer risk and ability to use a wheelchair. It is hypothesized that safe and efficient wheelchair use, as indicated by high FEW-C safety and function scores, will be associated with reduced pressure ulcer risk, as indicated with higher Braden scores, despite some apparent contradictions between underlying factors driving the scores. In the parent study, we aimed to improve wheelchair function and reduce pressure ulcer risk by providing an individually configured lightweight manual wheelchair. In this aim we explore the relationship between pressure ulcer risk and functional wheelchair outcomes.

A systematic review by Pancorbo-Hidalgo et al. (2006) examined various pressure ulcer risk assessment tools. They compared the Braden scale, Waterlow scale and the Norton scale (Pancorbo-Hidalgo, Garcia -Hidalgo, Garcia-Fernandez, Lopez-Medina, & Alvarez-Nieto, 2006). The meta analysis concluded that the Braden scale was used in the maximum number of studies and showed the best reliability and validity in a variety of settings (Pancorbo-Hidalgo et al., 2006). The Braden Scale is known to be a better predictor for pressure ulcers than nursing judgment (Pancorbo-Hidalgo et al., 2006). The Braden scale is measured assessing six risk factors, which are sensory perception, moisture, activity, mobility, nutrition & friction and shear.

An assistive technology assessment is essential to evaluate the capabilities, needs and environmental interactions of potential users. The Functioning Everyday with a Wheelchair (FEW) measurement was developed in 2005 and is used to measure the effectiveness of the manual wheelchair in meeting the consumer's needs. The FEW-C assesses five areas of functioning in a wheelchair: reaching forward, reaching side-by-side, using brakes, transfers from wheelchair and use of a sink from the wheelchair (Schein et al., 2011). The FEW-C scores relate to safe functioning associated with wheelchair use. In comparison, the activity component

of the Braden score assesses the degree of physical activity, whereas the mobility component of the Braden score assesses the individual's ability to change and control body position. Together, the activity-mobility components of the Braden scale demonstrate the individual's ability to transfer, shift weight, and walk.

Understanding and interpreting the association of these scores will allow clinicians to predict functioning in wheelchair based upon Braden scores. Communication between nurses and therapists will help improve safe and independent functioning during wheelchair use. The relationship between the FEW-C (safety and independence components) and Braden Scale total scores and the activity and mobility subscale components of the Braden Scale score with the total of the FEW-C score are assessed by this aim.

### 1.2.3 Rationale for Aim 3

**To determine the effect of individually-configured lightweight manual wheelchairs on users' mobility and function**

This aim focuses on the effect of individually-configured lightweight manual wheelchairs on users' mobility and function. Users' mobility and function will be measured using the Functioning Everyday with a Wheelchair-Capacity (FEW-C), Nursing Life Space Diameter (NHLSD) and Wheelchair Skills Test (WST) tools. The FEW-C and the NHLSD each have independence and safety components. Each of these components were tested separately to get a better understanding of the various aspects of the outcome measures.

Various research studies highlighted the increasing importance of the effect of an individually configured lightweight manual wheelchair on the safety and function of wheelchair users. In a study on rehabilitation in Amyotrophic Lateral Sclerosis, Majmudar et al. (2014)

found the use of lightweight or ultra-lightweight manual wheelchairs was one of the measures used to maximize patient independence, function, safety, and quality of life (Majmudar, Wu, & Paganoni, 2014). Orkunribido (2013) studied the details of posture and center of gravity during wheelchair use. Trunk posture (upright/flexed), type of seat cushion (flat polyurethane/proposal low profile), and feet condition (supported/dangling) depend on the wheelchair and center of gravity. Orkunribido (2013) concluded that the occupant's safety in the wheelchair depends on the seat cushion and perception of safety. The study indicated the risk of falling from a wheelchair is increased when the user slouches forward. The author states that the way in which a user is positioned in the wheelchair affects user safety during transfers (Okunribido, 2013). Kirby & Smith (2001), in a qualitative analysis on one fall from a wheelchair due to mismatched brakes, identify the wheelchair fit to be one of the factors associated with safe functioning in a wheelchair (Kirby & Smith, 2001). Giesbrecht et al. (2012), validated wheelchair fit as one of the factors associated with safe functioning in a wheelchair (Giesbrecht, Mortenson, & Miller, 2012).

The wheelchair and seating configuration also affects pressure ulcer risk. Pressure ulcer risk associated with wheelchair use is influenced by postural-related imbalances and also by inactivity and low functional capacity caused by poor wheelchair fit (Brienza et al., 2010). Poor wheelchair fit leads to an individual adopting postures that increase pressure over bony prominences, reduces an individual's ability to propel the wheelchair and limits the ability to reach forward and side to side (Gavin-Dreschnack et al., 2005).

The challenge is to reduce the number of falls and injuries without lowering activity (Aizen et al., 2007). Wheelchair-related injuries appear to be due to failed attempts while transferring independently in or out of the chair or while conducting functional activities while in

the wheelchair such as leaning forward (Gavin-Dreschnack et al., 2005). Environmental modifications such as bathroom modifications, widened doorways/hallways, kitchen modifications, railings and/or easy open doors enhance safe wheelchair use (Berg, Hines, & Allen, 2002).

This aim will compare the skill component of the tools, by comparing function in the treatment group, i.e., those who received skin protection cushions in individually configured lightweight manual wheelchairs, to a comparison group who received nursing home provided wheelchairs with related adjustments and skin protection cushions.

## 1.3 DISSERTATION STRUCTURE

Chapter 2 describes the parent study and the various data and outcome measures collected. The process of recruitment and details of the different stages of data collection during the study will also be elaborated upon.

Chapter 3 is a secondary analysis of data of the study sample in individuals who had a fall. General falls and specifically wheelchair-related falls were studied as part of this analysis and are presented through Aim 1 in Chapter 3. Two groups were compared as part of this analysis – provision of an individually-configured lightweight wheelchairs and skin protection cushions vs. provision of skin protection cushions with related adjustments to existing facility wheelchair.

Chapter 4 describes Aim 2, the relationship between the Braden and the FEW-C, and presents the results and discussion.

Chapter 5 is a secondary analysis of the randomized control trial on wheeled mobility in prevention of pressure ulcers. The secondary hypothesis of the RCT-WC2 analyzing the function, mobility and ability to propel the wheelchair in individuals residing in nursing homes is presented through Aim 3 in Chapter 5.

Chapter 6 summarizes the findings from the three studies.

# 2.0 DESCRIPTION OF THE PARENT STUDY

## 2.1 OVERVIEW

### 2.1.1 Randomized Clinical Trial on Wheeled Mobility for Preventing Pressure Ulcers (RCT-WC2): (Institutional Board Review number: PRO09120362)

The parent study, a Randomized Clinical Trial on Wheeled Mobility for Preventing Pressure Ulcers, was designed based on the hypothesis that improperly fitted wheelchairs, even when used with skin protection cushions, result in poor posture and position. This decreases the individual's ability to propel the chair and independence to reach. The resulting dependence promotes inactivity and immobility, which leads to long periods of high pressure, which increases the risk of developing pressure ulcers.

The RCT-WC2 had one primary hypothesis and one secondary hypothesis:

1. At-risk elderly wheelchair users using an individually-configured lightweight manual wheelchair will have a lower incidence of pressure ulcers than those using a facility supplied manual wheelchair with related adjustments;

2. At-risk elderly wheelchair users using an individually-configured lightweight manual wheelchair will have better functional performance than those using a facility supplied manual wheelchair with related adjustments;

    a. At-risk elderly wheelchair users using an individually-configured lightweight manual wheelchair will have better functional mobility skill scores at endpoint (Functioning Everyday with a Wheelchair-Capacity; FEW-C) than those using a facility supplied manual wheelchair with related adjustments;

    b. The extent and frequency of functional mobility in the living space of the nursing home will increase more for at-risk elderly wheelchair users using an individually-configured lightweight manual wheelchair than those using a facility supplied manual wheelchair with related adjustments, based on the Nursing Home Life-Space Diameter (NHLSD) tool; and

c. At-risk elderly wheelchair users with an individually-configured lightweight manual wheelchair will demonstrate less deterioration in Activities of Daily Living (ADL) Self-Performance scores and ADL Support scores than those using a facility supplied manual wheelchair with related adjustments, based on the Minimum Data Set (MDS) (Section G) quarterly review data.

## 2.2 HISTORY

The RCT-WC2 is a follow-up to the RCT-SC whose main objective was to establish the efficacy of skin protection wheelchair cushions in preventing pressure ulcers in an elderly, nursing home population. In RCT-SC, 232 individuals received an intervention. A total of 113 participants were assigned to the treatment group and 119 were assigned to the control group. The treatment group received a skin protection cushion with a individually configured lightweight manual Breezy Ultra 4 light wheelchair (Sunrise Medical, U.S. LLC., Fresno, CA) or a Guardian Escort wheelchair (Sunrise Medical, U.S. LLC., Fresno, CA). The control group received a segmented foam cushion with an individually configured lightweight manual Breezy Ultra 4 wheelchair or a Guardian Escort wheelchair. Eight out of 119 (6.7%) individuals in the control group developed pressure ulcers over their ischial tuberosities and 1/113 (0.9%) of individuals in the treatment group developed a pressure ulcer ($p<0.04$). This clinical trial demonstrated significant differences in pressure ulcers occurring over the ischial tuberosities between segmented foam and skin protection wheelchair cushion groups.

The significant results in the RCT-SC validated the statistical and clinical significance of the skin protection cushions and light weight wheelchairs in reducing the incidence of pressure ulcers. In the RCT-SC sample, a significant difference ($p<0.002$) in pressure ulcer incidence was

observed in the residents who could self-propel, where 6.4% developed pressure ulcers compared to those who could not self-propel (19.5%) (Brienza et al., 2010). The effects of the wheelchair compared to the effects of the seat cushion could not be demonstrated in RCT-SC since the study group did not receive a properly fitted chair. The RCT-SC also gave rise to questions associated with the role that the fit of the wheelchair had on the reduction of pressure ulcer incidence. These differences in reach and mobility led to the design and conception of the RCT-WC2.

Nursing homes in the Pittsburgh and Greater Pittsburgh area were recruited. A total of seventeen nursing homes were part of this study. All participating nursing homes had to have Pennsylvania Department of Health (PADOH) and Federal Wide Assurance (FWA) approval. The recruitment for every nursing home varied from a minimum of two residents to forty-four residents per nursing home. The nursing homes ranged from sixty beds to five hundred and eighty-nine beds per facility.

## 2.3 INTERVENTION

The intervention was administered by two teams. The *skin team* consisted of a wound care nurse, who completed the initial screening process and weekly follow-up skin assessments to record pressure ulcer outcomes. The *seat team* consisted of occupational and physical therapist who completed the wheelchair intervention, measured wheelchair outcomes at certain time points (see below), addressed changing wheelchair seating needs and maintained study equipment. The seat team was also comprised of student research assistants who helped the assessing clinician and helped with the weekly follow-ups. Various forms were used to document every phase of the

study. All forms used in the study are presented in appendices. The forms and their associated time line have been described in Appendix B.

Participants were randomized into one of two groups:

*Control group:* Participants randomized to this group received a skin protection cushion with related adjustments in the nursing home provided manual wheelchair.

*Treatment group:* Participants allocated to this group received a Breezy Ultra 4 individually-configured lightweight manual wheelchair and a skin protection cushion.

Individuals in both groups were given one of three cushions: Quadtro (The ROHO group; Belleville, IL), Jay 3 (Sunrise Medical; Fresno, CA) or Vicair Vector (Comfort Company; New Berlin, WI). Every resident was followed for up to a period of six months every week by a clinician who checked the seating system and by a nurse who checked for seating surface-related pressure ulcers.

### 2.3.1 Equipment used in the study

The three skin protection cushions used were:

(a) A combination of gel and foam: JAY 3 (Sunrise Medical; Fresno, CA)

(b) Segmented air bladder: Quadtro (The ROHO group; Belleville, IL)

(c) Air packets distributed within cushion sections based on positioning needs: Vicair Vector (Comfort Company; New Berlin, WI).

**Figure 2.1. Jay 3 cushion: Combination of Gel and foam**

**Figure 2.2. Vicair Vector cushion: Air packets distributed**


**Figure 2.3. ROHO Quadtro Cushion: Segmented Air Cushion**

**Figure 2.4. Breezy Ultra 4: High-strength, lightweight manual wheelchair**

The Breezy Ultra 4 was the high-strength, lightweight manual wheelchair provided to residents who were randomized to the treatment group. The control group residents were provided a skin protection cushion with related adjustments to the wheelchairs provided by nursing homes. Even though the initial aim of the parent study was to provide a lightweight individually-configured wheelchair to the treatment group and not make changes to the nursing home wheelchair for the control group, some related adjustments had to be made to the control group wheelchairs to accommodate the study cushions for safety reasons and certain ethical issues were addressed with regards to posture, comfort and safety. The adjustments made to the control group wheelchair included the addition of drop seats to maintain seat-to-floor height, adjustment of leg rest height, and provision for a wheelchair seat tilt to prevent sliding out of the wheelchair. When these adjustments failed to accommodate individual seating needs safely, a provision was made for a different nursing home wheelchair.

## 2.4 METHODS

The parent study clinical trial was conducted to test the hypothesis that the incidence of sitting acquired pressure ulcers is lower for participants with individually-configured lightweight manual wheelchairs with skin protection cushions than for those with skin protection cushions in nursing home provided manual wheelchairs.

This dissertation uses descriptive data about the falls reported to the research team on a weekly basis during the resident's tenure in the study to help classify falls as a general fall or a wheelchair-related fall. The research staff clinician in charge evaluated the cause of each fall and

assessed whether the causative factor of the fall could be prevented or corrected. The University of Pittsburgh Institutional Review Board approved the protocol.

The study consisted of:

(a) Eligibility screening,

(b) Obtaining baseline data,

(c) Randomization,

(d) Wheelchair intervention and cushion assignment,

(e) Day 7 wheelchair assessment by seat team,

(f) Day 14 wheelchair assessment by seat team,

(g) Weekly wheelchair follow-ups,

(h) Weekly skin assessment,

(i) Endpoint assessment.

Table 1 presents the data collected at each study time point. The FEW-C data were collected during the pre-randomization phase, Day 14 assessment and endpoint assessment. The WST data were collected during the intervention, Day 7 assessment, Day 14 assessment and endpoint assessment. Incidence of a pressure ulcer, death, or 26 weeks of tenure in the study were predefined study endpoints. Other endpoints that occurred included withdrawals due to inability of study equipment to accommodate wants/needs, or change in functional status that interfered with an individual's ability to sit in a wheelchair.

Table 1: Data collection summary

| | Braden Risk Assessment Scale | Functioning Everyday with a Wheelchair | Nursing home life-space diameter | Wheelchair Skills Test | Minimum Data Set | Wheelchair and cushion adjustments | Pressure ulcer status |
|---|---|---|---|---|---|---|---|
| Eligibility screening | √ | | | | | | √ |
| Baseline (Pre-rand) | | √ | √ | | | | |
| Wheelchair intervention and cushion assignment | | | | √ | √ | | |
| Day 7 wheelchair assessment by seat team | | | | √ | | √ | |
| Day 14 wheelchair assessment by seat team | | √ | | √ | | √ | |
| Weekly wheelchair follow-ups | | | | | | √ | |
| Weekly skin assessment | √ | | | | | | √ |
| Endpoint assessment | √ | √ | √ | √ | √ | √ | √ |

### 2.4.1 Research design

The RCT-WC2 was a single blind randomized clinical trial. The research nurse who conducted the skin assessments was blind to the randomization group of the subject.

The participant was first consented, by self-consent or by a health proxy when indicated. A flow chart showing the data collection process has been represented in Figure 2.5.

### 2.4.2 Screening:

A skin screening was completed by the skin team to ensure no seated-surface pressure ulcers, followed by a visual seat verification by the seat team to determine that the study equipment was suitable. The eligibility criteria for the study are listed in Table 2.

### 2.4.3 Post-randomization process:

After screening, ineligible residents did not continue to randomization. If the residents met the eligibility criteria, they were randomized by the seat team, followed by the seating assessment and equipment issue. Once the resident received the equipment, the active follow-up phase of the study began.

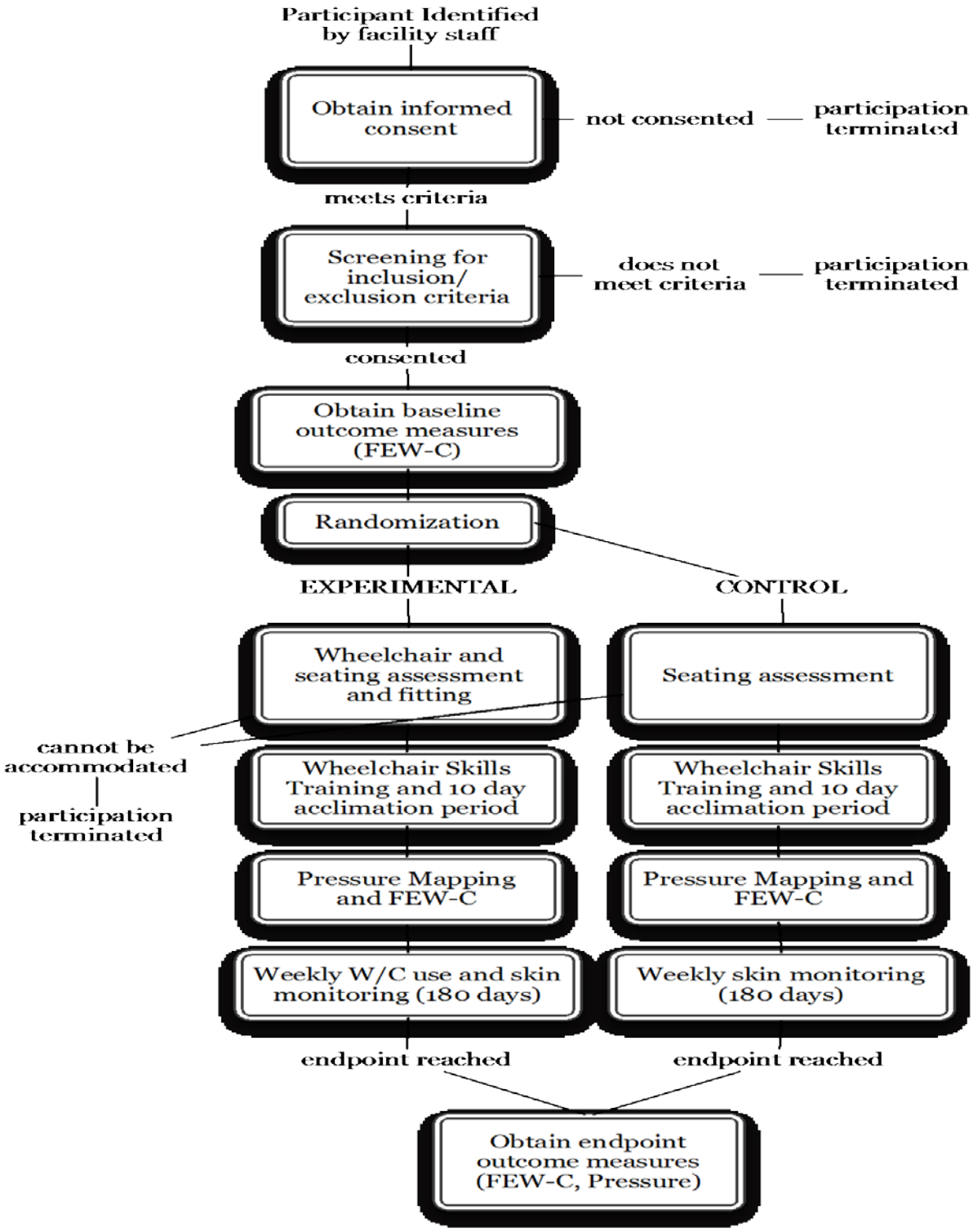



**Figure 2.5. Flow chart showing the data collection process**

Table 2. Randomized controlled trial on wheeled mobility for preventing pressure ulcers (RCT-WC2) inclusion and exclusion criteria.

| Criteria |
|---|
| **Inclusion Criteria** |
| Male or Female 60 years or older |
| Braden Risk assessment score ≤18 |
| A combined Braden Activity-mobility subscale score ≤5 |
| Tolerance for total daily wheelchair sitting time ≥6 hours |
| Current use of manual wheelchair |
| Ability to accommodate seating and positioning needs with the selected study wheelchair |
| Informed written consent |
| **Exclusion Criteria** |
| Body weight ≥250 pounds |
| Hip width ≥20 inches |
| Wheelchair seating requirements that exceed the accommodating capability of study chair |
| Current use of cushioning material other than a standard cushion |
| Current use of a HCPCS Code K 0005 wheelchair |

The skin and seat teams followed up weekly with the participant until an endpoint was reached. The participant could reach endpoint based on the seat or skin team's discretion. The study endpoints are listed in Table 3. The seat team assessed each participant for weekly changes in seating needs and completed equipment maintenance whenever needed. During the weekly

assessment, the seat team also determined whether the participant had been using study equipment and if any falls or adverse events occurred.

Table 3. Randomized controlled trial on wheeled mobility for preventing pressure ulcers (RCT-WC2) study endpoints

| Study Endpoints |
| --- |
| Development of seated-surface pressure ulcer |
| 26 weeks since initiation of seating intervention |
| Discharge from long term care |
| Withdrawal by research team due to non-compliance or changing needs |
| Withdrawal by family/subject |
| Death |

### 2.4.4 Outcome measures

Various outcome measures were used to objectively evaluate the effects of study intervention. This section describes the outcome measures from the parent study that were used for the dissertation analyses.

#### 2.4.4.1 Braden Risk Assessment Scale Score (Appendix D)

The Braden Risk Assessment Scale (BRA) for pressure ulcers was initially developed for individuals in long term care settings to encourage early identification of pressure ulcers in those identified as being at risk (Lewicki, Mion, Splane, Samstag, & Secic, 1997). The Braden Risk

Assessment scale is one of several screening instruments identified in the Agency for Health Care Policy and Research Prediction and Prevention Clinical Practice Guidelines (Lewicki et al., 1997). The Braden Risk Assessment scale consists of six subscales, sensory perception, skin moisture, activity, mobility, friction and shear. The patient risk scores from the Braden Risk Assessment Scale score ranged from 6 to 23. Lower scores indicate a greater risk. A cut-off point of 18 divided the patients into 2 risk groups. A score of ≥18 indicated a significant risk for developing a pressure ulcer, whereas a score of 19 or greater indicated no significant risk (Lewicki et al., 1997). For nurses' aides and licensed practical nurses, the reliability of the Braden Risk Assessment scale ranged from r = 0.83 to r = 0.94. However the reliability increased to r = 0.99 when used by registered nurses (Bergstrom, Braden, Laguzza, & Holman, 1987).

#### 2.4.4.2 Pressure Mapping

Pressure mapping yields objective data on peak pressure and overall pressure distribution when the user is seated. Pressure mapping was a tool used by the seating clinician to help identify cushions with the best pressure distribution and least pressure points for each recruited individual. Pressure distribution was measured with a thin sensor mat (Force Sensor Array system (FSA), Vista Medical, Manitoba-Canada) that was placed between the skin protection cushion and the user's buttocks. The thin sensor mat contains 16 x 16 array of sensors.

The data computed from the sensors are presented in two different ways:

(a) a contoured map which was color coded, and

(b) numerical values.

The FSA files were converted to an Excel workbook. Three values were objectively recorded on the Interface Pressure form (Appendix J): peak pressure index, peak pressure, and average of top four pressure indices.

#### 2.4.4.3 Nursing Home Life-Space Diameter (Appendix P)

The NHLSD is a measure of the extent and frequency of mobility among skilled nursing facility residents (Tinetti & Ginter, 1990). The NHLSD (Peel et al., 2005; Tinetti & Ginter, 1990) is a tool used to calculate a nursing home resident's life space during the previous 2 weeks. The total scores of the NHLSD range from 4 to 78, and staff recall for 2 weeks achieved 0.92 inter-rater reliability (Tinetti & Ginter, 1990). The NHLSD has shown to be significantly related to independence in ADLs ($r = 0.45 - 0.53$, $p < 0.001$) and participation in social activities ($r = 0.56$, $p < 0.001$) (Tinetti & Ginter, 1990).

#### 2.4.4.4 Functioning Everyday with a Wheelchair-Capacity (Appendix I)

A team of researchers at the University of Pittsburgh developed a 10-item self-report outcome measurement tool called Functioning Everyday with a Wheelchair (FEW) as a dynamic indicator of perceived user function related to wheelchair use (Schmeler, 2006). The FEW has demonstrated good test-retest reliability (Mills, Holm, & Schmeler, 2007). Two observational versions of the FEW – Capacity (FEW-C) and FEW-Performance, have also been developed. The FEW-C was developed with the item content as the functioning every day with a wheelchair self-report and modeled after the performance assistance self-care skills (Mills et al., 2007; Schmeler, 2006). The FEW-C was designed to be used in a controlled clinical environment or laboratory setting. It is a criterion-referenced, performance-based observation system used to

measure functional abilities of individuals using a wheelchair with respect to wheeled mobility and seating interventions.

#### 2.4.4.5 Wheelchair Skills Training (WST) (Appendix T)

The wheelchair skills test was administered to train and measure wheelchair skills (Kirby et al., 2002). The test was used to eliminate training as a confounding variable in both groups. A subset of six training tasks from the WST were used. The scoring system was divided based on performance and safety. The intraclass correlation coefficient (ICC) for test-retest reliability for the skill score was 0.901, indicative of substantial agreement, and 0.254 for the safety score, indicative of none to slight agreement (Lindquist et al., 2010). The ICC for intra-rater reliability is excellent for the performance score (0.950) and poor for the safety score (0.228) (Lindquist et al., 2010). The ICC for interrater reliability is excellent for the performance score (0.855) and poor for the safety score (0.061) (Lindquist et al., 2010).

#### 2.4.4.6 Minimum Data Set (MDS) (Appendix K)

The Minimum Data Set (MDS) is a tool to monitor resident status in long-term care facilities. Federal policies require that MDS be completed quarterly for all nursing home residents unless a resident has a significant deterioration in health status. MDS version 3.0 was implemented on October 1, 2010 and the latest entry using this version of MDS was collected for all study participants. The MDS is a part of United States federally mandated process that focuses on clinical assessments of nursing home residents to help with screening for unrecognized, unevaluated common syndromes and conditions. The MDS data has been used for various purposes, the main one being effective inter-staff communication and documentation of patient

status. Various research studies use the MDS to retrospectively analyze different aspects of care. French et al. (2007) state that the resident's MDS assessment and care planning instrument is a key component in resident safety efforts (French et al., 2007).

## 2.5 PARTICIPANTS

A total of 258 nursing home residents were enrolled in the study. Table 4 below describes the characteristics of the study population.

### 2.5.1 Sample population

Participants were recruited from 17 nursing homes in the greater Pittsburgh area. The total number of licensed beds in the nursing home ranged from 60-589. A 1:1 allocation randomization scheme stratified by clinical facility was prepared. A telephone-based randomization system was used and residents were assigned to either the treatment group (the intervention of an individually configured lightweight manual wheelchair with a skin protection cushions) or the control group (the provision of a skin protection cushion on a nursing home provided wheelchair). The sample consisted of 258 participants with 131 in the control group and 127 in the treatment group. Participants had a mean age of 85.75 (±8.66) years and had lived in a nursing home for a mean of 2.01 (±2.49) years. Participant demographic characteristics are shown in Table 4. Participants were primarily white (91.8%) and female (78.5%), with the majority having a diagnosis related to the heart (62.64%), vascular system (55.64%),

musculoskeletal/integument system (61.86%), neurological system (57.19%) and psychiatric illnesses (63.25%).

Table 4. Characteristics of the study sample by randomization group

| | **Total Sample** | **Treatment Group** | **Control group** | **p-value** |
|---|---|---|---|---|
| **Parameter** | **Mean (Standard Deviation)** | | | |
| Age | 85.75 (8.662) | 85.71 (8.40) | 85.79 (8.94) | 0.191 |
| Length of stay in a nursing home at time of enrollment (in years) * | 2.01 (2.49) | 2.06 (2.88) | 1.97 (2.05) | 0.275 |
| Number of medications ** | 13.82 (5.348) | 13.55 (5.4) | 14.08 (5.30) | 0.571 |
| | **Frequency (Percentage)** | | | |
| GENDER | | | | |
| Female | 202 (78.5) | 97 (76.4) | 105 (80.2) | 0.448 |
| RACE | | | | |
| White | 236 (91.8) | 117 (92.1) | 119 (90.8) | 1.000 |
| Black | 21 (8.1) | 10 (7.9) | 11 (8.4) | 1.000 |
| DIAGNOSIS relating to: | | | | |
| Heart | 161(62.64) | 79 (62.2) | 82 (62.6) | 0.898 |
| Vascular system | 143 (55.64) | 70 (55.1) | 73 (55.7) | 0.900 |
| Hematopoietic system | 32 (12.45) | 16 (12.6) | 16 (12.2) | 1.000 |
| Respiratory system | 85 (33.07) | 49 (38.6) | 36 (27.5) | 0.084 |
| Eyes, Ears and Nose | 46 (17.89) | 18 (14.2) | 28 (21.4) | 0.144 |
| Upper Gastrointestinal system | 55 (21.3) | 27 (21.3) | 28 (21.4) | 1.000 |
| Lower Gastrointestinal system | 36 (14) | 22 (17.3) | 14 (10.7) | 0.152 |
| Liver system | 5 (1.9) | 2 (1.6) | 3 (2.3) | 1.000 |
| Renal system | 43 (16.73) | 16 (12.6) | 27 (20.6) | 0.095 |
| Genitourinary system | 56 (21.78) | 27 (21.3) | 29 (22.1) | 0.881 |
| Musculoskeletal/Integument | 159 (61.86) | 76 (59.8) | 83 (63.4) | 0.523 |
| Neurological system | 147 (57.19) | 72 (56.7) | 75 (57.3) | 0.900 |
| Endocrine, Metabolic, Breast | 67 (26.07) | 25 (19.7) | 42 (32.1) | 0.023 |
| Psychiatric | 160 (63.25) | 77 (60.6) | 83 (63.4) | 0.609 |
| Diabetes | 57 (22.17) | 27 (21.3) | 30 (22.9) | 0.765 |
| Other | 65 (25.29) | 33 (26.0) | 32 (24.4) | 0.886 |

| Table 4 (Cont'd) | | | | |
|---|---|---|---|---|
| INCONTINENCE | | | | |
| Urine | 193 (75.09) | 98 (77.2) | 95 (72.5) | 0.122 |
| Feces | 169 (65.75) | 81 (63.8) | 88 (67.2) | 0.008 |
| Previous History of pressure ulcers | 44 (17.12) | 27 (21.3) | 17 (13) | 0.129 |
| History of hip surgery | 31 (12.06) | 17 (13.4) | 14 (10.7) | 0.570 |

Table 5. Classification of subjects based on reasons for reaching endpoint

| **Reason for reaching endpoint** | **Frequency (Percent)** | **Treatment Group (Percent)** | **Control Group (Percent)** |
|---|---|---|---|
| Development of a seated surface pressure ulcer | 33 (12.8) | 19 (14.96) | 14 (10.69) |
| Completed 26 weeks in the study | 131 (51.2) | 70 (55.91) | 61 (46.56) |
| Death | 13 (5.0) | 8 (6.30) | 5 (3.82) |
| Withdrawal by subject/family | 19 (7.4) | 8 (6.30) | 11 (8.40) |
| Withdrawal by study team | 48 (18.6) | 19 (14.96) | 30 (22.90) |
| Total | 244 (94.9) | 124 (97.64) | 121 (92.37) |
| Missing | 14 (5.4) | 3 (2.36) | 10 (7.63) |
| Grand Total | 258 (100) | 127 (100) | 131 (100) |

Table 5 shows the classification of subjects based on the various reasons for reaching endpoint. Reasons for reaching endpoint included development of seated surface pressure ulcer, completion of 26 weeks in the study, death, and withdrawal by a team or family member. Of the 258 subjects, 131 (51.2%) reached endpoint due to completion of the 26-week follow-up in the study while 33 (12.8%) reached endpoint due to development of a seated surface pressure ulcer.

# 3.0 ROLE OF INDIVIDUALY FIT MANUAL LIGHTWEIGHT WHEELCHAIRS ON FALL RISK IN FULL TIME NURSING HOMES WHEELCHAIR USERS

## 3.1 INTRODUCTION

### 3.1.1 Epidemiology of falls

A significant health burden is experienced from falls and fall related injuries (Chen et al., 2011). Each year, 30% of individuals above the age of 65 experience at least one fall a year and half of these individuals fall recurrently (Davis et al., 2010). In individuals 65 years and older, the Centers for Disease Control and Prevention reports falls to be the leading cause of deaths due to injuries. Individuals who fall are at greater risk for institutionalization than individuals who do not fall (Tinetti, Liu, & Claus, 1993). Fear of falling and increasing self-restriction of activities is a result of the psychological impact of a fall (Tinetti et al., 1993). An older person presenting to an emergency department with a fall is at a high risk of falling again if they do not receive care to manage the risks of factors associated with the fall (Kalula, De Villiers, Ross, & Ferreira, 2006; Paniagua, Malphurs, & Phelan, 2006; Salter et al., 2006). Due to the high costs associated with falls, loss of functional status and death, policy makers and health care providers focus their efforts on preventing falls and minimizing injuries.

### 3.1.2 Falls in nursing homes

According to the “Nursing home compendium” compiled by the Centers for Medicare and Medicaid Services in 2013, there are a total of 15,643 nursing homes in the United States of

America (Medicare & Services, 2013). A total of 1,409,749 individuals reside in nursing homes (Medicare & Services, 2013).

Table 6- Summary percentages of falls in nursing home residents

| | **65-74 years** | **75-84 years** | **85-94 years** | **95+ years** |
|---|---|---|---|---|
| **≥1 falls causing no injury** | 10.2% | 11.3% | 12.2% | 13.1% |
| **≥1 injurious falls** | 4.2% | 5.3% | 6.2% | 7.0% |

Table 6 summarizes, by the category of age, the percentage of nursing home individuals who had at least one fall in a given year (Medicare & Services, 2013). As seen in Table 6, there is an increase in the number of falls as well as number of injurious falls as age increases. In individuals 75-84 years of age, a total of 159,365 (11.3%) residents had at least one fall in any given year, with 74,770 (5.3%) of the falls being injurious (Medicare & Services, 2013). The mean age of individuals who have one fall or more is 80.6 years; and individuals who have more than one injurious fall is 82.1 years. The report has no information about wheelchair related falls (Medicare & Services, 2013).

Reasons for falls in nursing home wheelchair users include the users' underlying impairment, cognition, inability to compensate for environmental barriers, inadequate facility care practices, and independence in wheelchair use and transfers (Masud & Morris, 2001; Nelson et al., 2010). Fall prevention strategies for individuals over 65 years in in-patient rehabilitation facilities have demonstrated decreased falls (Aizen et al., 2007). However, there are relatively few studies focusing on fall risks in full time manual wheelchair users.

### 3.1.3 Literature review

Patient safety is one of the most important goals of a care plan. Due to the high level of threat falls represent to patient safety, and realizing that many people at risk for falls use wheelchairs, this literature review was initiated to determine whether links have been established between wheelchair use and falls for older nursing home residents. Cochrane, OVID, PubMed, Google scholar, PEDRO and CINHAL were the search engines used. The following key words were used either in combination or independently: falls, accidental falls, wheelchair falls, nursing home residents, wheelchair users, safety, geriatric/elderly population. Studies published from 1989 to 2015 were used to create a body of evidence that serves as background and supports the rationale for this study.

Various studies included in this review were based on the characteristics of the sample and the context of the research. For example, studies about wheelchair-related falls were included even if the focus wasn't on individuals above 65 years. In a similar way, studies looking at factors affecting fall risk in individuals were also included even if the sample wasn't of nursing home-based individuals. This was done because there was limited existing research studying wheelchair related falls in nursing home residents for full time manual wheelchair users. Various factors such as polypharmacy, diagnosis of depression or delirium, balance issues, and poor postural control were said to have contributed to falls (Handfield-Jones, 1989). This review focuses on using these factors from the existing studies to examine their role in wheelchair related falls.

### 3.1.4 Factors associated with falling

A fall is a multifactorial complex phenomenon (Al-Aama, 2011). Falls and various factors associated with falling have been extensively studied, with over 400 factors identified (Masud & Morris, 2001). Factors related to a fall can be "intrinsic," which means some event or condition affects postural control; or "extrinsic" where the environmental factor is the main cause of the fall (Masud & Morris, 2001). Individuals who have had a fall are one and a half times more likely to experience a subsequent fall (Chen et al., 2011; Davis et al., 2010; Fries et al., 2000; Hofmann et al., 2003). A bidirectional relationship between fear of falling and falling has also been identified (Fonad et al., 2008; Fries et al., 2000; Hofmann et al., 2003). Impairment in gait, balance and/or transfer skills have been identified as risk factors for falling (Fuller, 2000). Falls are associated with lower levels of functional ability and inability to understand or follow commands (Teasell, McRae, Foley, & Bhardwaj, 2002). Rubenstein (1994) analyzed falls sustained per hour of activity level, and attributed them to increased exposure to environmental hazards (Daechsel & BSR, 1988; Rubenstein et al., 1994). A post fall evaluation supports identifying causes of falls which helps in reduction of secondary falls (Aizen et al., 2007; Kirby & Smith, 2001). Evaluating a fall after it has occurred is important in recognizing and correcting the cause of the fall (Kirby & Smith, 2001). Identification of risk factors and appropriately addressing those risk factors associated with a particular fall helps prevent more falls with the same cause (Aizen et al., 2007; Kirby & Smith, 2001). It is important to understand the factors associated with falling and how to control them to avoid subsequent falls which can lead to morbidity, mortality, functional deterioration, hospitalization, institutionalization and added expenditures of health and social services (Masud & Morris, 2001).

Nelson et al., (2010) found pain to be a risk factor for wheelchair-related falls in veterans with spinal cord injury residing in the community (Nelson et al., 2010). Pain decreases the

efficiency of movement and causes dysfunctional postures during wheelchair activities (Nelson et al., 2010). After the first week of the onset of a disease, the risk of falls moves from intrinsic factors to extrinsic environment and activity related factors (Aizen et al., 2007). A high incidence of falls in individuals found in the stroke rehabilitation units was thought to be due to cognitive impairment (Aizen et al., 2007). Post-operative cognitive dysfunction might possibly explain the high incidence of falling while engaging in a risk-taking activity among patients hospitalized for hip surgery on the in-patient rehabilitation unit (Aizen et al., 2007). A study which investigated the effect of a multifactorial intervention program on reduction of falls and fall-related injuries, showed a prevention program targeting residents, staff, and the environment may reduce falls and femoral fractures (Jensen, Lundin-Olsson, Nyberg, & Gustafson, 2002). Precautionary measures should be taken to prevent the individual with a history of previous falls from falling again (Fries et al., 2000).

The role of individually configured lightweight manual wheelchairs was investigated in light of the following research questions:

1. Do individuals using individually-configured lightweight manual wheelchairs *with a previous history of falls* have a lower incidence of falling compared to individuals using nursing home wheelchairs with related adjustments?

2. In a six-month study follow-up, do individuals with individually-configured lightweight manual wheelchairs have a lower incidence of falling compared to individuals with nursing home wheelchairs with related adjustments?

### 3.1.5 Role of mobility related assistive technology devices with falls

After the first week of the onset of a disease, the risk of falls moves from intrinsic factors to extrinsic environment and activity-related factors (Aizen et al., 2007). Improper use of assistive devices like canes, crutches, walkers or wheelchairs (which are markers of abnormal gait) may directly increase the risk of falling by impairing compensatory mechanisms (French et al., 2007).

Use of an appropriate assistive device has been suggested to address fall risk factors associated with gait disturbances, issues with balance, and during transfers (Fuller, 2000). A cross-sectional study examining multiple mobility device use and fall status among middle-aged and older adults with multiple sclerosis determined an association between use of mobility aids and falling (Finlayson, Peterson, & Asano, 2013). However, the cross-sectional nature of the study wasn't able to determine the direction of the association. Wheelchair use has been suggested to be a factor increasing fall risk (Aizen et al., 2007). It is a challenge to reduce the number of falls and injuries without lowering activity (Aizen et al., 2007). One wheelchair related death occurs per week in the United States (Fonad et al., 2008; Gavin-Dreschnack et al., 2005). Wheelchair-related injuries in the group of individuals above 65 years of age were higher compared to younger age groups (Xiang, Chany, & Smith, 2006).

Boswell-Ruys, Harvey, Delbaere, and Lord, (2010), conducted an observational study and a cross-sectional survey to develop a scale assessing concern about falling for people with spinal cord injuries who are dependent on manual wheelchairs. The Spinal Cord Injury-Falls Concern Scale (SCI-FCS) addressed concerns related to falls during 16 activities of daily living associated with falling (Boswell-Ruys, Harvey, Delbaere, & Lord, 2010). Activities such as transfers from wheelchair to different surfaces, reaching from a wheelchair, and/or pushing the wheelchair on different surfaces may be considered risk factors for falling (Boswell-Ruys et al., 2010). However, this study did not account for wheelchair fit or training after wheelchair acquisition.

Aizen et al., (2007) investigated the incidence, characteristics, and risk factors that predicted falls in different populations hospitalized in a geriatric rehabilitation hospital. A total of 168 patients were evaluated for the predisposing and situational risk factors of the fall (Aizen

et al., 2007). It was found that risk factors differed among three subgroups, namely: patients hospitalized for stroke rehabilitation, hip surgery rehabilitation, and other rehabilitation patients (Aizen et al., 2007). Wheelchairs contributed to falls when the study sample subjects used improper transfer techniques or when the wheelchair was in poor repair (Aizen et al., 2007). The incidence of wheelchair related falls differed between facilities due to the individual's host-related activities, patients with risky behaviors, decreased transfer capacity or other patient characteristics (Aizen et al., 2007). Individually tailored and prescribed wheelchairs should be used as an intervention measure for individuals who have had a fall (Aizen et al., 2007).

Kirby et al. (1994) studied the wheelchair accidents caused by tips and falls among non-institutionalized manual wheelchair users in Nova Scotia. They classified risk factors associated with wheelchair related accidents into four groups: the user, the chair, the system (access to professionals) and the environment (purpose of wheelchair use, terrain, etc.) (Kirby, Ackroyd-Stolarz, Brown, Kirkland, & MacLeod, 1994). Their aim was to emphasize the importance of the wheelchair prescription process and wheelchair use training in different high-risk environments (e.g.: ramps) (Kirby et al., 1994).

Xiang, Chany & Smith (2006) used data from the National Electronic Injury Surveillance System (NEISS) and conducted a detailed analysis of injuries among wheelchair users. Due to the increased number of wheelchair related injuries from 1991, they analyzed wheelchair related falls in emergency departments and devised a conceptual model (Xiang et al., 2006). This conceptual model classified potential risk factors into four broad categories: engineering factors (for example, type of wheelchair, wheelchair occupant restraint systems, anti-tippers, wheelchair locks etc.); characteristics of wheelchair users (socio- demographic factors, diagnosis, etc.); physical environment (terrain of the surroundings, door widths, modification of surroundings,

etc.) and social environment (inappropriate prescription of wheelchair by health professionals, inadequate maintenance of wheelchair, etc.) (Xiang et al., 2006). Modifications to any of the four broad factors can possibly reduce tips and falls which may result in a reduction of wheelchair related factors (Xiang et al., 2006). The researchers aimed at focusing on dynamic systems associated with wheelchair use rather than focusing on the wheelchair user's individual accountability. The research study's focus was on the society's responsibility to meet needs of wheelchair users by making necessary modifications (Xiang et al., 2006).

According to the model for examining wheelchair-related falls in a study by Gavin-Dreschnack, et al. (2005), hazardous conditions give rise to adverse events as a result of the interaction among the following five variables: 1) characteristic of the user, 2) wheelchair type and features, 3) healthcare practices by providers and patients, 4) wheelchair activities and 5) characteristics of the environment (Gavin-Dreschnack et al., 2005). The model by French et al. (2007) suggested that a multifaceted fall reduction program for the nursing home should include resident risk factor assessment and modification, staff education, gait assessment and intervention, assistive device assessment and optimization and environmental assessment and modification (French et al., 2007).

Wheelchairs may be an extrinsic factor affecting falls in the elderly (Handfield-Jones, 1989). Hence, a need to analyze wheelchair related falls and analyze the factors causing these falls exists. Falls from wheelchairs can be due to mismanagement of the wheelchair by the user with respect to the environment (Kirby & Smith, 2001). It has been suggested that the prevalence of falls can be decreased when changes are made to the environment, staffing and restorative activity program in cost-sensitive nursing homes environments (Hofmann et al., 2003). A study of a multifactorial fall prevention intervention found a history of falls in the previous 12 months

to be a risk factor for future falling (Russell et al., 2010). Wheelchair falls affect the function, activity, independence and quality of life of the user (Gavin-Dreschnack et al., 2005). Poorly fitting wheelchairs lead to poor posture which results in higher pressure and greater pressure ulcer risk (Brienza et al., 2010). A need exists to provide a skin protection cushion, together with a seating evaluation for an individually configured lightweight manual wheelchair by a clinician trained to conduct seating evaluations (Friedman et al., 1995). Various modifications to the wheelchair characteristics can possibly enhance wheelchair user safety (Gavin-Dreschnack et al., 2005). In the geriatric population there is limited research that emphasizes the importance of an individually configured lightweight manual wheelchairs in reducing fall risk.

## 3.2 METHODS

This study was conducted to test the following hypotheses:

1. In individuals residing in nursing homes *who have a recent (2-6 month) prior history of falls*, providing a seating and wheelchair evaluation with an individually configured lightweight wheelchair and skin protection cushion reduces the incidence of falling compared to individuals with nursing home provided wheelchairs and skin protection cushions with related adjustments.

2. In individuals residing in nursing homes, providing individually configured lightweight manual wheelchairs and skin protection cushions reduces the incidence of falling compared to individuals using nursing home provided manual wheelchairs and skin protection cushions using related adjustments.

### 3.2.1 Research design

The study is a retrospective secondary analysis of a fixed data set from the National Institutes of Health grant titled: An RCT on Wheeled Mobility for Preventing Pressure Ulcers (Grant number:

2R01HD041490). A 1:1 random allocation telephone-based system was used to randomize the subjects in the treatment or control group. Individuals in the treatment group received an individually-configured Breezy Ultra 4 Lightweight Manual Wheelchair with a skin protection cushion. Individuals in the control group received a skin protection cushion in the nursing home provided chair. One of three skin protection cushions was used: either the ROHO Quadtro, Sunrise Jay 3 or Vicair Vector cushion. Weekly fall data were analyzed for this study. Individuals were followed for 26 weeks unless they reached a protocol endpoint (development of a seating surface pressure ulcer, death or withdrawal from the study). Fall data collected during each weekly follow up were considered for this data analysis. Incident of a fall, mechanism of the fall, and related injuries were collected using medical record reviews or interviews with key personnel in facilities where medical record reviews were not possible.

### 3.2.2 Definition of a fall

Falls are defined in many ways depending on the contexts and are understood differently in different healthcare settings by diverse professionals. However, many research studies require a fall to include “unintentional” contact with the ground. This excludes falls due to road accidents, episodes of violence, etc. The ICD-9 defines falls as an unexpected event where the person falls to the ground from an upper level or the same level. A fall has been defined by the World Health Organization as an event that results in a person coming to rest inadvertently on the ground or floor or other lower level. The ICD-9 codes wheelchair falls as 884.3 and ICD-10 codes wheelchair falls as W05.

### 3.2.3 Classification of falls

Falls were classified in the parent study as follows:

1. Falls occurring during a wheelchair transfer,

2. Falls occurring during wheelchair use other than a transfer, and

3. Other non-wheelchair use related falls.

If the fall was wheelchair related (as indicated in item 1 and 2 above), the subject's health status and wheelchair configuration were reviewed. Modifications were made as needed to the wheelchair to prevent the reoccurrence of a similar event. Whenever appropriate the research staff suggested to the nursing home staff that they process paperwork for positioning seat belts. Wheelchair axle positions were adjusted with respect to the castor height, i.e., the wheelchair was "dumped" so the front end of the wheelchair was higher than the rear end of the chair, which gave the resident the ability to use gravity to their advantage and prevent sliding from the chair. If the fall was not wheelchair related, the action taken by the nursing home was noted by the study team. Wheelchair adjustments were made and the inter-staff communications were documented weekly.

The Minimum Data Set (MDS) is a part of United States federally mandated processes which focuses on clinical assessments of nursing home residents to help with screening for unrecognized, unevaluated common syndromes and conditions. In order to efficiently document residents' status on a periodic basis, MDS data is collected annually, semi-annually, quarterly and/or whenever there is a change in the functional status (Ray et al., 1997). The MDS data has been used for various purposes, the main one being effective inter-staff communication and documentation of patient status. Various research studies use the MDS to retrospectively analyze different aspects of care. Section J of the MDS, addressing the health conditions of the individual, documents history of falls in the sixteenth question. This study used section J of MDS

data to determine the history of falls for hypothesis 2.1 from MDS data collected just prior to subject entry into the study.

The parent study used the categorization system from MDS version 3.0 of the MDS to classify the injury level resulting from falls. Further, a three-level categorization system based on the MDS 3.0 version was used:

No Injury: No evidence of any injury was noted on physical assessment by the nurse or primary care clinician; no complaints of pain or injury by the resident; no change in the resident's behavior is noted after the fall.

Injury (except major): Skin tears, abrasions, lacerations, superficial bruises, hematomas and sprains; or any fall-related injury that causes the resident to complain of pain.

Major injury: Bone fractures, joint dislocations, closed head injuries with altered consciousness, subdural hematomas.

### 3.2.4 Data Analysis

Only participants with MDS information on fall history were included in the analyses for this aim. Data were summarized as frequencies and percentages for categorical variables. Numerical summaries were conducted to understand the data and ensure no outliers. A Pearson's Chi-Square test for independence was conducted during which subjects were characterized by group randomization and with respect to prior history of falling. The data was categorized based on intervention group, fall history before being recruited in the study, and presence of falls during the study follow up period after equipment was issued. Only the subjects with a known prior history of falling as measured by the MDS were considered in the analyses. An interaction was tested between the effect of the individually configured lightweight manual wheelchair for those who fell with a history of falls and the effect of the individually configured lightweight manual

wheelchair for those who fell without a history of falls using a logistic regression model. The significance threshold for all statistical analyses was set at 0.10, and were performed using SPSS 23.0 for Windows.

## 3.3 RESULTS

Of the 258 individuals who were entered into the study, 131 were randomized to the control group and 127 individuals were randomized to the treatment group.

### 3.3.1 Subject baseline characteristics

Participants had a mean age of 85.75 (±8.66) and had lived in a nursing home for a mean of 2.01 (±2.49) years. Participants took an average of 13.82 (±5.348) medications on a given day. Descriptive characteristics of subjects are shown in Table 7. Participants were primarily white (91.8%) and female (78.5%), with a majority having a diagnosis relating to the heart (62.64%), vascular system, (55.64%), musculoskeletal/integument system (61.86%), neurological system (57.19%) and psychiatric illness (62.25%). A high prevalence of incontinence was observed in the sample with urinary incontinence (75.090) being greater than fecal incontinence (65.75). Previous history of pressure ulcers was prevalent in 17.12% of the study sample. Individuals who had hip surgery accounted for 12.06% of the study sample. A total of 201 individuals were included for the analysis of Aim 1 on falls. The individuals who had missing information of history of falls data in the MDS were excluded from these analyses. Of the 201 individuals, 166 had no prior history of falling and 35 had a prior history of falling.

Table 7. Descriptive analysis of the sample

| | Total Sample | Treatment Group | Control group | p-value |
|---|---|---|---|---|
| **Parameter** | **Mean (Standard Deviation)** | | | |
| Age | 85.75 (8.662) | 85.71 (8.40) | 85.79 (8.94) | 0.191 |
| Length of stay in a nursing home (in years) * | 2.01 (2.49) | 2.06 (2.88) | 1.97 (2.05) | 0.275 |
| Number of medications ** | 13.82 (5.348) | 13.55 (5.4) | 14.08 (5.30) | 0.571 |
| **Frequency (Percentage)** | | | | |
| Gender | | | | |
| Female | 202 (78.5) | 97 (76.4) | 105 (80.2) | 0.448 |
| Race | | | | |
| White | 236 (91.8) | 117 (92.1) | 119 (90.8) | 1.000 |
| Black | 21 (8.1) | 10 (7.9) | 11 (8.4) | 1.000 |
| DIAGNOSIS relating to | | | | |
| Heart | 161(62.64) | 79 (62.2) | 82 (62.6) | 0.898 |
| Vascular system | 143 (55.64) | 70 (55.1) | 73 (55.7) | 0.900 |
| Hematopoietic system | 32 (12.45) | 16 (12.6) | 16 (12.2) | 1.000 |
| Respiratory system | 85 (33.07) | 49 (38.6) | 36 (27.5) | 0.084 |
| Eyes, Ears and Nose | 46 (17.89) | 18 (14.2) | 28 (21.4) | 0.144 |
| Upper Gastrointestinal system | 55 (21.3) | 27 (21.3) | 28 (21.4) | 1.000 |
| Lower Gastrointestinal system | 36 (14) | 22 (17.3) | 14 (10.7) | 0.152 |
| Liver system | 5 (1.9) | 2 (1.6) | 3 (2.3) | 1.000 |
| Renal system | 43 (16.73) | 16 (12.6) | 27 (20.6) | 0.095 |
| Genitourinary system | 56 (21.78) | 27 (21.3) | 29 (22.1) | 0.881 |
| Musculoskeletal/Integument | 159 (61.86) | 76 (59.8) | 83 (63.4) | 0.523 |
| Neurological system | 147 (57.19) | 72 (56.7) | 75 (57.3) | 0.900 |
| Endocrine, Metabolic, Breast | 67 (26.07) | 25 (19.7) | 42 (32.1) | 0.023 |
| Psychiatric | 160 (63.25) | 77 (60.6) | 83 (63.4) | 0.609 |
| Diabetes | 57 (22.17) | 27 (21.3) | 30 (22.9) | 0.765 |
| Other | 65 (25.29) | 33 (26.0) | 32 (24.4) | 0.886 |
| | | | | |
| INCONTINENCE | | | | |
| Urine | 193 (75.09) | 98 (77.2) | 95 (72.5) | 0.122 |
| Feces | 169 (65.75) | 81 (63.8) | 88 (67.2) | 0.008 |

| Table 7 (cont'd) | | | | |
|---|---|---|---|---|
| Previous History of pressure ulcers | 44 (17.12) | 27 (21.3) | 17 (13) | 0.129 |
| History of hip surgery | 31 (12.06) | 17 (13.4) | 14 (10.7) | 0.570 |

### 3.3.2 Falls

As indicated in Table 8, 29 individuals in the treatment group and 41 individuals in the control group fell at least once. The total number of individuals who had wheelchair-related falls in the treatment and control groups were 25 and 30, respectively. There were no statistical differences between the falls in general or the wheelchair related falls in the treatment and control group with p-values of 0.161 and 0.547 respectively.

Table 8. Number of subjects who fell and wheelchair related falls during the study for the entire study population

| | Treatment Group n=127 | Control Group n=131 | Total n=258 | p-value |
|---|---|---|---|---|
| Subjects who fell | 29 (22.84%) | 41 (31.30%) | 70 (27.13%) | 0.161 |
| Wheelchair-related falls during the study | 25 (19.69%) | 30 (22.90%) | 55 (21.32%) | 0.547 |

In Table 9 and Table 10, the Pearson's Chi-Square analysis of all falls during the study and wheelchair-related falls are shown, for those participants with a known history of falls (n=201).

Table 9. Pearson's Chi Square test of falls during the study for those with known history of falls

| | Treatment | Control | p-value | Interaction p-value |
|---|---|---|---|---|
| History of falls (n=35) | 23 | 12 | 0.292 | 0.658 |
| Fall during study (n%) | 7 (30.4%) | 6 (50%) | | |
| No History of falls (n=166) | 77 | 89 | 0.382 | |
| Fall during the study (n%) | 18 (23%) | 27 (30%) | | |

Table 10. Pearson's Chi Square test of wheelchair-related falls during the study for those with known history of falls

| | Treatment | Control | p-value | Interaction p-value |
|---|---|---|---|---|
| History of falls (n=35) | 23 | 12 | 0.709 | 0.473 |
| Fall during study (n%) | 7 (30.4%) | 5 (41.66%) | | |
| No History of falls (n=166) | 77 | 89 | 1.000 | |
| Fall during the study (n%) | 16 (20.77%) | 19 (21.34%) | | |

The alpha level for statistical significance was set to be at $p \geq 0.1$. A borderline difference (p-value = 0.292) exists between the treatment and the control groups for individuals who fell during the study with a previous history of falls (Table 9). There is no statistical difference (p-value=0.709) between the treatment and the control groups for individuals who fell during the study from their wheelchair with a previous history of falls (Table 10). The difference in the percentage of falls in the study between the treatment and control groups appear large enough to be clinically relevant, however because of the imbalance of the sample size between groups and small sample size, it did not reach statistical significance. The interaction p-value for falls in the study with a known history of falling was p=0.658 and for the wheelchair-related falls for those with a known history of falls was p=0.473. The p-values computed by the Pearson's Chi-Square test were not significant (p>0.10), as were the interaction p-values (Table 9 & 10). The interaction tested whether the effect of the individually configured lightweight manual wheelchair for those who fell with a history of falls is the same as the effect of the individually configured lightweight manual wheelchair of those who fell without a history of falls.

Table 11. Distribution of individuals by randomization group with respect to history of falls and falls during the study

| **History of Falls** | **Falls during the study** | **Randomization Group** | | **Total** |
|---|---|---|---|---|
| | | **Treatment n (%)** | **Control n (%)** | |
| No | No | 59 (76.62) | 62 (69.66) | 121(72.89) |
| | Yes | 18 (23.37) | 27 (30.33) | 45 (27.10) |
| | Total | 77 | 89 | 166 |
| Yes | No | 16 (69.56) | 6 (50) | 22 (62.86) |
| | Yes | 7 (30.43) | 6 (50) | 13 (37.14) |
| | Total | 23 | 12 | 35 |

To compare in further detail, the effectiveness of an individually-configured lightweight wheelchair with skin protection cushion on wheelchair related falls, the difference in the

percentages of falls in the treatment group with a history of falls was compared to the difference in the percentages of falls in the control group with a history of falls. Table 11 presents the falls during the study of participants with a history of falls. The difference in falls between groups was 6.96% for those with no history of falls, and 19.56% for those with history of falls, with the treatment group having less falls. Since there was a large difference between these percentages, an interaction was tested. In spite of the large difference in falls, the interaction proved to be insignificant. Even though the difference in the treatment and control groups wasn't statistically significant, individuals who had a history of falls benefitted more from being in the treatment group compared to those without any history of falls.

A power analysis was conducted to determine the sample size of a future study to detect the difference found in this pilot (Table 12). A clinical trial can be designed to test the effect of the wheelchair on wheelchair-related falls. Data specific to wheelchair-related falls history can be collected, followed by prospective fall data collection in nursing home residents in two groups, one who receive standard nursing home care concerned with wheelchair provision, and the other group who receives an individually configured light-weight manual wheelchair. The staff biases could be potentially eliminated if the assignment of treatment groups were randomly assigned to nursing homes.

Table 12. Power analysis- showing the required detectable effect and required sample size to show significant differences

| | **Sample size** | | **Detectable Effect** | |
|---|---|---|---|---|
| **General falls** | **T = 103** | **C = 103** | T = 23 | C = 12 |
| | Pt = 30% | Pc=50% | **Pt ≤7.5%** | Pc = 50% |
| **Wheelchair related falls** | **T = 314** | **C = 314** | T = 23 | C = 12 |
| | Pt = 30% | Pc = 41% | **Pt ≤3.5%** | Pc=41% |

The power for wheelchair-related falls with a history of falling was calculated using the Power and Sample Size software (PASS) with 80% power and alpha level 0.05% using a test for two proportions with a 2-sided Fisher's exact test. Table 12 is a summary of the power analysis showing the required detectable effect and required sample size to show significant differences. When it is assumed that 30% of the treatment group fall during the study and 50% of the control group fall during the study the number of participants required to have a significant difference with an 80% power is 103 per group or a total of 206 total individuals. With the current sample size of the study (258 residents), the smallest effect difference that can be detected if the treatment group has 23 individuals and the control group has 12 individuals. This was assuming the individuals in the control group with the history of falls has a 50 percent incidence of falling then we get a significant difference in treatment in comparison to the control if the treatment group percentage of falls is less than or equal to 7.5%. When it is assumed that 30 % of the treatment group fall during the study and 41% of the control group fall from their wheelchair during the study the number of participants required to have a significant difference with 80% power is 314 per group or a total of 628 total individuals. With the current sample size of the study which is a total of 258 residents, the smallest effect difference we can detect if the treatment group has 23 individuals and the control group has 12 individuals. This was assuming the individuals in the control group with the history of falls has a 50 percent incidence of falling for wheelchair related falls then we get a significant difference in treatment vs control if the treatment group percentage of falls is less than or equal to 3.5%.

## 3.4 DISCUSSION

Wheelchair fit is an important contributing factor impacting wheelchair related falls in nursing home residents who are at a high risk for developing pressure ulcers as determined by Braden scores. There has been minimal focus on the importance of wheelchair fit on falling especially in the elderly nursing home dwelling population. A study by Gell et al. (2015) indicated in their analysis that use of wheelchairs is the third device after a cane and walker used by individuals 65 years and older (Gell, Wallace, Lacroix, Mroz, & Patel, 2015). The high rate of falls in the nursing home population shouldn't be termed as inevitable but should trigger institutions to take various steps to prevent an individual from falling (Ray et al., 1997). Self-selected wheelchairs and wheelchairs selected without professional input or evaluations have issues associated with fit and function (Gavin-Dreschnack et al., 2005).

This is one of the few studies that has focused on wheelchair related falls and the importance of wheelchair fit while accounting for prior history of falls and the safety of the wheelchair user. A similar study looked at the correlation between the history of falling and the incidence of falling in the elderly population but did not focus on individuals who were full time wheelchair users (Finlayson et al., 2013; Ray et al., 1997; Rubenstein et al., 1994). There have been studies assessing wheelchair related falls in various populations (Aizen et al., 2007; Berg et al., 2002; Boswell-Ruys et al., 2010; Chen et al., 2011; Finlayson et al., 2013; Jørgensen et al., 2016; Yang, Feldman, Leung, Scott, & Robinovitch, 2015). The wheelchair was listed as a factor in increasing risk of falling in a study analyzing the risk factors for falling among people aged 45 to 90 years with multiple sclerosis (Finlayson et al., 2013). However, not many studies have discussed and analyzed wheelchair related fall risk specifically in nursing home residing full time manual wheelchair users. In a study by Jensen et al. (2002), the main focus was on fall

and injury prevention (with an emphasis on femur fractures as a result of falls) in individuals in residential care facilities aged 65 years and older. Environmental modification, use of appropriate assistive devices and medication management together with individual exercise prescription reduced the incidence of falling by 8% (Jensen et al., 2002). Elderly individuals using wheelchairs fall due to various reasons. The causes of falls from wheelchairs may be due to the underlying impairment of the individual, inability to compensate to environmental barriers and possible inadequate practices that lead to increased risk associated with falling (Nelson et al., 2010).

Individuals with a prior history of falling are at a higher risk for falling as supported by the literature and this study. In a study by Lord et al. (2005), 30% of the individuals had a prior history of falling for a fall intervention protocol on fall risk and fall in community dwelling individuals 75 years or older (Lord et al., 2005). Lord el als. (2010) results are consistent with the findings of our study as they suggest an increased incidence of falls in individuals with prior history of falling. A study by Gell et al. (2015) had similar findings stating that individuals who used a device with a prior history of falls had a higher incidence of falling in comparison to individuals with a history of falling and no prior device use without a history of falling (Gell et al., 2015).

Based on the recommendation of Gavin-Dreschnack et al. (2005), this aim analyzed the incidence of wheelchair related falls in nursing home residing individuals and also attempted to determine the details of the fall characteristics, grouping them into wheelchair related and non-wheelchair related falls (Gavin-Dreschnack et al., 2005). Use of an assistive device is considered a significant factor for falling in the elderly thus putting individuals using a wheelchair at a

higher risk for falling (Aizen et al., 2007; Calder & Kirby, 1990; Costello & Edelstein, 2008; Finlayson, Peterson, & Cho, 2006; Fonad et al., 2008).

The present study assessed wheelchair related falls in individuals residing in nursing homes who used a wheelchair as their primary means of mobility. No differences were noted in wheelchair related falls between the individuals with individually configured lightweight manual wheelchairs and individuals with nursing home provided wheelchairs. In the context of this study, providing individually configured lightweight manual wheelchairs with skin protection cushions did not change the risk of falling in individuals residing in nursing homes who have a 2-6 month history of falls (30%) compared to individuals using nursing home provided wheelchairs and skin protection cushions (Table 10). Individually configured manual wheelchairs with skin protection cushions did not change the risk for all falls among individuals residing in nursing homes regardless of their fall history compared to individuals using nursing home provided wheelchairs (19.69%) and skin protection cushions (22.90%) (Table 8). The lack of change for falling could be due to the small sample size of individuals who had a wheelchair-related fall. Further analysis and research needs to be done with an adequate sample size to help understand the effect of wheelchair fit on wheelchair related falls. Gavin-Dreschnack et. al (2005) previously stated a need for increased attention to be directed towards the appropriate prescription of wheelchair seating systems (Gavin-Dreschnack et al., 2005).

Wheelchair fit is important when studying wheelchair related falls because poorly fitting wheelchairs may result in poor posture (e.g., poor accommodation of spinal deformities, posterior pelvic rotation, pelvic obliquity,) that will result in poor body mechanics and lower functioning levels (Fonad et al., 2008; Fuller, 2000; Gell et al., 2015; Jensen et al., 2002; Mikołajewska, 2013). The poorly fit wheelchair may lead to risky behaviors and/or increased

fall risk. It was anticipated that the provision of properly fit wheelchairs to the treatment group would reduce falls by improving comfort and ease of transfers. It is also possible though that the properly fit wheelchair allowed the person to feel more comfortable and mobile, thereby increasing their exposure to potential falls from the wheelchair

The incidence of wheelchair related falls in the treatment group were lower than the control group but not statistically significant. The difference in fall incidence between the treatment and control groups was greater for those with a history of falls than those without a history of falling. Though the results were not statistically significant, further data collection and analyses are needed to prove statistical and clinical significance. This study resulted in a small number of individuals who fell, affecting its power. These data could be used as a pilot study to determine the effect size needed to power a larger follow-up study.

Several factors may have led to the lack of significant differences in falls between the groups. It may be wrong to assume that all individuals in the control group were improperly fit to their wheelchairs. Since the study protocol involved subjects who received a skin protection cushion, this intervention resulted in adjustments to the control wheelchair to ensure that all participants were safe and comfortable, and that positioning relative to the footrests or floor as well as mobility was not adversely affected. The addition of the cushion and the positioning of the footrests may have inadvertently affected falls rates.

. The control group had more people withdraw from the study (n=41) versus the treatment group (n=27). It is unclear why more subjects withdrew from the study in the control group.

In a randomized control trial by Lord et al. (2005) that analyzed the effect of a fall prevention program on fall risk and falls in older individuals, a difference was observed in fall

incidence between the treatment and control group. (Lord et al., 2005). The percentage differences (6.44%) in the study by Lord et al. (2005) were lower than the percentage differences between the treatment and control groups of this study (3.21%).

### 3.4.1 Limitations

Considering the small sample size of individuals who had a fall, and specifically a wheelchair related fall with a previous history of falls, the study did not have enough power to report a significant result. The weekly fall reports and the MDS information of falls in the study depended on the nursing home staff's perception and reporting of a fall, which could lead to potential underreporting and could not be controlled for in this model. The research team made sure all participants were safe and comfortable in their chair.

It may have been wrongly assumed that all individuals in the control group were improperly fit to their wheelchairs. The control group may have by chance procured an adequate fit wheelchair, thus reducing the validity of randomization. The use of poorly fit wheelchairs by the control group may have been underestimated. Even though the control group did not receive custom fit equipment from the study, some individuals in the treatment group may have received equipment from the nursing staff that provided a good fit.

There could have been an increased reporting of falls of individuals in the study. Hence, the incidence of falls may have been affected by possible nursing home staff awareness of residents' participation in the study. This was consistent with a study by Yang et al. (2014) which compared video footage with the reporting of staff members for falling in a long term care facility and found discrepancies between staff reports and fall incidence reporting (Yang et al., 2015). The effect was probably the same for individuals in the treatment and control groups. This effect may have differed in the treatment and control group given it was an unblinded study. The

study sample was primarily white and female and not representative of the entire nursing home elderly population.

### 3.4.2 Future work

The sample size of individuals who fell with a history of falls was small. This study can be used as pilot information to design a future study. The hypothesis of the future study will assess if nursing home residing individuals using custom fit wheelchairs are at a lower risk for falling from their wheelchair compared to individuals using standard nursing home wheelchairs.

# 4.0 ASSOCIATION OF WHEELCHAIR FUNCTION WITH PRESSURE ULCER RISK

## 4.1 INTRODUCTION

### 4.1.1 Need to study wheelchairs and functioning in wheelchairs

The wheelchair is one of the most important therapeutic devices (Kirby, 1997) and one of the most valuable assistive technology devices in the field of rehabilitation. (Kirby et al., 2002) The ultimate outcome measure of wheelchair use is how safe and effective they are for users in their own environments. (Kirby et al., 2002) Even though there has been research conducted on wheelchairs, there is room for improvement in the process of wheelchair prescription and improvement in the interaction between the wheelchair user, the wheelchair and the environment in which wheelchair users function. Safe independent use or satisfactory performance in daily activities is not guaranteed by procurement of a manual wheelchair (Best, Miller, Routhier, Eng, & Goldsmith, 2014). A need exists to study the wheelchair characteristics, the importance of training associated with wheelchair use and functioning in the wheelchairs, to reduce the negative consequences due to manual wheelchair use. In comparison to individuals who do not use a wheelchair, some of the negative consequences of wheelchair use include reduced economic and social inclusion, decreased social participation and lower quality of life (Hanson, Neuman, & Voris, 2003; W Ben Mortenson et al., 2012).

Outcome measures are important to objectively quantify the issue or disease process (Bergstrom et al., 1987; Schmeler, 2006; R. O. Smith, 1996). The main aim of the parent study was to assess pressure ulcer outcomes in nursing home residents using manual wheelchairs

followed by a secondary aim of assessing an individual's function in a wheelchair. Two Braden Risk Assessment Scale and the Functioning Every Day with a Wheelchair were used in the study at baseline to determine if there was an association between the two measures. They are described below:

1. The Braden Risk Assessment Scale (Bergstrom et al., 1987) for pressure ulcer risk assessment, and
2. The Functioning Every day with a Wheelchair – Capacity (FEW-C) score (Schmeler, 2006) for the assessment of a wheelchair user's ability to function in a wheelchair.

### 4.1.2 Functioning Everyday with a Wheelchair Capacity (FEW-C) Measure

According to the American Physical Therapist Association, measuring outcomes is important in collectively comparing care and determining the effectiveness with respect to direct management of individual patient care (Gardner, 2011). The aim of using a standardized tool is to establish a universal, objective method to gain a better understanding of the item being assessed. Standardized tools and outcome measures help with the establishment of a baseline status of patients to quantify change with progression of the disease. Rehabilitation-based outcome measures range from overviews of function, community reintegration and specific kinesiological measures. (Boninger, Cooper, Baldwin, Shimada, & Koontz, 1999; Gresham, Granger, Linn, & Kulas, 1999; Wood-Dauphinee, Opzoomer, Williams, Marchand, & Spitzer, 1988) Objective development of outcomes is dependent on the availability of appropriate and preferably standardized measurement tools. (R. O. Smith, 1996). It has become increasingly important that rehabilitation practitioners document the effects of their intervention, especially with the current emphasis on evidence-based and cost-effective practice (Gardner, 2011; Kirby et al., 2002).

An assistive technology assessment is essential to evaluate the capabilities, needs and environmental interactions of potential users. According to a report by the Agency for Healthcare

Research and Quality titled “Wheeled Mobility Service Delivery,” insufficient research on the provision of wheeled mobility and associated services may result in an absence of high-quality products for consumers (Greer, Brasure, & Wilt, 2012). Poorly fitting wheelchairs lead to poor posture which results in higher pressure and greater pressure ulcer risk (Brienza et al., 2010). A misfit wheelchair leads to poor posture and positioning which in turn causes difficulty with activities and leads to reduced mobility and activity which in turn affects the quality of life. It is important to understand the functioning capabilities of individuals in a wheelchair to enhance function and safety for the users. The Functioning Everyday with a Wheelchair (FEW-C) measurement was developed in 2005 and is used to measure the effectiveness of the manual wheelchair in meeting the consumer’s needs. The FEW-C assesses five areas of functioning in a wheelchair: 1) reaching forward, 2) reaching side-by-side, 3) using breaks, 4) transfers from wheelchair, and 5) use of sink from wheelchair (Schein et al., 2011). The FEW-C scores measure safe functioning and independence associated with wheelchair use.

### 4.1.3 Braden Risk Assessment Scale (BRA)

Pressure ulcers are a significant health problem as they decrease quality of life in older patients (Gorecki et al., 2009). The prevalence of pressure ulcers in nursing homes occur at estimated rates of 2% to 28% (Cuddigan, Berlowitz, & Ayello, 2001; D. M. Smith, 1995). Sixteen percent of nursing home residents with high immobility have pressure ulcers as compared to five percent of nursing home residents without high immobility (Park-Lee & Caffrey, 2009). The treatment costs for a single full thickness pressure ulcer can be as high as $70,000 (Reddy, Gill, & Rochon, 2006), while total costs of pressure ulcers in the U.S. surpasses $11 billion per year (Reddy et al., 2006).

The Braden scale was developed by Barbara Braden and Nancy Bergstorm in 1987. The Braden scale assesses six risk factors for pressure ulcers: 1) sensory perception, 2) moisture, 3) activity, 4) mobility, 5) nutrition and 6) friction and shear (Bergstrom et al., 1987). The activity component of the Braden score assesses the degree of physical activity whereas the mobility component of the Braden score assesses the individual's ability to change and control body position. Together, the activity and mobility components of the Braden scale rate the individual's ability to transfer, shift weight, and ambulate.

Table 13- Description of pressure ulcer risk assessment scales

| **Pressure ulcer risk assessment scale** | **Year developed** | **Components assessed** |
|---|---|---|
| Braden Scale | 1987 | Sensory perception, moisture, activity, mobility, nutrition, and friction & shear. |
| Waterlow Scale | 1985 | Build/weight for height, skin type visual areas, sex age, malnutrition screening tool, continence, mobility & special risks |
| Norton Scale | 1962 | Physical condition, mental condition, activity, mobility & incontinence. |

Various risk assessment tools exist to assess pressure ulcer risk. A systematic review by Pancorbo-Hidalgo et al. (2006) examined various risk assessment tools. They compared the Braden scale, Waterlow scale and the Norton scale shown in Table 13 (Pancorbo-Hidalgo et al., 2006). The meta-analysis concluded that the Braden scale was more frequently and showed the best reliability and validity in a variety of settings (Pancorbo-Hidalgo et al., 2006). The Braden Scale is known to be a better predictor for pressure ulcers than nursing judgment, The Norton or Waterlow scales. This is based on the sensitivity to specificity balance of 57.1%/67.5% in comparison to the Norton and Waterlow scales, which have sensitivity values of 46.8% and 82.4%, respectively, with specificity scores of 61.8% and 27.4%, respectively (Pancorbo-Hidalgo et al., 2006).

### 4.1.4 Comparison of Braden Risk Assessment Scale and Functioning Every day with a Wheelchair (FEW-C)

The Braden Scale is generally administered by physicians, registered nurses and licensed nurse practitioners. The FEW-C is primarily administered by an occupational therapist, physical therapist, an assistive technology practitioner or anyone who is an expert in assessing wheelchair seating needs. Even though the Braden risk assessment scale and the FEW-C measure two different constructs and appear unrelated in what they measure, that is, pressure ulcer risk and wheelchair function, the two have common components. The tools both measure activity and mobility.

The Braden Scale defines activity as degree of physical activity. The risk factor of inactivity is scored according to the following descriptions:

1. Bedfast–Confined to bed.
2. Chairfast–Ability to walk severely limited or nonexistent. Cannot bear own weight and/or must be assisted into chair or wheelchair.
3. Walks occasionally–Walks occasionally during day, but for very short distances, with or without assistance. Spends majority of each shift in bed or chair.
4. Walks frequently–Walks outside the room at least twice a day and inside room at least once every 2 hours during waking hours.

The Braden Scale defines mobility as ability to change and control body position. The risk factor of immobility is scored according to the following four descriptions:

1. Completely immobile–Does not make even slight changes in body or extremity position without assistance.
2. Very limited–Makes occasional slight changes in body or extremity position but unable to make frequent or significant changes independently.

3. Slightly limited–Makes frequent though slight changes in body or extremity position independently.
4. No limitation–Makes major and frequent changes in position without assistance.

The FEW-C scale is more specific in measuring components of the ability of an individual to function in a wheelchair. The FEW-C measures wheelchair function using five subtasks:

1. On/Off brakes
2. WC transfers
3. Reach forward
4. Reach side to side
5. Personal hygiene

Each of the five sub-tasks is scored in two areas, namely, independence and safety. The independence area uses a five-point scale for scoring:

0: Unable

1: Physical Assist

2: Visual Assist

3: Verbal Assist

4: No Assist

The safety area uses a four-point scale for scoring:

0: Severe risk–prevent harm

1: Risk–Potential harm

2: Minor risk–no assist

3: Safe practices

Understanding and interpreting the relationships between the Braden Risk assessment total score, Braden activity-mobility total and the FEW-C safety and independence total scores

will alert nurses to safe functioning in wheelchair issues for people with lower Braden scores and alert therapists to elevated pressure ulcer risk for people with lower FEW-C scores. A better understanding of the association between the two scores enhances communication between nurses and therapists and can be a more efficient way of reducing risk of developing pressure ulcers and enhance safe functioning with wheelchair use. This new understanding could help predict patient needs and outcomes and will also improve inter-professional communication. Accrediting organizations like Medicare mandate outcome reporting that requires quantifying measuring and reporting mobility outcomes. Third party payers of insurance companies require improved levels of research evidence for more adequate coverage policies. The understanding of the association between these two scores will assist with creating a research base to enhance inter-professional communication, understand the patients functionality levels better and thus could be potentially used as an evidence based practice.

The relationship between the FEW-C scores and Braden risk assessment scores was assessed and analyzed to answer the following research questions-

1. Is there an association between the FEW-C independence and Braden total scores?
2. Is there an association between the FEW-C independence and Braden activity-mobility sub-scale scores?
3. Is there an association between the FEW-C safety and Braden total scores?
4. Is there an association between the FEW-C independence and Braden activity-mobility scores?

## 4.2 METHODS

This study's aim was to test the general hypothesis:

1. The total and combined activity and mobility sub scale components of the Braden scale score will predict the functional status as reflected by the FEW-C scores.

Four specific hypotheses were tested:

*Hypothesis 1.1*: The total Braden score and the FEW-C independence score will be related.

*Hypothesis 1.2*: The combined Braden activity and mobility components score and the FEW-C independence score will be related.

*Hypothesis 1.3*: The total Braden score and the FEW-C safety score will be related.

*Hypothesis 1.4*: The Braden activity-mobility components score and the FEW-C safety score will be related.

### 4.2.1 Research Design

This study is a secondary analysis of a study from the National Institutes of Health grant titled, "An RCT on wheeled mobility for preventing pressure ulcers" (Grant number: 2R01HD041490). The FEW-C scores collected prior to randomization and the Braden scores collected during the screening process were considered for this data analysis. The baseline data was collected through the Subject Baseline Data form (Appendix O). The study participants were either self-consents or a proxy consent was obtained in case of the involvement of a health proxy. The University of Pittsburgh IRB approved the protocol.

### 4.2.2 Participants

Screening of the subjects and skin assessment was completed by the research nurse followed by a visual verification by the occupational therapist assessing the seating system. The eligibility criteria for the study is detailed below in Table 14.

Table 14. Randomized controlled trial on wheeled mobility for preventing pressure ulcers (RCT-WC2) inclusion and exclusion criteria.

| Criteria |
|---|
| **Inclusion Criteria** |
| Male or Female 60 years or older |
| Braden Risk assessment score ≤18 |
| A combined Braden Activity-mobility subscale score ≤5 |
| Tolerance for total daily wheelchair sitting time ≥6 hours |
| Current use of manual wheelchair |
| Ability to accommodate seating and positioning needs with the selected study wheelchair |
| Informed written consent |
| **Exclusion Criteria** |
| Body weight ≥250 pounds |
| Hip width ≥20 inches |
| Wheelchair seating requirements that exceed the accommodating capability of study chair |
| Current use of cushioning material other than a standard cushion |
| Current use of a HCPCS Code K 0005 wheelchair |

If the resident was ineligible, participation in the research study was terminated instantly. If the residents met the eligibility criteria, they were randomized by the seat team followed by the seating assessment and equipment issue.

### 4.2.3 Statistical Methods

Statistical analyses were completed using SPSS 23.0 for Windows. Data are summarized as mean, median, mode and range for continuous variables; number and frequencies for categorical

variables. Graphical and quantitative summaries were created to understand the data, to screen for outliers and to determine if any transformations were needed.

Four analyses were presented:

1. Association of Total Braden and FEW-C Independence Scores
2. Association of Braden Activity-Mobility Scores and FEW-C Independence Scores
3. Association of Total Braden and FEW-C Safety Scores
4. Association of Braden Activity-Mobility Scores and FEW-C Safety Scores

One unadjusted and two adjusted models will be presented using regression models for each analysis. Adjusted variables will be determined using clinical expertise and be compared using step-wise procedures to predict the outcome variables of FEW-C independence and FEW-C safety scores. Independent sample t-tests were used to assess if FEW-C independence and safety scores vary by the Braden total scores and the Braden Activity-Mobility sum.

The three models presented for each analysis are:

1. Unadjusted Model–looks at the unadjusted association between the two variables
2. Fully Adjusted Model–looks at the association between the key covariate and outcomes, after adjusting for all variables identified by clinical judgment
3. Stepwise Model–looks at the association between the key covariate and outcomes, after entering only those variables in the model that are statistically significant using step-wise procedures.

Thirty candidate variables for the regression model were selected based on clinical judgment (Table 15).

Table 15: Potential Adjustment variables from the subject baseline data used for the regression model

| Potential Adjustment variables | | |
|---|---|---|
| Age | Primary diagnosis of upper gastrointestinal system | Incontinence |
| Race | Primary diagnosis of the lower gastrointestinal system | History of pressure ulcers |
| Ethnicity | Primary diagnosis of the liver | Number of medications |
| Body Mass Index | Primary diagnosis of the renal system | Primary means of mobility |
| Length of stay in the nursing home | Primary diagnosis of the genitourinary system | Transfer assistance sit to stand |
| Primary diagnosis of heart | Primary diagnosis of the musculoskeletal/integument system | Transfer assistance bed to chair |
| Primary diagnoses of vascular conditions | Primary diagnosis of neurological system | Transfer assistance to sit to supine |
| Primary diagnoses of hematopoietic conditions | Primary diagnosis of the endocrine/metabolic and breast system | History of hip surgery |
| Primary diagnoses of respiratory conditions | Primary diagnosis of psychiatric illness | Alert and orientation |
| Primary diagnoses of eyes, ears, nose, throat and larynx | Primary diagnosis of diabetes | Agitation and combativeness |

## 4.3 RESULTS

### 4.3.1 Baseline Characteristics

The sample consisted of 258 participants with 131 in the control group and 127 in the treatment group. Participants had a mean age of 85.75 (±8.66) years and had lived in a nursing home for a mean of 2.01 (±2.49) years. Participant demographic characteristics are shown in Table 16.

Participants were primarily white (91.8%) and female (78.5%), with majority having the diagnosis relating to the heart (62.64%), vascular system (55.64%), musculoskeletal/integument system (61.86%), neurological system (57.19) and psychiatric illnesses (62.25).

Table 16. Descriptive analysis of study sample (n=258)

| Parameter | Mean (Standard Deviation) |
|---|---|
| Age | 85.75 (8.662) |
| Length of stay in a nursing home (in years) * | 2.01 (2.49) |
| Number of medications ** | 13.82 (5.348) |
| | **Frequency (Percentage)** |
| Gender | |
| Female | 202 (78.5) |
| Race | |
| White | 236 (91.8) |
| Black | 21 (8.1) |
| DIAGNOSIS relating to | |
| Heart | 161(62.64) |
| Vascular system | 143 (55.64) |
| Hematopoietic system | 32 (12.45) |
| Respiratory system | 85 (33.07) |
| Eyes, Ears and Nose | 46 (17.89) |
| Upper Gastrointestinal system | 36 (14.00) |
| Liver system | 5 (1.9) |
| Renal system | 43 (16.73) |
| Genitourinary system | 56 (21.78) |
| Musculoskeletal/Integument system | 159 (61.86) |
| Neurological system | 147 (57.19) |
| Endocrine, Metabolic, Breast system | 67 (26.07) |
| Psychiatric | 160 (63.25) |
| Diabetes | 57 (22.17) |

| | | |
|---|---|---|
| | Other | 65 (25.29) |

Table 16 Continued

| | | |
|---|---|---|
| INCONTINENCE | | |
| | Urine | 193 (75.09) |
| | Feces | 169 (65.75) |
| Previous History of pressure ulcers | | 44 (17.12) |
| History of hip surgery | | 31 (12.06) |

*N=255

**N=246

### 4.3.2 Descriptive characteristics of Braden scores

Descriptive characteristics of the Braden Risk Assessment scores are presented in Table 17. At baseline, the mean Braden score across the sample of 258 nursing home residents was 14.84, and the mean activity mobility score was 4.58. The largest Braden Activity Mobility score is 7 which does not meet the eligibility criteria. This participant was removed from the analyses. The largest Braden total score is 18, which is reflective of the inclusion criteria of the study which states a Braden score ≤18.

Table 17. Descriptive statistics of the baseline Braden scores.

| | Braden Activity-Mobility | Braden Total |
|---|---|---|
| Valid | 258 | 258 |
| Missing | 0 | 0 |
| Mean (Standard Deviation) | 4.58 (0.52) | 14.84 (1.65) |
| Minimum | 4 | 10 |
| Maximum | 7 | 18 |

Table 18. Descriptive statistics of the baseline FEW-C scores.

| | FEW-C Independence | FEW-C Safety |
|---|---|---|
| Valid | 250 | 250 |
| Missing | 8 | 8 |
| Mean (Standard Deviation) | 11.80 (5.23) | 11.38 (4.12) |
| Minimum | 0.00 | 0.00 |
| Maximum | 20.00 | 15.00 |

Descriptive characteristics of the baseline FEW-C scores are presented in Table 18. The mean FEW-C scores are 11.80 and 11.38 for independence and safety, respectively. The range of the FEW-C Independence is 0-20 and the FEW-C Safety is 0-15.

### 4.3.3 Bivariate analysis

Graphical summaries (Figure 4.1 & Figure 4.2) were created to assess the research question testing the association of Braden Activity-Mobility scores on the FEW-C independence and FEW-C safety scores.

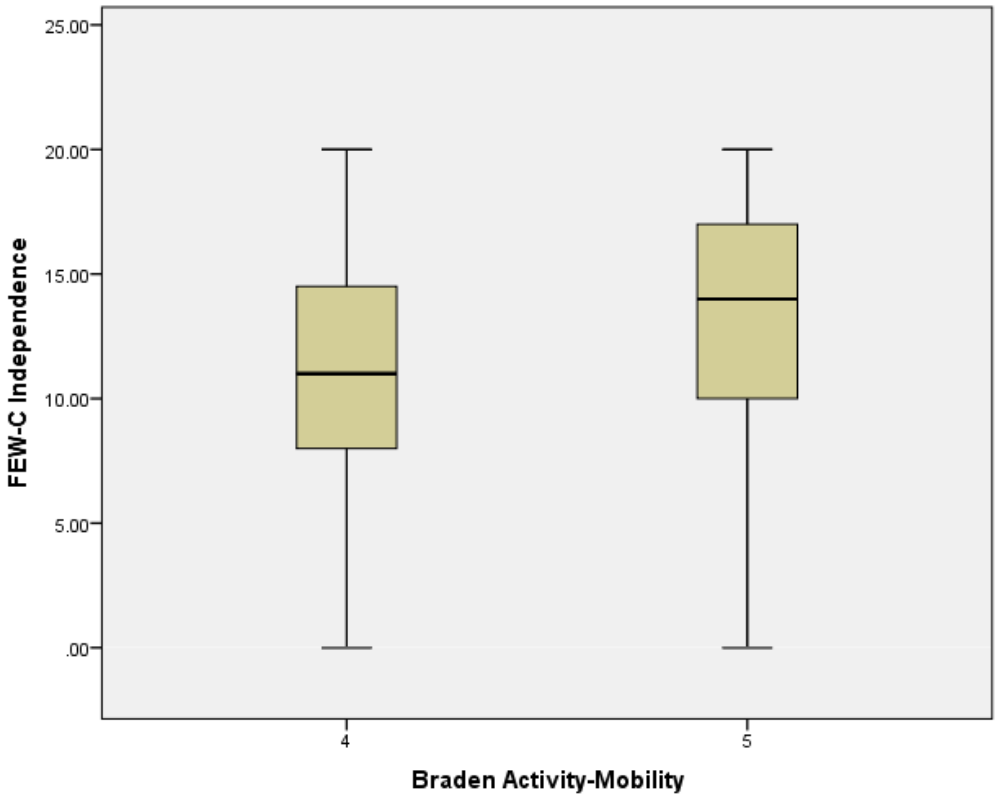



**Figure 4.1. Box plot of FEW-C Independence scores by Braden Activity-Mobility scores at baseline**

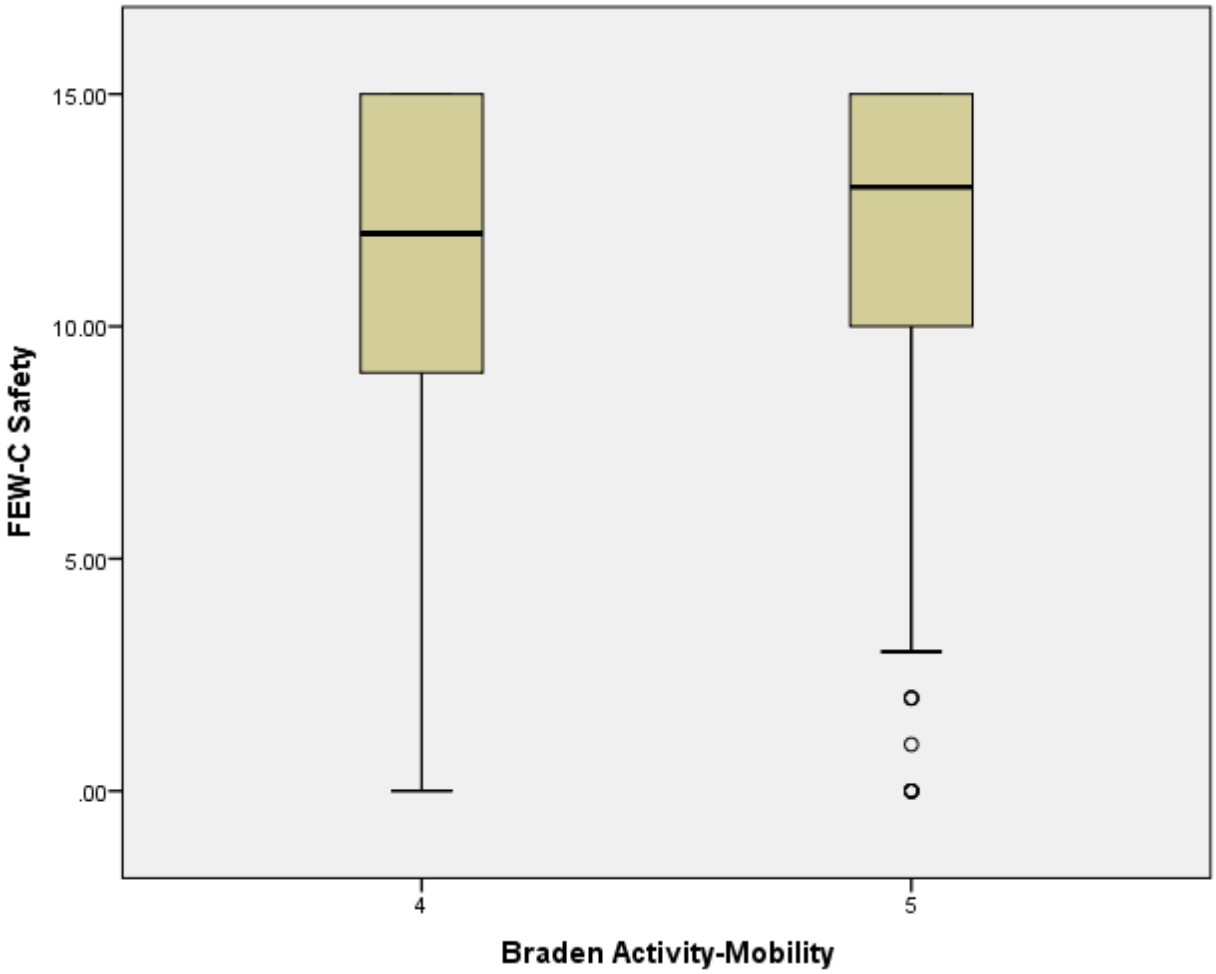



**Figure 4.2. Box plot of FEW-C Safety score by Braden Activity-Mobility score at baseline**

The Inter-Quartile Range (IQR) between the groups that have a Braden Activity-Mobility score of 4 don't appear to be much different from the group that has a Braden Activity-Mobility score of 5. The difference in the medians looks minimal between the two groups. Based on the minimal difference in the medians and a minimal difference between the inter-quartile ranges of Braden activity–mobility sums of 4 and 5, it is less likely that there will be a statistical difference in the prediction of the Braden activity-mobility component scores and FEW-C safety scores. Further observation of Figure 4.1 & 4.2 indicates higher FEW-C independence and safety scores

when the Braden activity-mobility component equals five in comparison to the FEW-C scores when the Braden activity-mobility scores equals four.

As observed in Figure 4.2, a total of nine individuals were beyond the IQR (error bars). Five of these individuals had a score of zero, one had a score of one, and three had a score of two.

Table 19. Independent sample t-test to assess if FEW-C Independence and Safety Scores vary by Braden Activity-Mobility total

| | **Braden Risk Assessment Score (Activity-Mobility total)** | | | | | |
|---|---|---|---|---|---|---|
| **FEW-C** | | **4 n=104** | **5 n=145** | **Diff** | **CI (lower, upper)** | **p-value** |
| | **Safety** | 11.00 | 11.68 | -0.68 | (-1.72, 0.36) | 0.198 |
| | **Independence** | 10.90 | 12.50 | -1.59 | (-2.90, -2.87) | 0.017 |

In Table 19 we see that the difference in the Activity-Mobility total score corresponds to a significant difference in the FEW-C independence total score (diff =-1.59, p=0.017) but not FEW-C safety total score (diff = -0.69, p=0.19). A total of nine individuals were removed from the analysis. One individual was deleted due to having an activity mobility total ≥5 and FEW-C data was missing for eight individuals.

Figure 4.3 is a scatter plot of the unadjusted analysis of the FEW-C independence scores on the Braden total scores. The Braden total score increases with an increase in the FEW-C independence scores. Based on the inclusion criteria, for individuals above 60 years of age with Activity-Mobility Braden score sum of 4 or 5, for every unit increase in the Braden

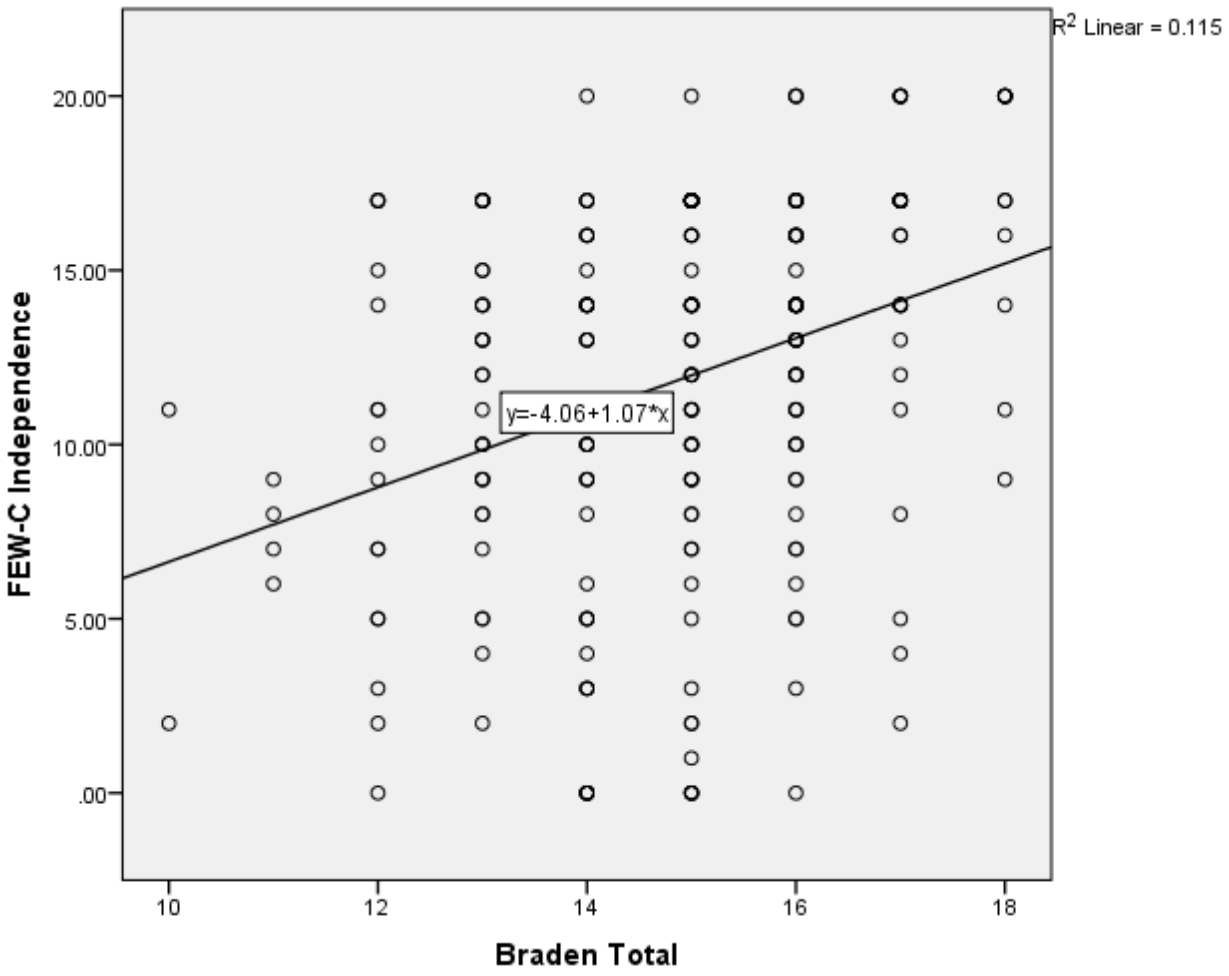



**Figure 4.3. Scatter plot with regression line of Braden Total and FEW-C Independence**

total Score the FEW-C independence score increases by 1.07, which is the coefficient for the x variable (Figure 4.3) and is also the value of the β coefficient (Table 19) of the unadjusted model assessing the relationship between the Braden total score and the FEW-C independence score.

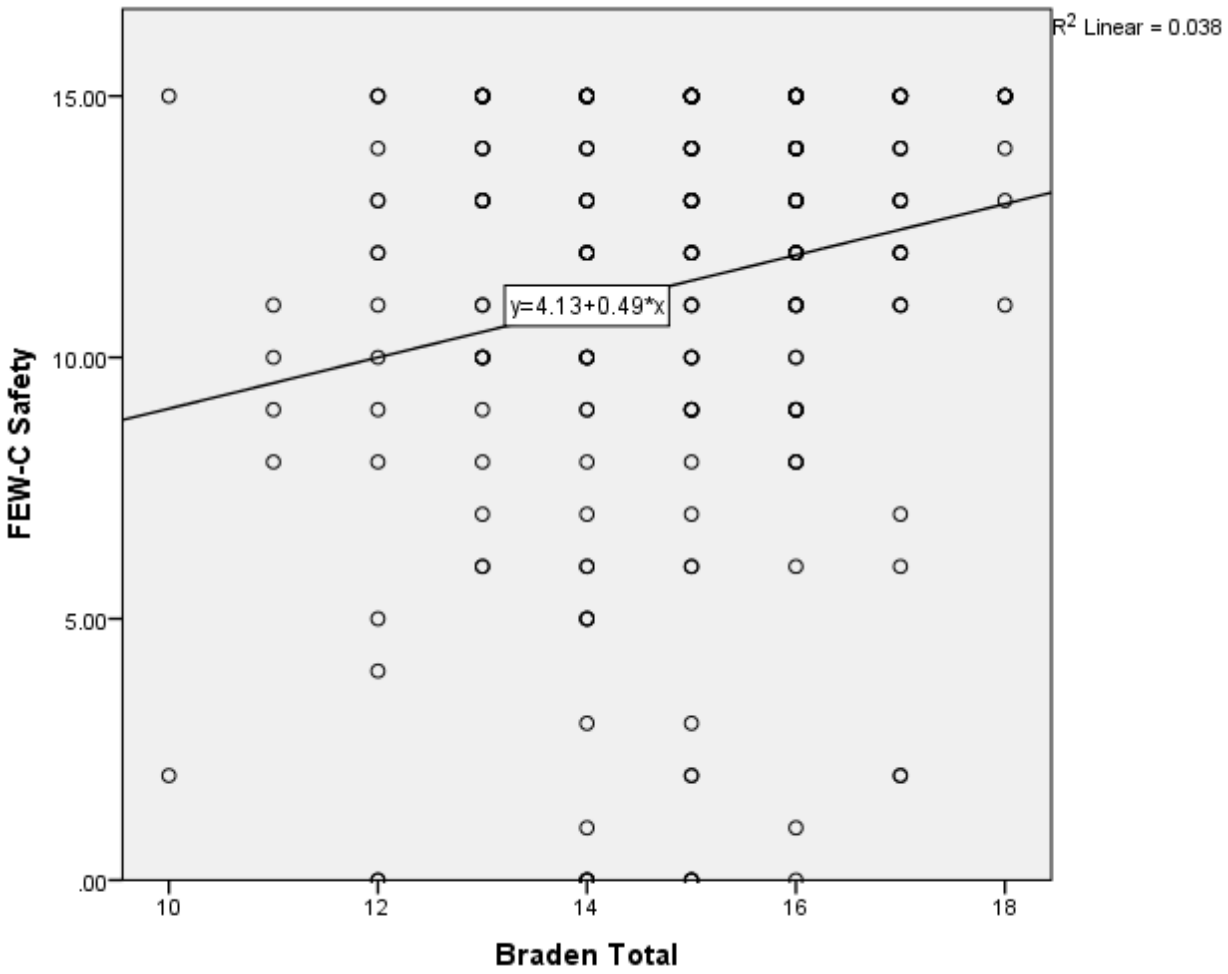



**Figure 4.4. Scatter plot with regression line of Braden Total and FEW-C Safety**

Figure 4.4 is a scatter plot of the unadjusted analysis of the FEW-C safety scores on the Braden total scores. For individuals above 60 years of age with Activity-Mobility Braden score sum of 4 or 5, for every unit increase in the Braden total Score the FEW-C independence score increases by 0.49. This is the coefficient for the x variable (Figure 4.4) and is also the value of the β coefficient (Table 20) of the unadjusted model assessing the relationship between the Braden total score and the FEW-C independence score.

### 4.3.4 Multivariate analysis

Table 20. Effect of Total Braden on FEW-C Independence

| **FEWC-Independence Total Score** | **Model 1 (Unadjusted) n=249** | **Model 2 (Fully Adjusted) * n=207** | **Model 3 (Stepwise) n=207** |
|---|---|---|---|
| Adjusted $R^2$ | 0.111 | 0.367 | 0.394 |
| | **β (p)** | **β (*p*)** | **β (*p*)** |
| Braden Total | 1.070 (<0.0001) | 0.800 (<0.0001) | 0.843 (<0.0001) |
| Age | | -0.106 (0.006) | -0.112 (0.001) |
| Primary diagnoses of heart conditions | | 1.034 (0.137) | 1.693 (0.004) |
| Primary diagnoses of the hematopoietic system | | 1.519 (0.132) | |
| Primary diagnoses of psychiatric conditions | | -1.105 (0.099) | |
| Alert and Oriented | | 6.647 (<0.0001) | 7.026 (<0.0001) |
| Agitation and combativeness | | 1.898 (0.090) | |
| Assistance required for sit to supine transfers- | | | |
| None | | -1.819 (0.394) | -1.404 (0.356) |
| Supervision | | 0.123 (0.932) | 0.755 (0.558) |
| Minimal | | 0 (ref) | 0 (ref) |
| Moderate | | -1.857 (0.059) | -1.675 (0.010) |
| Maximum | | -4.181 (0.015) | -4.246 (<0.0001) |
| Global p | | 0.138 | <0.0001 |

*Adjusted for variables in table 20 with the exception of incontinence, only significant ones shown (p< 0.15).

Table 20 presents the association of the Braden total score and the FEW-C independence scores where the total Braden score is the independent variable and the FEW-C independence score the dependent variable. The total Braden Score has a significant relationship on the FEW-C independence scores in all three models. This is evident by the p-values of <0.0001 for the unadjusted, fully adjusted and step-wise models. The β coefficient changes minimally across the models ranging from 1.07 to 0.800. A difference of 0.27 between the βvalues of FEW-C independence scores between the unadjusted and the fully adjusted models is not clinically significant even though the unadjusted (p-value<0.0001), fully adjusted (p-value<0.0001) and

stepwise models (p-value<0.0001) found a statistically significant relationship of the Braden total scores as a predictor of the FEW-C independence scores. The sample size decreased from 249 in the unadjusted model to 207 in the fully adjusted and stepwise models. This is due to the missing values of the co-variates in the fully adjusted and stepwise models. The value of the adjusted $R^2$ increases when comparing the unadjusted model ($R^2$=0.111) to the fully adjusted model ($R^2$=0.367) and when comparing the fully adjusted model to the stepwise model ($R^2$ = 0.394). This is due to better fit and fewer covariates, respectively.

Table 21. Number of individuals with missing values for different variables collected in the subject baseline data

| | **History of Pressure ulcers** | **Number of medications** | **FEW-C** |
|---|---|---|---|
| **History of Pressure Ulcers** | 32 | 4 | 0 |
| **Number of Medications** | 4 | 5 | 2 |
| **FEW-C** | 0 | 2 | 5 |
| **Missing all variables** | 1 | | |
| **Total** | 37 | 12 | 8 |

Table 21 explains the number of missing values for different variables collected during the post-randomization phase. A total of 36 subjects were missing data for history of pressure ulcers, 11 for number of medications and 7 for FEW- C scores. One individual did not have data for any of the variables mentioned. Table 21 helps understand the reduction in sample size from the unadjusted to fully adjusted to stepwise models. All three mentioned variables were part of the unadjusted models in all four analyses.

Table 22. Effect of Braden Activity Mobility on FEW-C Independence

| **FEWC-Independence Total Score** | **Model 1 (Unadjusted) n=249** | **Model 2 * (Fully Adjusted) n=207** | **Model 3 (Stepwise) n=207** |
|---|---|---|---|
| Adjusted $R^2$ | 0.019 | 0.320 | 0.344 |
| | **β (*p*)** | **β (*p*)** | **β (*p*)** |
| Braden A-M | 1.593 (0.017) | 1.153 (0.085) | 1.435 (0.021) |
| Age | | -0.101 (0.014) | -0.105 (0.003) |
| Alert & oriented | | 6.583 (<0.0001) | 7.020 (<0.0001) |
| Incontinent | | -0.956 (0.256) | -1.936 (0.007) |
| Primary diagnoses of hematopoietic conditions | | 1.666 (0.111) | |
| Primary diagnoses of psychiatric conditions | | -1.263 (0.070) | |
| Assistance for sit to stand transfers: | | | |
| Supervision | | 3.268 (0.099) | 3.642 (0.047) |
| Minimal | | 0 (ref) | 0 (ref) |
| Moderate | | -0.453 (0.821) | -0.579 (0.754) |
| Maximum | | -1.084 (0.650) | -0.803 (0.714) |
| Unable to do | | -6.058 (0.296) | -5.368 (0.309) |
| Mechanical lift | | 1.195 (0.755) | 1.182 (0.738) |
| Global p | | 0.006 | 0.002 |
| Assistance for bed to chair transfers: | | | |
| None | | 3.629 (0.555) | 4.156 (0.468) |
| Supervision | | 1.304 (0.833) | -1.084 (0.849) |
| Minimal | | 0.120 (0.973) | 0.428 (0.893) |
| Moderate | | 1.096 (0.706) | 0.834 (0.752) |
| Maximum | | 0.723 (0.804) | 0.639 (0.811) |
| Mechanical lift | | 0 (ref) | 0 (ref) |
| Global p | | 0.966 | <0.0001 |
| Assistance required for sit to supine transfers: | | | |
| None | | -2.106 (0.344) | -2.702 (0.196) |
| Supervision | | 0.050 (0.974) | 0.052 (0.969) |
| Minimal | | 0 (ref) | 0 (ref) |
| Moderate | | -2.179 (0.032) | -1.891 (0.046) |
| Maximum | | -4.529 (0.012) | -4.123 (0.011) |
| Global p | | 0.096 | <0.0001 |

**Adjusted for all variables in table 20, only significant ones shown (p< 0.15).

Table 22 presents the association of the Braden activity-mobility score and the FEW-C independence scores where the total Braden activity-mobility score is the independent variable and the FEW-C independence score the dependent variable. The total Braden activity-mobility score has a significant relationship with the FEW-C independence scores in the unadjusted and step-wise models. This is evident by the p-values of 0.017, and 0.021. The β coefficient (1.593) changes very little across the models ranging from 1.153 to 1.593. A difference of 0.158 between the β values of the unadjusted and step wise models of FEW-C independence scores is not clinically significant even though all the unadjusted model found a statistically significant relationship (p-value=0.017) of the Braden total scores as a predictor of the FEW-C independence scores and trends towards significance in the fully adjusted (p-value=0.085) and stepwise models (p-value=0.021). The sample size decreases from 249 in the unadjusted model to 207 in the fully adjusted and stepwise models. This is due to the missing values of the co-variates in the fully adjusted and stepwise models. The value of the adjusted $R^2$ increases when comparing the unadjusted model ($R^2$=0.019) to the fully adjusted model ($R^2$=0.320) and when comparing the fully adjusted model to the stepwise model ($R^2$ = 0.344). This is due to better fit and fewer covariates, respectively.

Table 23 presents the association of the Braden total score and the FEW-C safety scores where the total Braden score is the independent variable and the FEW-C safety score the dependent variable. The total Braden total Score has a significant relationship with the FEW-C safety scores in all three models. This is evident by the p-values of 0.002, 0.016 and 0.012. The β coefficient (0.498) changes very little across the models ranging from 0.498 to 0.386. A difference of 0.112 between the βvalues of FEW-C safety scores between the unadjusted and the fully adjusted models is not clinically significant even though the unadjusted (p-value=0.002),

fully adjusted (p-value=0.016) and stepwise models (p-value=0.012) found a statistically significant relationship of the Braden total scores as a predictor of the FEW-C safety scores. The sample size decreases from 249 in the unadjusted model to 207 in the fully adjusted and stepwise models. This is due to the missing values of the co-variates in the fully adjusted and stepwise models. The value of the adjusted $R^2$ increases when comparing the unadjusted model ($R^2$=0.034) to the fully adjusted model ($R^2$=0.275) and when comparing the fully adjusted model to the stepwise model ($R^2$ = 0.333). This is due to better fit and fewer covariates, respectively.

Table 23. Effect of Total Braden on FEW-C Safety

| **FEWC-Safety Total Score** | **Model 1 (Unadjusted) n=248** | **Model 2 * (Fully Adjusted) n=207** | **Model 3 (Stepwise) n=207** |
|---|---|---|---|
| Adjusted $R^2$ | 0.034 | 0.275 | 0.333 |
| | **β (*p*)** | **β (*p*)** | **β (*p*)** |
| Braden Total | 0.498 (0.002) | 0.413 (0.016) | 0.386 (0.012) |
| Age | | -0.057 (0.0800 | -0.071 (0.012) |
| Primary diagnoses of heart conditions | | 1.130 (0.054) | 1.277 (0.013) |
| Other primary diagnosis | | -1.149 (0.077) | -1.037 (0.074) |
| Alert & Oriented | | 4.971 (<0.0001) | 5.038 (<0.0001) |
| Assistance for sit to stand transfers- | | | |
| Supervision | | 2.168 (0.211) | 2.912 (0.132) |
| Minimal | | 0.917 (0.524) | 0.842 (0.571) |
| Moderate | | 0 (ref) | 0 (ref) |
| Maximum | | -2.915 (0.019) | -2.336 (0.037) |
| Unable to do | | -4.913 (0.277) | -3.655 (0.363) |
| Mechanical lift | | -2.397 (0.374) | -1.725 (0.472) |
| Global p | | <0.0001 | <0.0001 |
| Assistance for bed to chair transfers- | | | |
| None | | -0.460 (0.926) | 0.447 (0.923) |
| Supervision | | -2.539 (0.615) | -0.710 (0.876) |
| Minimal | | -3.051 (0.283) | -2.227 (0.383) |
| Moderate | | -2.150 (0.362) | -1.364 (0.515) |
| Maximum | | -1.582 (0.504) | -1.164 (0.583) |
| Mechanical lift | | 0 (ref) | 0 (ref) |
| Global p | | 0.904 | 0.930 |
| Assistance required for sit to supine transfers- | | | |
| None | | -0.746 (0.678) | -1.380 (0.403) |
| Supervision | | -0.393 (0.748) | -0.534 (0.625) |
| Minimal | | 0 (ref) | 0 (ref) |
| Moderate | | -0.665 (0.420) | -0.730 (0.332) |
| Maximum | | -1.981 (0.170) | -2.196 (0.085) |
| Global p | | 0.722 | 0.458 |

*Adjusted for variables in Table 20 with exception of incontinence, only significant ones shown ($p < 0.15$).

Table 24. Effect of Braden Activity-Mobility on FEW-C Safety

| **FEWC-Safety Total Score** | **Model 1 (Unadjusted) n=248** | **Model 2 * (Fully Adjusted) n=207** | **Model 3 (Stepwise) n=207** |
|---|---|---|---|
| Adjusted $R^2$ | 0.003 | 0.261 | 0.391 |
| | **β (*p*)** | **β (*p*)** | **β (*p*)** |
| Braden A-M | 0.683 (0.198) | 0.730 (0.182) | 0.777 (0.118) |
| Age | | -0.053 (0.112) | -0.074 (0.010) |
| Primary diagnoses of heart conditions | | 0.946 (0.116) | 1.224 (0.018) |
| Other diagnosis | | -1.034 (0.115) | -1.008 (0.086) |
| Alert and oriented | | 4.947 (<0.0001) | 5.126 (<0.0001) |
| Assistance for sit to stand transfers- | | | |
| Supervision | | 2.164 (0.183) | 2.421 (0.108) |
| Minimal | | 0 (ref) | 0 (ref) |
| Moderate | | -0.527 (0.749) | -0.714 (0.634) |
| Maximum | | -3.265 (0.097) | -2.999 (0.091) |
| Unable to do | | -4.779 (0.316) | -4.262 (0.317) |
| Mechanical lift | | -2.395 (0.447) | -2.336 (0.408) |
| Global p | | <0.0001 | <0.0001 |
| Assistance required for sit to supine transfers- | | | |
| None | | -1.038 (0.570) | -1.331 (0.425) |
| Supervision | | -0.531 (0.679) | -0.405 (0.714) |
| Minimal | | 0 (ref) | 0 (ref) |
| Moderate | | -0.862 (0.300) | -0.793 (0.297) |
| Maximum | | -2.204 (0.132) | -2.155 (0.095) |
| Global p | | 0.622 | 0.500 |

*Adjusted for variables in table 20, only significant ones shown (p< 0.15).

Table 24 presents the association of the Braden activity-mobility score and the FEW-C safety scores where the total Braden activity-mobility score is the independent variable and the FEW-C safety score the dependent variable. The total Braden activity-mobility score does not have a significant relationship with the FEW-C safety scores in all three models. This is evident by the p-values of 0.198, 0.182 and 0.118. The β coefficient (0.683) changes very little across the models ranging from 0.683 to 0.777. A difference of 0.094 between the βvalues of FEW-C safety scores between the unadjusted and the fully adjusted models is not clinically significant since all three models, the unadjusted (p-value=0.198), fully adjusted (p-value=0.182) and stepwise

models (p-value=0.118) found a no statistical significance between the Braden activity-mobility scores as a predictor of the FEW-C safety scores. The sample size decreases from 249 in the unadjusted model to 207 in the fully adjusted and stepwise models. This is due to the missing values of the co-variates in the fully adjusted and stepwise models. The value of the adjusted $R^2$ increases when comparing the unadjusted model ($R^2$=0.003) to the fully adjusted model ($R^2$=0.261), and when comparing the fully adjusted model to the stepwise model ($R^2$ = 0.391). This is due to better fit and fewer covariates, respectively.

## 4.4 DISCUSSION

A secondary analysis of a study aimed at preventing pressure ulcers in nursing home residents using lightweight manual wheelchairs was conducted. A relationship between the Braden total and FEW-C independence scores, Braden activity-mobility and FEW-C independence scores, and Braden total and FEW-C safety scores was identified. Even though the inclusion criteria included individuals with limited abilities (with respect to ambulation, sensation and mobility) as defined by the Braden score, this did not limit the range of the FEW-C scores. Understanding the relationship between the Braden scores and the FEW-C scores is important as it will help with identifying and meeting the clients overall needs rather than the current health care system-specific needs like identifying only pressure ulcer related needs without associating it with overall health of the person in the wheelchair.

Best et al (2014) discussed the importance of wheelchair skill training in elderly individuals using a wheelchair. Like Best et al (2014), we attempted to emphasize the importance

of training to use the wheelchair in order to enhance maximal function. An association between mobility, participation and wheelchair related factors (comfort, wheelchair fit and ability to use the wheelchair) in long-term care residents who use wheelchairs as their primary means of mobility has been identified (W Ben Mortenson et al., 2012). This is like the findings of this study where the importance of wheelchair fit has been elaborated and analyzing concluding that individually configured wheelchairs have a better function. The presence of a diagnosis of depression was found to be associated with decreased wheelchair skills, mobility and participation frequency (Brown et al., 2014; Hegeman, Kok, Van der Mast, & Giltay, 2012; Taylor et al., 2014).

Participation frequency of wheelchair use was directly or indirectly related with mobility and was associated with ease of use, wheelchair transfers, ability to independently propel the wheelchair and comfort. The total Braden and the FEW-C independence scores were associated with being alert and oriented (see Table 20). The Braden Activity Mobility scores on the FEW-C independence scores were associated with the alertness and orientation status of the wheelchair user. Similarly, the model that looked at the effect of the total Braden in the FEW-C safety scores found an association between the alert and oriented status of the wheelchair user and assistance of the wheelchair user required to transfer from sit to stand (see Table 23). The model that looked at the effect of the total Braden in the FEW-C safety scores found a significant association between the alert and oriented status of the wheelchair user and assistance of the wheelchair user required to transfer from sit to stand (see Table 24).

Mortenson et al. (2012), found that residents wheelchair mobility and participation may be improved by addressing wheelchair related factors like the individuals ability to maneuver a wheelchair, the ability of the individual to function in their wheelchair and comfort.(W Ben

Mortenson et al., 2012). There were no studies in the literature that have attempted to address persons in long term care with individually configured wheelchairs. In addition, there is limited research on the use of the FEW-C as an outcome measure.

If a nurse observes a lower Braden total score and/or a Braden Activity-Mobility score, a referral can be made to a therapist to assess the seating system to assess the person's function in maneuvering their manual wheelchair. This study helps to establishment t the connection between the Braden and the FEW-C scores. A future study could be performed to determine if lower FEW-C scores indicate higher pressure ulcer risk. It is recommended that clinicians, both nursing and rehabilitation staff), understand the relationship between the Braden and FEW-C scores to address the client's needs with respect to assessing both wheelchair functioning and pressure ulcer risk. Currently, health professionals analyze each of these scores separately, leading to a piecemeal view of the patients' health and quality of life. A better understanding of the relationship between the Braden and FEW-C scores can enhance inter-professional communication and referrals; further improving the quality of life of individuals. Since the FEW-C is a scale that is not used very often, other scores as suggested by Kon et al. (2015) like the visual analogue scale (VAS) could be considered to be used in the future (Kon et al., 2015). The VAS has been more widely used than the FEW-C which makes it a more reliable tool to use for assessing function in a wheelchair.

### 4.4.1 Limitations

The study sample was primarily female and isn't representative of the entire nursing home population. According to the CDC data analysis in 2014 of nursing home residents, 66.8% were females and 33.2% were males which wasn't representative of this study (women were 78.5% in the study sample). There were large numbers of missing values for covariates such as history of

pressure ulcers and number of medications, which were accounted for in the fully adjusted and stepwise models, and which affected the number of individuals considered for these models. The information of history of pressure ulcers and number of medications was taken from the patient chart which wasn't always complete and updated which lead to the large number of missing data points. Due to the study inclusion criteria of individuals with a total Braden score ≤18 and activity-mobility score ≤5, only this sub-population of nursing home residents was studied. Residents who demonstrated the ability to exhibit safer and more independent wheelchair functioning may have been excluded. The inclusion criteria were designed to include those at risk for pressure ulcers, and is not representative of the entire nursing home population using manual wheelchairs.

### 4.4.2 Future work

A study could be designed that specifically determines the association between the Braden and FEW-C at various score points identifying individuals at different risk levels for pressure ulcers and different functional levels with using their wheelchairs. A clustered randomized clinical trial can be designed in the nursing home setting. This study would aim at testing the effectiveness of a comprehensive wheelchair assessment using the entire Braden score as a trigger point for inclusion in the study and provision of appropriate wheelchair in the prevention of a pressure ulcer in individuals who are at a high risk of developing pressure ulcers. The hypothesis of this study would be individuals residing in nursing homes who are at a high risk of developing a pressure ulcer would have a reduced incidence of pressure ulcer if they are provided a well fit wheelchair after a comprehensive wheelchair assessment compared to the current standard of care. This trial would have two groups: the control group would receive standard care, and the treatment group would receive a comprehensive wheelchair assessment and wheelchair

education to enhance function based on a pre-determined Braden Risk assessment score. Other than measuring pressure ulcer risk and wheelchair function, added outcomes that could be measured could include quality of life, pressure ulcers, wheelchair mobility and function in the wheelchair.

# 5.0 EFFECT OF WHEELCHAIR FIT ON INDIVIDUALLY-CONFIGURED LIGHTWEIGHT MANUAL WHEELCHAIR ON MOBILITY AND FUNCTION

## 5.1 INTRODUCTION

Wheelchair fit is known to have a positive effect on the wheelchair user's functioning abilities and safety levels. Appropriate wheelchair fit comfort and positioning are important factors associated with maximizing and individual's ability to propel the wheelchair, enhancing functional levels while seated in the wheelchair, and performing these tasks safely. Poor wheelchair fit leads to an individual adopting postures that increase pressure over bony prominences, reduces an individual's ability to propel the wheelchair and limits the ability to reach forward and side to side (Gavin-Dreschnack et al., 2005). The wheelchair occupant's trunk posture (upright/flexed), feet condition (supported/dangling) and type of seat cushion (flat polyurethane/proposal low profile) depend on the wheelchair and position of the center of gravity (Okunribido, 2013). The risk of falling from a wheelchair is increased when the user slouches forward (Okunribido, 2013). The occupant's safety in the wheelchair depends on the seat cushion and perception of safety (Okunribido, 2013). Research studies have identified emphasized various factors that are affected because of improperly configured wheelchairs, which in turn affects the quality of life of the wheelchair users.

Postural related imbalances, inactivity, and low functional capacity are factors that affect the pressure ulcer risk in full time wheelchair users (Brienza et al., 2010). Wheelchair-related injuries appear to be due to failed attempts while transferring independently in or out of the chair, or while conducting functional activities while in the wheelchair such as leaning forward

(Gavin-Dreschnack et al., 2005). In a qualitative analysis on one fall from a wheelchair due to mismatched brakes, Kirby & Smith (2001) identify the wheelchair fit as one of the factors associated with safe functioning in a wheelchair (Giesbrecht et al., 2012). Falls from wheelchairs can be due to mismanagement of the wheelchair by the user with respect to the environment (Kirby & Smith, 2001). Environment modifications such as bathroom modifications, widened doorways/hallways, kitchen modifications, railings and/or easy open doors enhance safe wheelchair use (Berg et al., 2002). In summary, improperly fit wheelchairs influence the functioning abilities of an individual as well as their safety levels.

A study describing rehabilitation in Amyotrophic Lateral Sclerosis states the importance of use of light-weight or ultra-lightweight manual wheelchairs as one of the measures to maximize patient independence, function, safety, and quality of life (Majmudar et al., 2014). Reducing the number of falls and injuries without lowering activity is a challenge (Aizen et al., 2007). The way in which a user is positioned in the wheelchair affects user safety during transfers (Okunribido, 2013). Appropriate wheelchair comfort and positioning are important factors associated with maximizing an individual's ability to propel the wheelchair, enhancing functional levels while seated in the wheelchair, and performing these tasks safely (Gavin-Dreschnack et al., 2005).

The role of custom fit lightweight wheelchairs on function, propulsion and mobility was tested using the following research questions:

1. Do individuals provided with an individually-configured manual lightweight wheelchair and skin protection cushion function better in the wheelchair compared to individuals using a facility-provided manual wheelchair modified with a skin protection cushion and related adjustments?
2. Do individuals provided with an individually-configured manual lightweight wheelchair and skin protection cushion propel better compared to individuals using a facility provided manual wheelchair modified with a skin protection cushion and related adjustments?

3. Do individuals with an individually-configured manual lightweight wheelchair and skin protection cushion have better mobility than individuals using facility-provided manual wheelchairs modified with skin protection cushions and related adjustments?

## 5.2 METHODS

This aim tested the following hypotheses:

1. Elderly wheelchair users at risk for pressure ulcers provided with individually-configured manual lightweight wheelchairs and a skin protection cushion have greater improvement in *functional independence and propulsion skills* as identified by the FEW-C and WST scores compared to individuals using nursing home provided manual wheelchairs modified with a skin protection cushion and related adjustments.

2. Elderly wheelchair users at risk for pressure ulcers provided with individually-configured lightweight manual wheelchairs and a skin-protection cushion have greater improvement in *functional and propulsion safety* measured by FEW-C and WST scores compared to individuals using nursing home provided manual wheelchairs modified with a skin protection cushion and related adjustments.

3. Elderly wheelchair users at risk for pressure ulcers provided individually-configured lightweight manual wheelchairs and a skin protection cushion have greater improvement in *mobility* as identified by the NHLSD total scores compared to individuals using nursing home provided wheelchairs modified with a skin protection cushion and related adjustments.

### 5.2.1 Research Design

The study is a secondary analysis of a fixed data set from the National Institutes of Health grant titled-An RCT on wheeled mobility for preventing pressure ulcers (Grant number: 2R01HD041490). The study participants, intervention and data collection methods are described in Chapter 2. The data used for this aim includes FEW-C data collected at the pre-randomization, day 14 and endpoint. WST data collected at post-randomization, day 7, day 14 and endpoint.

NHLSD data was collected at the pre-randomization and endpoint. In order to avoid discrepancy in the results to the various reasons associated with a person being removed from the study, only the subjects who reached study endpoint due to completion of 26 weeks using study equipment were used for the purposes of the analysis of this aim.

### 5.2.2 Data Analysis

Data are summarized as mean and standard deviations for continuous variables. An independent samples t- test was conducted. The data was compared based on intervention group. The significance threshold was set at 0.05. Statistical analyses were completed using SPSS 23.0 for Windows.

Mean values were computed for the NHLSD, FEW-C and WST scores at different time points of outcome measure assessment during the study. These time points included pre-randomization, post-randomization, 7 days after equipment prescription, 14 days after equipment prescription and at endpoint. This analysis included only those individuals who reached endpoint as a result of completing 26 weeks in the study (Table 25). Independent t-tests assessing group differences in mean change were calculated to assess change in score between the different time points for FEW-C, WST and NHLSD. As part of the post-hoc analysis, a chi-square analysis was done to determine if there was a difference between groups in improvement in FEWC scores from pre-randomization to endpoint. Furthermore, the improvement scores were assessed for all the assessments. A change in score of greater than zero between two time points was considered as improvement. Improvement scores were assessed between different time points for different assessments. The NHLSD and FEW-C scores were assessed between pre-randomization and endpoint whereas the WST was assessed between day 14 and endpoint.

## 5.3 RESULTS

The parent study recruited a total of 258 individuals, of which 131 were assigned to the control group and 127 individuals were assigned to the treatment group. However, only the individuals who completed 26 weeks using the study equipment were included in the analyses for the hypotheses. The sample size for this aim was a total of 131 individuals with 69 in the treatment group and 62 in the control group.

### 5.3.1 Baseline characteristics

Descriptive characteristics of the participants are shown in Table 25. Participants had a mean age of 84.04 (±8.77) and had lived in a nursing home for a mean of 2.06 (±2.16) years. Participants took an average of 13.08 (±5.019) medications on a given day. Participants were primarily white (91.6%) and female (80.2%), with the majority having a diagnosis related to the heart (62.6%), vascular system, (54.2%), musculoskeletal/integument system (61.1%), neurological system (62.6%) and psychiatric illnesses (64.9%). A high prevalence of incontinence was observed in the sample, with urinary incontinence (69.5%) being greater than fecal incontinence (62.6%). Previous history of pressure ulcers was prevalent in 15.3% of the study sample. Individuals who had hip surgery accounted for 12.20% of the study sample. The differences between groups were non-significant for all variables except for fecal incontinence (p-value=0.010) and previous history of pressure ulcers (p-value=0.047).

Table 25. Descriptive analysis of the sample

| | Total Sample (N=131) | Treatment Group (N=69) | Control group (N=62) | p-value |
|---|---|---|---|---|
| **Parameter** | | **Mean (Standard Deviation)** | | |
| Age | 84.04 (8.771) | 84.12 (8.962) | 83.95 (8.626) | 0.915 |
| Length of stay in a nursing home (in years) | 2.10 (2.159) | 2.06 (2.121) | 2.151 (2.217) | 0.819 |
| Number of medications (N=128) | 13.08 (5.019) | 12.67 (4.977) | 13.52 (5.068) | 0.339 |
| | | **Frequency (Percentage)** | | |
| GENDER | | | | |
| Female | 105 (80.2) | 54 | 51 | 0.663 |
| RACE | | | | |
| White | 120 (91.6) | 63 | 57 | 1.000 |
| Black | 11 (8.4) | 6 | 5 | 1.000 |
| DIAGNOSIS relating to | | | | |
| Heart | 82 (62.6) | 43 | 39 | 1.000 |
| Vascular system | 71 (54.2) | 39 | 32 | 0.602 |
| Hematopoietic system | 18 (13.7) | 9 | 9 | 1.000 |
| Respiratory system | 43 (32.8) | 24 | 19 | 0.710 |
| Eyes, Ears and Nose | 22 (16.8) | 8 | 14 | 0.106 |
| Upper Gastrointestinal system | 26 (19.8) | 17 | 9 | 0.189 |
| Lower Gastrointestinal system | 19 (14.5) | 12 | 7 | 0.457 |
| Liver system | 3 (2.3) | 1 | 2 | 0.603 |
| Renal system | 25 (19.1) | 9 | 16 | 0.077 |
| Genitourinary system | 27 (20.6) | 14 | 13 | 1.000 |
| Musculoskeletal/Integument | 80 (61.1) | 40 | 40 | 0.477 |
| Neurological system | 82 (62.6) | 41 | 41 | 0.473 |
| Endocrine, Metabolic, Breast | 35 (26.7) | 15 | 20 | 0.235 |
| Psychiatric | 85 (64.9) | 42 | 43 | 0.361 |
| Diabetes | 30 (22.9) | 16 | 14 | 1.000 |
| Other | 37 (28.2) | 22 | 15 | 0.340 |

| Table 25 (cont'd) | | | | |
|---|---|---|---|---|
| INCONTINENCE (N=94) | | | | |
| Urine | 91 (69.5) | 49 | 42 | 0.251 |
| Feces | 82 (62.6) | 41 | 41 | 0.010 |
| Previous History of pressure ulcers N=114 | 20 (15.3) | 15 | 5 | 0.047 |
| History of hip surgery | 16 (12.2) | 10 | 6 | 0.436 |

Table 26. Classification of subjects based on reasons for reaching endpoint

| Reason for reaching endpoint | Frequency (Percent) | Treatment Group (Percent) | Control Group (Percent) |
|---|---|---|---|
| Development of a seated surface pressure ulcer | 33 (12.8) | 19 (14.96) | 14 (10.69) |
| Completed 26 weeks in the study | 131 (50.8) | 69 (54.33) | 62 (47.32) |
| Death | 13 (5.0) | 8 (6.29) | 5 (3.82) |
| Withdrawal by subject/family | 19 (7.4) | 8 (6.29) | 11 (8.40) |
| Withdrawal by study team | 47 (18.2) | 18 (14.17) | 29 (22.14) |
| Total classified endpoints | 243 (94.2) | 122 (96.06) | 121 (92.36) |
| Missing | 14 (5.4) | 4 (3.15) | 10 (7.63) |
| Total | 258 (100) | 127 (100) | 131 (100) |

Table 26 shows the classification of subjects based on the various reasons for reaching endpoint. Reasons for reaching endpoint included development of seated surface pressure ulcers, completion of 26 weeks in the study, death, and withdrawal by a team or family member. To eliminate the different time points at which endpoint was achieved, the analysis of this study was conducted on only those individuals who reached endpoint due to completion of 26 weeks in the study. Of the 258 subjects, 131 (50.8%) reached endpoint due to completion of the 26-week follow-up in the study of which 69 (54.33%) were from the treatment group and 62 (47.32%) were from the control group. To eliminate different time points at which endpoint was achieved, the analysis for the hypotheses was conducted on only those 131 individuals who reached endpoint due to completion of 26 weeks in the study.

### 5.3.2 FEW-C

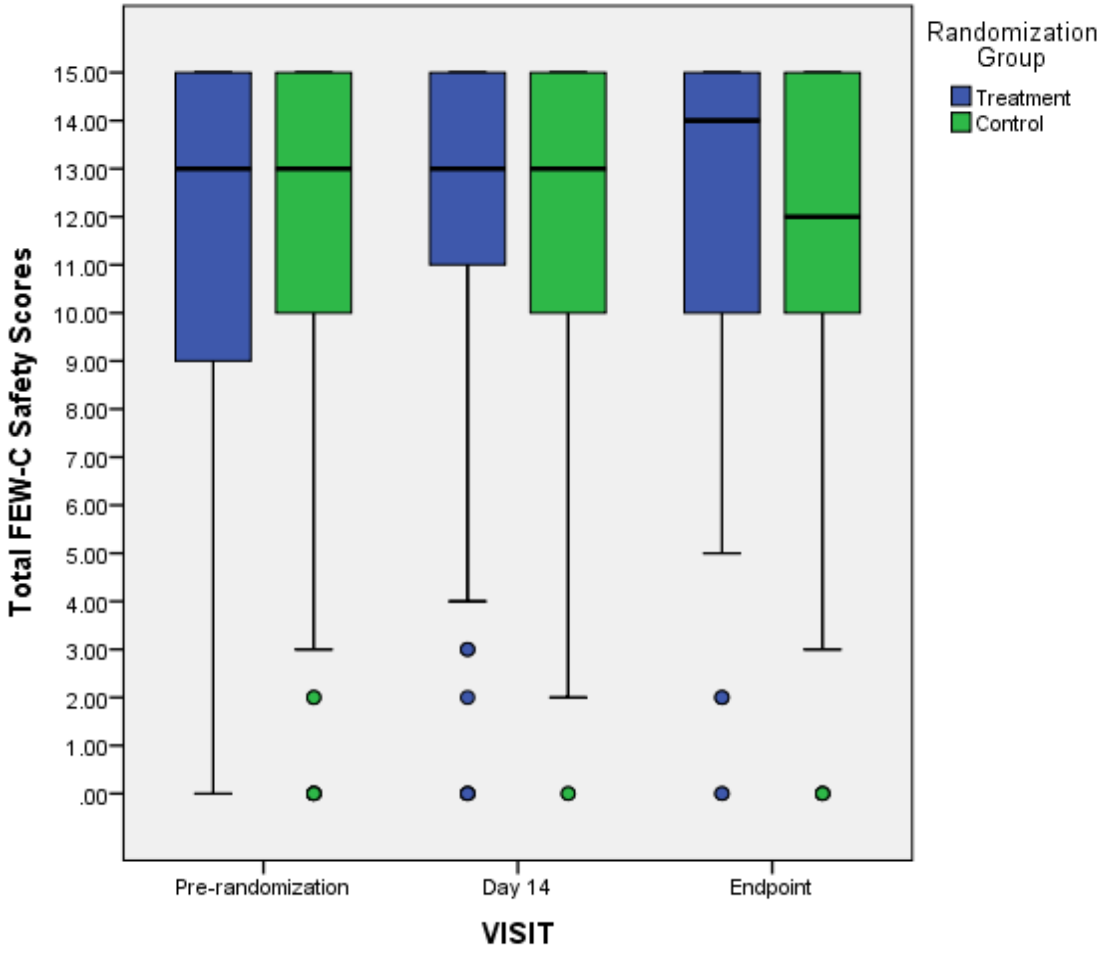



**Figure 5.1. Clustered box plot of FEW-C Safety scores along different time points**

Figure 5.1 is a clustered box plot of the Total FEW-C Safety Scores over different time points: Pre-randomization, Day 14 and Endpoint for all 258 subjects. The upper quartiles of both treatment and control groups are the same. However, at the lower quartiles there are differences between the randomization groups at the pre-randomization and Day 14 phases. The difference in the medians look minimal at the pre-randomization and Day 14 phases. But a larger difference between the randomization groups is seen in the medians at the endpoint phase.

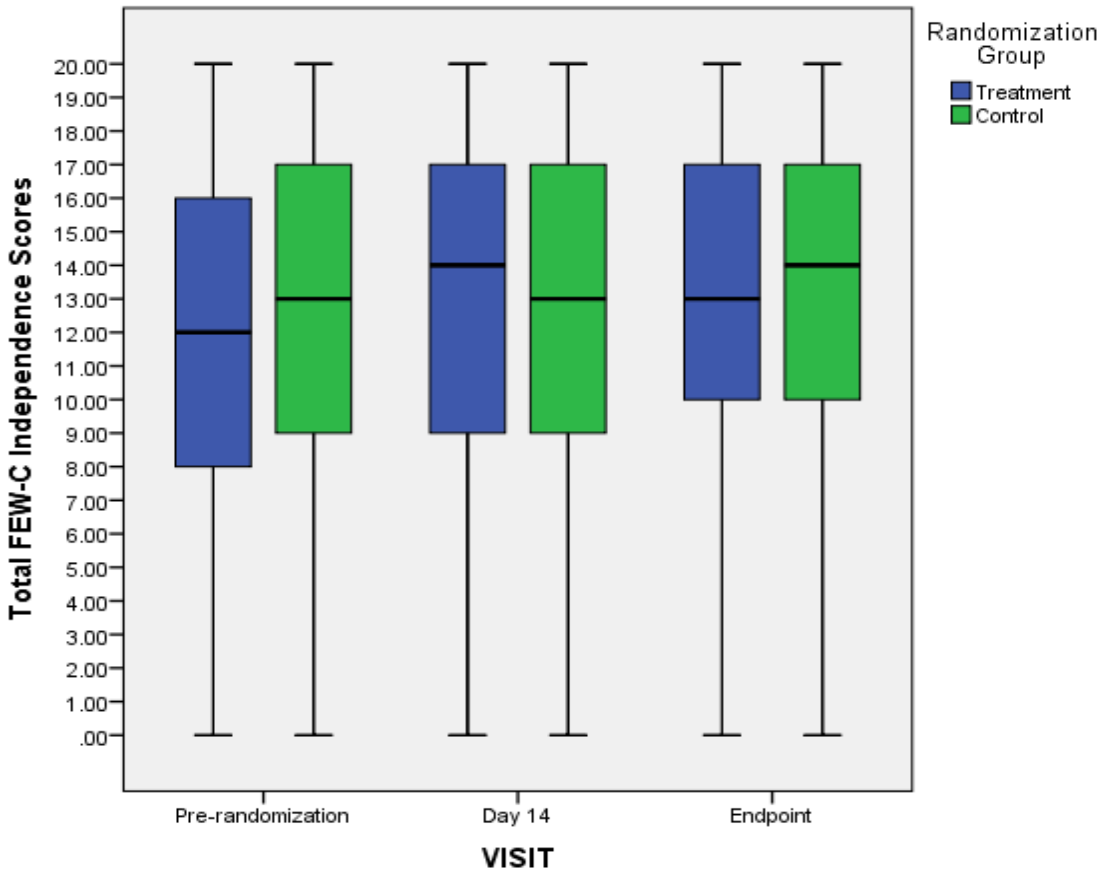



**Figure 5.2. Clustered box plot of FEW-C Independence scores along different time points**

Figure 5.2 is a clustered box plot of the Total FEW-C Independence Scores over different time points: Pre-randomization, Day 14 and endpoint for all 258 subjects. The IQR's don't appear to be much different. The difference in the medians look minimal between all the time points. Figures 5.5 and 5.6 were conducted as additional visual analysis to gain a better undertanding of the scores distribution in the dataset. It will also enhance the understanding of the multi-variate analysis conducted.

Table 27. Descriptive characteristics of all participants FEW-C at different time points: Pre-Rand, Day14 & Endpoint (N=258)

| | Treatment (N=127) | | | | Control (N=131) | | | |
|---|---|---|---|---|---|---|---|---|
| | N | | Mean | Std. deviation | N | | Mean | Std. Deviation |
| | Valid | Missing | | | Valid | Missing | | |
| Pre-Rand FEW-C Safety | 126 | 1 | 11.25 | 4.356 | 124 | 7 | 11.46 | 3.995 |
| Pre-Rand FEW-C Independence | 126 | 1 | 11.48 | 5.195 | 124 | 7 | 12.10 | 5.290 |
| Day 14 FEW-C Safety | 107 | 20 | 11.73 | 4.048 | 99 | 32 | 11.49 | 4.124 |
| Day 14 FEW-C Independence | 107 | 20 | 12.40 | 5.154 | 99 | 32 | 11.87 | 5.458 |
| Endpoint FEW-C Safety | 85 | 42 | 11.92 | 3.675 | 74 | 57 | 11.31 | 4.068 |
| Endpoint FEW-C Independence | 85 | 42 | 12.94 | 5.308 | 74 | 57 | 12.47 | 5.545 |

The descriptive characteristics of the FEW-C at different time points of all parent study population (N=258) at Pre-Randomization, Day 14 and Endpoint are shown in Table 27. At pre-randomization, which is before the equipment was provided to the subjects, the mean safety score in the treatment group (11.25) was lower than the control group (11.46). The mean independence scores for the treatment group (11.48) was lower than the control group (12.10). Two weeks after the equipment was provided to the subjects, the mean independence scores in the treatment group (12.40) was higher than the control group (11.87) together with the mean safety scores in the treatment group (11.73) was higher than the control group (11.49). Higher mean scores for the treatment compared to the control group was observed at endpoint as well for both independence and safety. The statistical significance for these differences wasn't tested.

Table 28. Descriptive characteristics of chosen sample FEW-C at different time points: Pre-Rand, Day14 & Endpoint (N=131)

| | Treatment (N=70) | | | | Control (N=61) | | | |
|---|---|---|---|---|---|---|---|---|
| | N | | Mean | Std. deviation | N | | Mean | Std. Deviation |
| | Valid | Missing | | | Valid | Missing | | |
| Pre-Rand FEW-C Safety | 69 | 1 | 11.74 | 3.807 | 60 | 1 | 11.98 | 3.181 |
| Pre-Rand FEW-C Independence | 69 | 1 | 11.74 | 4.418 | 60 | 1 | 12.68 | 4.939 |
| Day 14 FEW-C Safety | 67 | 3 | 12.48 | 3.548 | 58 | 3 | 11.86 | 3.931 |
| Day 14 FEW-C Independence | 67 | 3 | 13.15 | 4.688 | 58 | 3 | 12.78 | 5.318 |
| Endpoint FEW-C Safety | 69 | 1 | 12.49 | 3.137 | 58 | 3 | 11.36 | 4.094 |
| Endpoint FEW-C Independence | 69 | 1 | 13.80 | 4.810 | 58 | 3 | 12.64 | 5.708 |

The descriptive characteristics of the FEW-C at different time points of the sample of individuals who reached endpoint at 26 weeks (N=131) at Pre-Randomization, Day 14 and Endpoint are shown in Table 28. At pre-randomization, which is before the equipment was provided to the subjects, the mean safety score in the treatment group (11.74) was lower than the control group (11.98). The mean independence scores for the treatment group (11.74) was lower than the control group (12.68). Two weeks after the equipment was provided to the subjects, the mean independence scores in the treatment group (13.15) was higher than the control group (12.78) together with the mean safety scores in the treatment group (12.48) was higher than the control group (11.86). Higher mean scores for the treatment compared to the control group was observed at endpoint as well for both independence and safety. The statistical significance for these differences wasn't tested.

### 5.3.3 WST

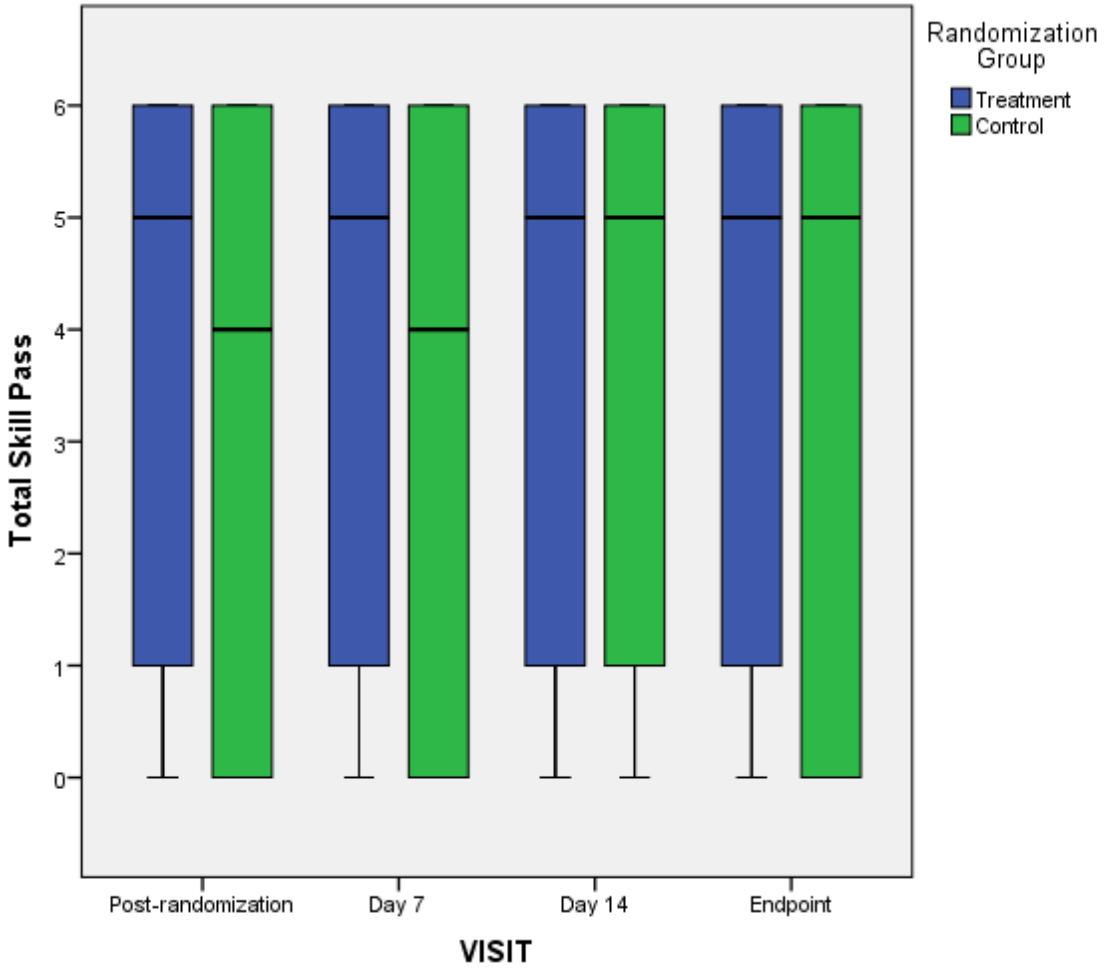



**Figure 5.3. Clustered box plot of WST Skills Pass scores along different time points**

Figure 5.3 is a clustered box plot of the WST Total Skills Pass Scores over different time points: Post-randomization, Day 7, Day 14 and endpoint for all 258 subjects. In the upper quartile,s both treatment and control groups are the same at all four time points. However, at the lower quartiles there are differences between the treatment and control groups at the post-randomization, Day 7, and endpoint phases. The difference in the medians look minimal at Day 14 and endpoint phases. However, a larger difference between the treatment and control groups is seen in the medians at the post-randomization and Day 7 phases. Based on the visual analysis of Figure 3.2, the ability of an individual to propel a wheelchair if in the treatment group stayed

about the same over all four time points. However, the control group individuals showed an overall improvement in the WST skill set occurring between Day 7 and Day 14.

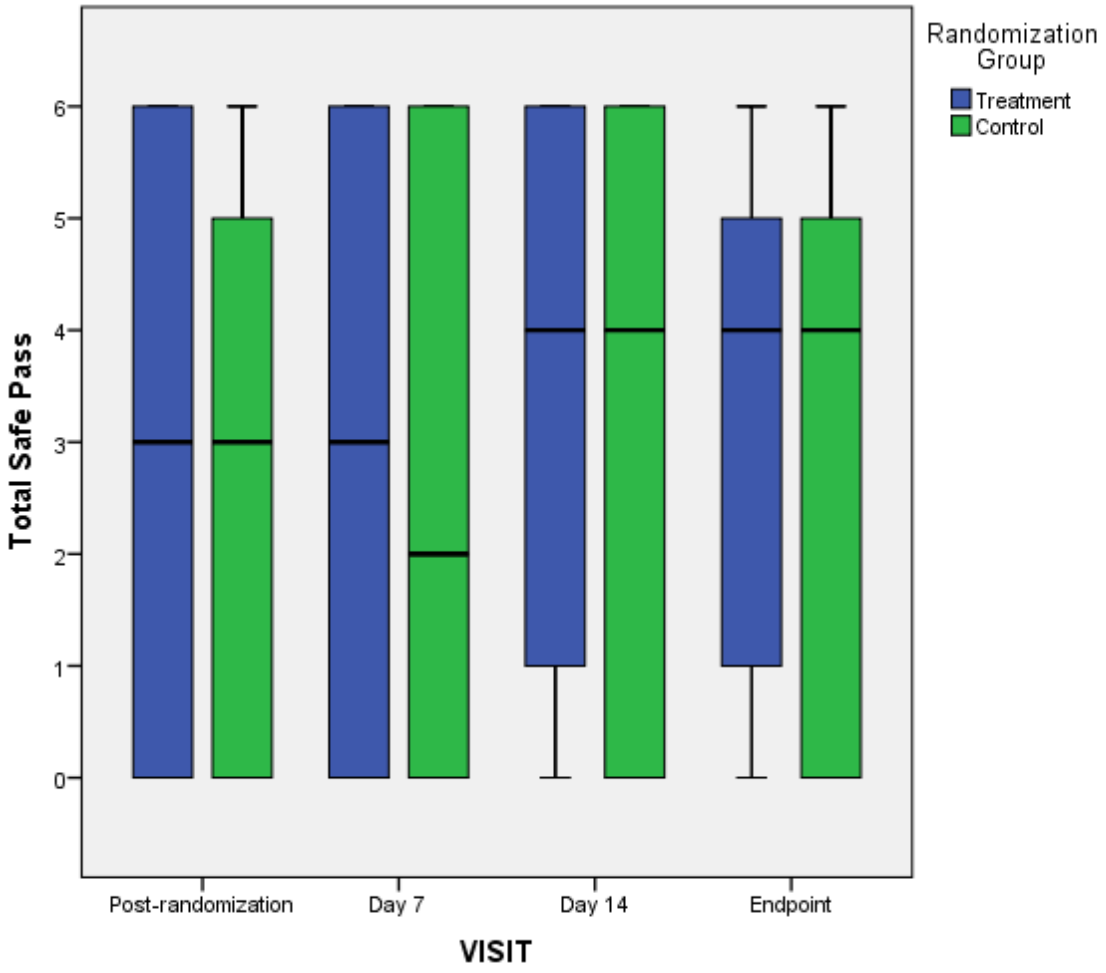



**Figure 5.4. Clustered box plot of WST Safe Pass scores along different time points**

Figure 5.4 is a clustered box plot of the WST Total Safety Pass Scores over different time points: Post-randomization, Day 7, Day 14 and endpoint for all 258 subjects. Differences in the upper quartiles are noticed between the groups at the post-randomization phase. Differences in the lower quartiles are noticed between groups at Day 14 and endpoint. Differences in the medians at the post-randomization, Day 14 and endpoint phases between groups seem minimal. The median of the treatment group is greater than the median of the control group at Day 7. A

trend towards an increase of median values was noticed for the treatment group between the four time points. The control group showed a decrease in median values from post-randomization to Day 7, and then an increase greater than post-randomization from Day 7 to Day 14 and endpoint.

The descriptive characteristics of the WST are shown. Different time points are at Post-Rand, Day 7, Day 14 and Endpoint are shown in Table 28 and Table 29 The WST safety and skills scores ranged from a minimum of 0 and a maximum of 6. The mean values for the WST skills and safety components at post-randomization, Day 7. Day 14 and endpoint for the treatment groups were greater than the mean values for the control groups at each of these time points (Table 29 & Table 30).

Table 29. Descriptive characteristics of WST Independence at different time points: Post-Rand, Day 7, Day 14 & Endpoint

| | Treatment (N=126) | | | | Control (N=131) | | | |
|---|---|---|---|---|---|---|---|---|
| | N | | Mean | Std. deviation | N | | Mean | Std. deviation |
| | Valid | Missing | | | Valid | Missing | | |
| Post-Rand WST Skill Pass | 120 | 6 | 3.74 | 2.482 | 114 | 17 | 3.34 | 2.548 |
| Day 7 WST Skill Pass | 114 | 12 | 3.64 | 2.406 | 104 | 27 | 3.11 | 2.618 |
| Day 14 WST Skill Pass | 107 | 19 | 3.96 | 2.495 | 100 | 31 | 3.49 | 2.596 |
| Endpoint WST Skill Pass | 84 | 42 | 3.93 | 2.483 | 74 | 57 | 3.47 | 2.624 |

Table 30. Descriptive characteristics of WST Safety at different time points: Post-Rand, Day 7, Day 14 & Endpoint

| | Treatment | | | | Control | | | |
|---|---|---|---|---|---|---|---|---|
| | N | | Mean | Std. deviation | N | | Mean | Std. deviation |
| | Valid | Missing | | | Valid | Missing | | |
| Post-Rand WST Safe Pass | 120 | 6 | 3.14 | 2.447 | 114 | 17 | 2.79 | 2.415 |
| Day 7 WST Safe Pass | 114 | 12 | 3.04 | 2.383 | 104 | 27 | 2.56 | 2.531 |
| Day 14 WST Safe Pass | 107 | 19 | 3.44 | 2.450 | 100 | 31 | 3.07 | 2.571 |
| Endpoint WST Safe Pass | 84 | 42 | 3.23 | 2.330 | 74 | 57 | 3.03 | 2.472 |

### 5.3.4 NHLSD

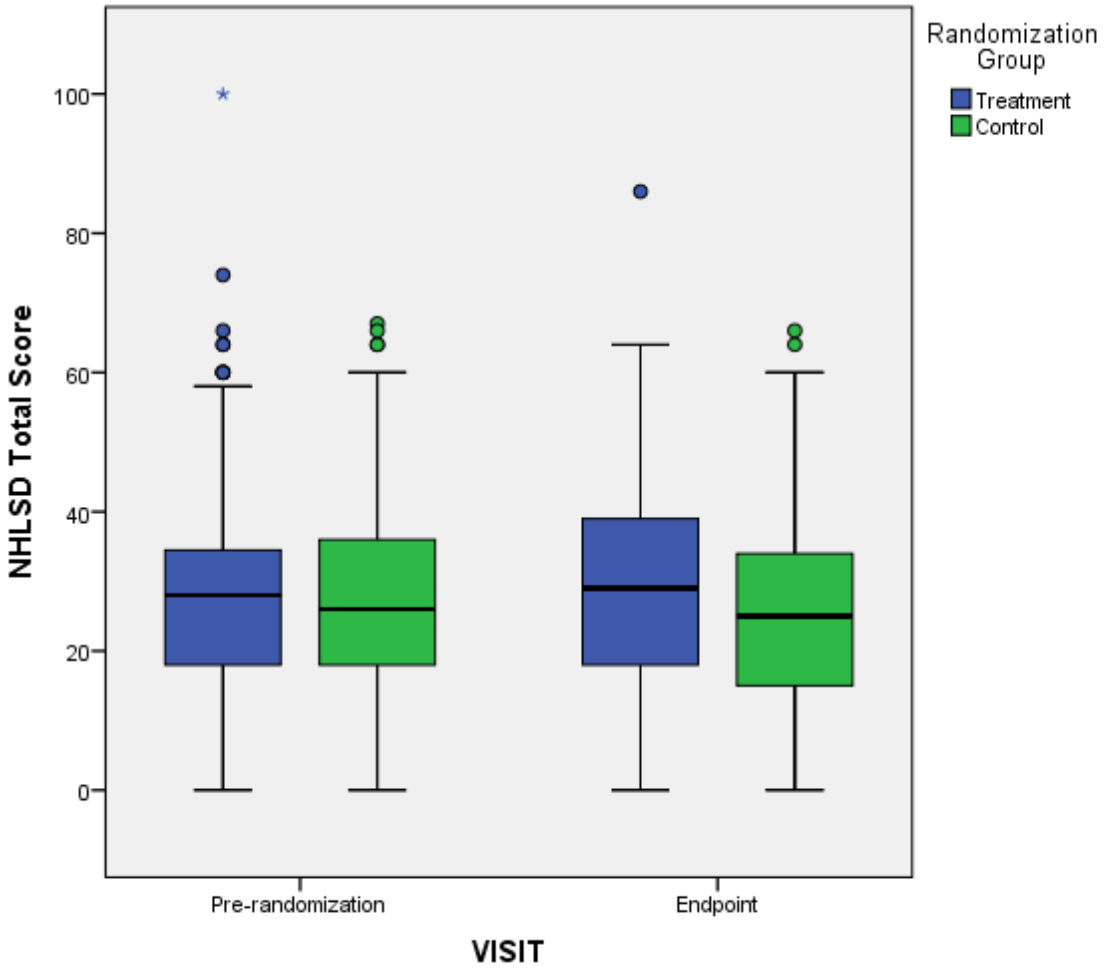



**Figure 5.5. Clustered box plot of NHLSD scores by time points**

Figure 5.5 is a clustered box plot of the NHLSD Scores at the different time points- Pre-randomization and Endpoint for all 258 subjects to explore the data. The interquartile ranges (IQR) between the groups don't appear to be much different in the pre-randomization phase. However, slight diffferences are observed in the IQR's between the groups at the endpoint phase. The difference in the medians between treatment and control groups looks minimal at both pre-randomization and endpoint. The findings of the visual analysis are that the treatment group had better mobility at endpoint compared to pre-randomization.

The descriptive characteristics of the NHLSD, at different time points that are Pre-Rand and Endpoint are shown in Table 31.

Table 31. Descriptive characteristics of NHLSD at different time points: Pre-Rand & Endpoint

| | | **Pre-Rand NHLSD Total Score** | **Endpoint NHLSD Total Score** |
|---|---|---|---|
| Treatment | N | 126 | 86 |
| | Missing | 0 | 42 |
| | Mean | 28.87 | 30.98 |
| | Std. Deviation | 16.717 | 16.090 |
| Control | N | 124 | 74 |
| | Missing | 7 | 57 |
| | Mean | 28.50 | 27.12 |
| | Std. Deviation | 14.662 | 14.840 |

### 5.3.5 Difference in scores at different time points

Table 32 shows the result of the independent t-tests assessing group differences in mean change in score between the different time points for FEW-C, WST and NHLSD. The level of statistical significance was set to be at 0.05. There is a borderline statistically significant difference between means of the group change in NHLSD scores between the pre-randomization and endpoint (p=0.087).

Table 32. Independence Samples t-test of the FEW-C, WST and NHLSD at different time points

| | t-test for equality of means | | | | |
|---|---|---|---|---|---|
| | Mean Difference | Std. Error Difference | 95% Confidence Interval of the Difference | | Sig (2-tailed) |
| | | | Lower | Upper | |
| **NHLSD** | | | | | |
| Endpoint & Pre-Rand | 5.04 | 2.92 | -0.75 | 10.83 | 0.087 |
| **FEW-C** | | | | | |
| Independence Endpoint & Pre-Rand | 2.14 | 0.79 | 0.58 | 3.71 | 0.008 |
| Independence Endpoint & day 14 | 1.03 | 0.74 | -0.43 | 2.49 | 0.164 |
| Independence Day 14 & Pre-rand | 1.27 | 0.70 | -0.13 | 2.66 | 0.075 |
| Safety Endpoint & Pre-Rand | 1.37 | 0.61 | 0.16 | 2.58 | 0.027 |
| Safety Endpoint & Day 14 | 0.76 | 0.59 | -0.41 | 1.93 | 0.203 |
| Safety Day 14 & Pre-Rand | 0.70 | 0.62 | -0.53 | 1.93 | 0.264 |
| **WST** | | | | | |
| Skills Pass Endpoint & Post-Rand | 0.41 | 0.40 | -0.38 | 1.21 | 0.305 |
| Skill Pass Endpoint & day 14 | 0.45 | 0.36 | -0.26 | 1.16 | 0.215 |
| Skill Pass Endpoint & day 7 | 0.52 | 0.46 | -0.39 | 1.44 | 0.260 |
| Skill Pass Day 14 & Day 7 | 0.35 | 0.42 | -0.47 | 1.18 | 0.400 |
| Skill Pass Day 14 & Post-Rand | 0.18 | 0.35 | -0.52 | 0.87 | 0.616 |
| Skill Pass Day 7 & Post-Rand | -0.09 | 0.41 | -0.91 | 0.73 | 0.832 |
| Safety Pass Endpoint & Post-Rand | 0.11 | 0.39 | -0.67 | 0.89 | 0.785 |
| Safety Pass Endpoint & day 14 | 0.45 | 0.41 | -0.36 | 1.26 | 0.275 |
| Safety Pass Endpoint & day 7 | 0.14 | 0.46 | -0.78 | 1.06 | 0.769 |
| Safety Pass Day 14 & day 7 | -0.04 | 0.45 | -0.93 | 0.84 | 0.926 |
| Safety Pass Day 14 & Post-Rand | -0.21 | 0.37 | -0.93 | 0.52 | 0.573 |
| Safety Pass Day 7 & Post-rand | 0.01 | 0.40 | -0.79 | 0.80 | 0.985 |

There is a significant difference of 2.14 between the means at pre-randomization and endpoint scores of the independence components of the FEW-C (p=0.008). There is a difference of 1.27 between means trending towards significance between the pre-randomization and Day14 scores of the independence scores of the FEW-C (p= 0.075). There is a statistically significant difference between the group means of change in FEW-C safety scores from pre-randomization to endpoint (p=0.027). The above results indicate that there were statistically significant

differences between treatment and control groups in the individuals' ability to function in a wheelchair between pre-randomization and endpoint. While looking at the differences between the safety and independence components of FEW-C, it took longer for an individual to develop safety skills associated with functioning in a wheelchair compared to an individuals' ability to develop only the skill to independently function in the wheelchair.

### 5.3.6 Post-hoc analysis

Various post hoc analysis were conducted to study the results in further detail.

A chi-square analysis was done to determine if there was a difference between groups in improvement in FEW-C independence and safety scores from pre-randomization to endpoint. A logistic regression model was developed for covariates affecting the improvement in the FEW-C independence and safety scores. Baseline characteristics were compared between the sample of individuals with improvement in FEW-C independence and safety scores to individuals with no improvement. A chi-square analysis was done to further compare different items in the FEW-C independence and safety scores between the groups at pre-randomization and endpoint to identify improvement in a specific item.

A chi-square analysis was done to determine if there was a difference between groups in improvement in NHLSD scores from pre-randomization to endpoint. A logistic regression model was developed for covariates affecting the improvement in the NHLSD scores. Baseline characteristics were compared between the sample in individuals with improvement in NHLSD scores to individuals with no improvement. A chi-square analysis was done to further compare different items in the NHLSD scores between the groups at pre-randomization and endpoint to identify improvement in a specific item.

A chi-square analysis was done to determine if there was a difference between groups in improvement in WST independence and safety scores from day 14 to endpoint. A logistic regression model was developed for covariates affecting the improvement scores in the WST independence and safety scores. Baseline characteristics were compared within the sample in individuals with improvement in WST independence and safety scores to individuals with no improvement. A chi-square analysis was done to further compare different items in the WST independence and safety scores between the groups at day 14 and endpoint was further done to identify improvement in a specific item.

#### 5.3.6.1 FEW-C

Table 33 describes results of the Chi square analysis of the FEW-C independence scores by treatment group and individuals who had an improvement in the FEW-C Independence scores compared to those who did not have an improvement between endpoint and pre-randomization. Individuals' were grouped as having improvement if the difference between their endpoint and pre-randomization FEW-C Independence and Safety scores was $\geq 0$. The p-value of 0.177 indicated that there was no significant difference between individuals who had an improvement in FEW-C independence scores compared to individuals who did not have an improvement in FEW-C independence scores by treatment group assignment.

Table 33: FEW-C Independence scores between treatment groups of individuals who had an improvement in their scores and those who did not show improvement in their scores

| | Treatment n (%) | Control n (%) | Total n (%) | p-value |
|---|---|---|---|---|
| No Improvement | 24 (30.76) | 30 (41.66) | 54 (36) | 0.177 |
| Improvement | 54 (69.23) | 42 (58.33) | 96 (64) | |
| Total | 78 (100) | 72 (100) | 150 (100) | |

Table 34: Regression model for covariates affecting the improvement scores in the FEW-C Independence scores

| **Improvement in FEW-C Independence scores ($R^2$=0.024)** | **Exp B/ Odds Ratio *(p)*** |
|---|---|
| Treatment group | 1.777 (0.163) |
| Diagnosis of Psychiatric Illnesses | 0.248 (0.003) |
| Alert and oriented | 6.227 (0.034) |
| Combativeness | 4.348 (0.077) |
| Nursing home 6 | 0.171 (0.038) |
| Nursing home 17 | 0.235 (0.093) |

A binary logistic regression analysis was conducted to predict improvement of the FEW-C independence scores using various covariates as predictors as determined by clinical judgment. $R^2$ of 0.024 indicates 2.4% variability of the response data around its mean (Table 34). Exp (B) value is the odds ratio. Borderline significance was noted for being in the treatment group, combative or in Nursing Home Site#17. Individuals' in the treatment group are 1.7 times more likely to have a one unit improvement in FEW-C Independence scores. Diagnoses of psychiatric illnesses represents the mean increase of 0.248 in response for one unit of change in the FEW-C independence scores while holding the other predictors in the model constant. The alert and oriented status of the patient represents the mean increase of 6.23 in response for one unit change in the FEW-C independence scores while holding the other predictors in the model constant. The combativeness status of the patient represents the mean increase of 4.35 in response for one unit change in the FEW-C independence scores while holding the other predictors in the model constant. Differences between Nursing Home Site # 6 and 17 represent the mean increase of 0.17

and 0.24 in response for one unit of change in the FEW-C independence scores while holding the other predictors in the model constant. In summary, since the odds ratio is greater than 1 for the treatment group, combativeness and being alert and oriented, it is indicative of a higher odd of the FEW-C independence scores. The odds ratio for diagnosis of psychiatric illness, nursing home site # 6 and nursing home site # 17 is less than 1 which is indicative of lower odds of improving the FEW-C independence scores.

Table 35 describes the baseline characteristics of the sample classified by the individuals whose FEW-C independence scores improved compared to those who had no improvement. There were no significant differences between groups as indicated by the p-values, of any of the baseline characteristics except for number of medications and presence of a psychiatric diagnosis as indicated by the p-value of 0.04 and 0.00.

Table 35: Baseline characteristics of the sample classified by the individuals whose FEW-C independence scores improved compared to those who had no improvement

| | Total Sample | Improvement | No Improvement | p-value |
|---|---|---|---|---|
| **Parameter** | | **Mean (Standard Deviation)** | | |
| Age * | 84.32 (9.122) | 84.72 (9.111) | 83.61 (9.185) | 0.477 |
| Length of stay in a nursing home at time of enrollment (in years) * | 1.99 (2.092) | 1.84 (2.017) | 2.24 (2.214) | 0.266 |
| Number of medications (N=148) | 13.36 (5.438) | 12.68 (4.947) | 14.57 (6.078) | 0.043 |
| | | **Frequency (Percentage)** | | |
| GENDER* | | | | |
| Female | 119 (79.3) | 79 (66.4) | 40 (33.6) | 0.294 |
| RACE* | | | | |
| White | 137 (91.3) | 89 (65.0) | 48 (35) | 0.547 |
| Black | 13 (8.7) | 7 (53.8) | 6 (46.2) | 0.547 |
| DIAGNOSIS relating to * | | | | |
| Heart | 96 (64.0) | 64 (66.7) | 32 (33.3) | 0.381 |
| Vascular system | 90 (60.0) | 57 (63.3) | 33 (36.7) | 0.864 |
| Hematopoietic system | 17 (11.3) | 11 (64.7) | 6 (35.3) | 1.000 |
| Respiratory system | 49 (32.7) | 32 (65.3) | 17 (34.7) | 0.858 |
| Eyes, Ears and Nose | 28 (18.7) | 15 (53.6) | 13 (46.4) | 0.275 |
| Upper Gastrointestinal system | 34 (22.7) | 23 (67.6) | 11 (32.4) | 0.688 |
| Lower Gastrointestinal system | 21 (14.0) | 14 (66.7) | 7 (33.3) | 1.000 |
| Liver system | 3 (2) | 3 (100) | 0 (0) | 0.553 |
| Renal system | 24 (16.0) | 18 (75.0) | 6 (25.0) | 0.254 |
| Genitourinary system | 32 (21.3) | 21 (65.6) | 11 (34.4) | 1.000 |
| Musculoskeletal/Integument | 89 (59.3) | 59 (66.3) | 30 (33.7) | 0.494 |
| Neurological system | 91 (60.7) | 60 (65.9) | 31 (34.1) | 0.603 |
| Endocrine, Metabolic, Breast | 38 (25.3) | 25 (65.8) | 13 (34.2) | 0.847 |
| Psychiatric | 94 (62.7) | 49 (52.1) | 45 (47.9) | 0.000 |
| Diabetes | 33 (22.0) | 25 (75.8) | 8 (24.2) | 0.150 |
| Other | 43 (28.7) | 31 (72.1) | 12 (27.9) | 0.259 |

| Table 35 (cont'd) | | | | | |
|---|---|---|---|---|---|
| INCONTINENCE | | | | | |
| | Urine*** | 108 (72.0) | 68 (63) | 40 (37) | 0.552 |
| | Feces*** | 97 (64.7) | 64 (66) | 33 (34) | 0.252 |
| Previous History of pressure ulcers ** | | 24 (16.0) | 14 (58.3) | 10 (41.7) | 0.639 |
| History of hip surgery * | | 16 (10.7) | 11 (68.8) | 5 (31.3) | 0.787 |

*N=150
**N=133
***N=111

Table 36: Representation of FEW-C safety scores between treatment groups with improvement in scores and those who did not show improvement in their scores

| | **Treatment n (%)** | **Control n (%)** | **Total n (%)** | **p-value** |
|---|---|---|---|---|
| No Improvement | 29 (37.18) | 34 (47.22) | 63 (42) | 0.248 |
| Improvement | 49 (62.82) | 38 (52.78) | 87 (58) | |
| Total | 78 (100) | 72 (100) | 150 (100) | |

Table 36 describes results of the Chi square analysis of the FEW-C safety scores by treatment group and individuals who had an improvement in the FEW-C Independence scores compared to those who did not have an improvement. The p-value of 0.248 indicated that there was no significant difference between individuals who had an improvement in FEW-C safety scores compared to individuals who did not have an improvement in FEW-C safety scores by treatment group assignment.

Table 37: Regression model for covariates affecting the improvement scores in the FEW-C Safety

| **Improvement in FEW-C Safety scores ($R^2$=0.017)** | **Exp B/ Odds Ratio *(p)*** |
|---|---|
| Treatment group | 1.999 (0.078) |
| Diagnosis of Musculoskeletal conditions | 4.037 (0.001) |
| Diagnosis of Diabetes | 2.824 (0.040) |
| Alert and oriented | 5.733 (0.075) |
| Combativeness | 11.705 (0.008) |

A binary logistic regression analysis was conducted to predict improvement of the FEW-C safety scores using various covariates as predictors as determined by clinical judgment. $R^2$ of 0.017 which indicates 1.7% variability of the response data around its mean. Diagnosis of musculoskeletal conditions, diagnosis of diabetes, and presence of combativeness were predictors of improvement in FEW-C safety scores. Exp (B) value is the odds ratio. Treatment group assignment represents the mean increase of 1.999 in response for one unit of change in the

FEW-C independence scores while holding the other predictors in the model constant (p=0.078). Diagnoses of musculoskeletal conditions represents the mean increase of 4.037 in response to one unit of change in the FEW-C independence scores while holding the other predictors in the model constant. Diagnoses of diabetes represents the mean increase of 2.824 in response to one unit of change in the FEW-C independence scores while holding the other predictors in the model constant. Alert and oriented status of a patient represents the mean increase of 5.733 in response for one unit of change in the FEW-C independence scores while holding the other predictors in the model constant. Presence of combativeness in an individual represents the mean increase of 11.705 in response to one unit of change in the FEW-C independence scores while holding the other predictors in the model constant. In summary, since the odds ratio is greater than 1 for the treatment group, diagnosis of musculoskeletal conditions, diagnosis of diabetes, being alert and oriented and combative, there is a greater chance of improvement in FEW-C safety scores for participants with these characteristics.

Table 38: Baseline characteristics of the sample classified by the individuals whose FEW-C safety scores improved compared to those who had no improvement

| | Total Sample | Improvement | No Improvement | p-value |
|---|---|---|---|---|
| **Parameter** | | **Mean (Standard Deviation)** | | |
| Age * | 84.32 (9.122) | 84.94 (8.967) | 83.46 (9.336) | 0.328 |
| Length of stay in a nursing home at time of enrollment (in years) * | 1.99 (2.092) | 1.98 (2.046) | 2.00 (2.170) | 0.947 |
| Number of medications (N=148) | 13.36 (5.438) | 13.48 (5.422) | 13.19 (5.501) | 0.752 |
| | | **Frequency (Percentage)** | | |
| GENDER* | | | | |
| Female | 119 (79.3) | 69 (58.0) | 50 (42) | 1.000 |
| RACE* | | | | |
| White | 137 (91.3) | 79 (57.7) | 58 (42.3) | 1.000 |
| Black | 13 (8.7) | 8 (61.5) | 5 (38.5) | 1.000 |
| DIAGNOSIS relating to * | | | | |
| Heart | 96 (64.0) | 54 (56.3) | 42 (43.8) | 0.608 |
| Vascular system | 90 (60.0) | 52 (57.8) | 38 (42.2) | 1.000 |
| Hematopoietic system | 17 (11.3) | 9 (52.9) | 8 (47.1) | 0.795 |
| Respiratory system | 49 (32.7) | 30 (61.2) | 19 (38.8) | 0.601 |
| Eyes, Ears and Nose | 28 (18.7) | 15 (53.6) | 13 (46.4) | 0.673 |
| Upper Gastrointestinal system | 34 (22.7) | 19 (55.9) | 15 (44.1) | 0.844 |
| Lower Gastrointestinal system | 21 (14.0) | 11 (52.4) | 10 (47.6) | 0.637 |
| Liver system | 3 (2) | 2 (66.7) | 1 (33.3) | 1.000 |
| Renal system | 24 (16.0) | 16 (66.7) | 8 (33.3) | 0.377 |
| Genitourinary system | 32 (21.3) | 20 (62.5) | 12 (37.5) | 0.687 |
| Musculoskeletal/Integument | 89 (59.3) | 59 (66.3) | 30 (33.7) | 0.018 |
| Neurological system | 91 (60.7) | 51 (56.0) | 40 (44.0) | 0.613 |
| Endocrine, Metabolic, Breast | 38 (25.3) | 20 (52.6) | 18 (47.4) | 0.453 |
| Psychiatric | 94 (62.7) | 53 (56.4) | 41 (43.6) | 0.613 |
| Diabetes | 33 (22.0) | 23 (69.7) | 10 (30.3) | 0.162 |
| Other | 43 (28.7) | 22 (52.1) | 21 (48.8) | 0.361 |

| Table 38 (cont'd) | | | | |
|---|---|---|---|---|
| INCONTINENCE | | | | |
| Urine*** | 108 (72.0) | 65 (60.2) | 43 (39.8) | 1.000 |
| Feces*** | 97 (64.7) | 59 (60.8) | 38 (39.2) | 0.779 |
| Previous History of pressure ulcers ** | 24 (16.0) | 15 (62.5) | 9 (37.5) | 0.650 |
| History of hip surgery * | 16 (10.7) | 9 (56.3) | 7 (43.8) | 1.000 |

*N=150

**N=133

***N=111

Table 38 describes the baseline characteristics of the sample classified by the individuals whose FEW-C safety scores improved compared to those who had no improvement. There were no significant differences between groups as indicated by the p-values, of any of the baseline characteristics except for diagnosis relating to musculoskeletal/integumentary conditions as indicated by the p-value of 0.018.

Table 39: Comparison of different items in the FEW-C scores between the groups at pre-randomization

| Pre-Randomization FEW-C Independence | Treatment | | | | | Control | | | | | p-value |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 1 | 2 | 3 | 4 | 0 | 1 | 2 | 3 | 4 | |
| On/Off Breaks | 16 (28.6) | 19 (15.1) | 9 (7.1) | 8 (6.3) | 54 (42.9) | 35 (28.2) | 17 (13.7) | 6 (4.8) | 9 (7.3) | 57 (46.0) | 0.932 |
| WC Transfers | 16 (12.7) | 103 (81.7) | 0 (0) | 0 (0) | 7 (5.6) | 21 (16.9) | 93 (75.0) | 0 (0) | 0 (0) | 10 (8.1) | 0.428 |
| Reach forward | 8 (6.3) | 6 (4.8) | 14 (11.1) | 16 (12.7) | 82 (65.1) | 8 (6.5) | 9 (7.3) | 9 (7.3) | 5 (4) | 93 (75) | 0.087 |
| Reach Side to side | 8 (6.3) | 6 (4.8) | 13 (10.3) | 20 (15.9) | 79 (62.7) | 8 (6.5) | 12 (9.7) | 9 (7.3) | 5 (4) | 20 (72.6) | 0.014 |
| Personal Hygiene | 29 (23.0) | 45 (35.7) | 8 (6.3) | 8 (6.3) | 36 (28.6) | 20 (16.1) | 47 (37.9) | 11 (8.9) | 6 (4.8) | 40 (32.3) | 0.618 |
| Pre-randomization FEW-C Safety | Treatment | | | | | Control | | | | | p-value |
| | 0 | 1 | 2 | 3 | | 0 | 1 | 2 | 3 | | |
| On/Off Breaks | 22 (17.5) | 27 (21.4) | 19 (15.1) | 58 (48.0) | | 23 (18.5) | 28 (22.6) | 16 (12.9) | 57 (46.0) | | 0.962 |
| WC Transfers | 15 (11.9) | 12 (9.5) | 35 (27.8) | 64 (50.8) | | 19 (15.3) | 15 (12.1) | 23 (18.5) | 67 (54.0) | | 0.342 |
| Reach forward | 8 (6.3) | 5 (4.0) | 15 (11.9) | 98 (77.8) | | 6 (4.8) | 4 (3.2) | 14 (11.3) | 100 (8.6) | | 0.933 |
| Reach Side to side | 9 (7.1) | 3 (2.4) | 15 (11.9) | 99 (78.6) | | 7 (5.6) | 2 (1.6) | 16 (12.9) | 99 (79.8) | | 0.926 |
| Personal Hygiene | 22 (17.5) | 15 (11.9) | 26 (20.6) | 63 (50.0) | | 19 (15.3) | 16 (12.9) | 27 (21.8) | 62 (50.0) | | 0.967 |

Table 39 describes the distribution of the sample size by treatment and control group for each of the items in the FEW-C tool at pre-randomization. FEW-C safety scores are from zero to three because there were no residents with the score of 4. Non-significant differences as indicated by the p-value have been reported for all the items except significant differences indicated for one item in the pre-randomization phase, reach forward (0.014).

Table 40 describes the distribution of the sample size by treatment and control group for each of the items in the FEW-C tool at endpoint. Non-significant differences as indicated by the p-value have been reported for all the items except, trending significant differences indicated for personal hygiene (0.115).

Table 40: Comparison of different items in the FEW-C scores between the groups at endpoint

| **Endpoint FEW-C Independence** | Treatment n (%) | | | | | Control n (%) | | | | | p-value |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 | 1 | 2 | 3 | 4 | 0 | 1 | 2 | 3 | 4 | |
| **On/Off Breaks** | 21 (25) | 12 (14.3) | 5 (6.0) | 7 (8.3) | 39 (46.4) | 21 (27.6) | 10 (13.2) | 5 (6.6) | 4 (5.3) | 36 (47.4) | 0.949 |
| **WC Transfers** | 9 (10.7) | 60 (71.4) | 1 (1.2) | 1 (1.2) | 13 (15.5) | 10 (13.2) | 58 (76.3) | 1 (1.3) | 1 (1.3) | 6 (7.9) | 0.686 |
| **Reach forward** | 4 (4.8) | 3 (3.6) | 3 (3.6) | 12 (14.3) | 62 (73.8) | 5 (6.6) | 4 (5.3) | 4 (5.3) | 7 (9.2) | 56 (73.7) | 0.805 |
| **Reach Side to side** | 5 (6.0) | 5 (6.0) | 4 (4.8) | 14 (16.7) | 56 (66.7) | 5 (6.6) | 4 (5.3) | 6 (7.9) | 6 (7.9) | 55 (72.4) | 0.504 |
| **Personal Hygiene** | 12 (14.3) | 25 (29.8) | 4 (4.8) | 8 (9.5) | 35 (41.7) | 15 (19.7) | 20 (26.3) | 8 (10.5) | 1 (1.3) | 32 (42.1) | 0.115 |
| **Endpoint FEW-C Safety** | Treatment | | | | | Control | | | | | p-value |
| | 0 | 1 | 2 | 3 | | 0 | 1 | 2 | 3 | | |
| **On/Off Breaks** | 13 (15.5) | 10 (11.9) | 16 (19.0) | 45 (53.6) | | 19 (25.0) | 12 (15.8) | 12 (15.8) | 33 (43.4) | | 0.343 |
| **WC Transfers** | 13 (15.5) | 14 (16.7) | 14 (16.7) | 43 (51.2) | | 13 (17.1) | 12 (15.8) | 14 (18.4) | 37 (48.7) | | 0.977 |
| **Reach forward** | 3 (3.6) | 2 (2.4) | 4 (4.8) | 75 (89.3) | | 5 (6.6) | 2 (2.6) | 7 (9.2) | 62 (81.6) | | 0.540 |
| **Reach Side to side** | 3 (3.6) | 3 (3.6) | 7 (8.3) | 71 (84.5) | | 4 (5.3) | 2 (2.6) | 7 (9.2) | 63 (82.9) | | 0.936 |
| **Personal Hygiene** | 8 (9.5) | 14 (16.7) | 17 (20.2) | 45 (53.6) | | 11 (14.5) | 7 (9.2) | 17 (22.4) | 41 (53.8) | | 0.458 |

#### 5.3.6.2 NHLSD

Table 41 describes results of the Chi square analysis of the NHLSD scores by randomization group and individuals who showed improvement in the NHLSD scores compared to those who did not experience improvement. Individuals' were grouped as having improvement if the difference between their endpoint and pre-randomization NHLSD scores was $\geq 0$. The p-value of 0.081 indicated that there was a trending significant difference between individuals who had an improvement in NHLSD scores compared to individuals who did not by treatment group assignment. This result indicates that individuals in the treatment group had greater movement in their wheelchairs than the individuals in the control group, though not statistically significant.

Table 41: Representation of NHLSD scores between treatment groups of individuals who had an improvement in their scores and those who did not

| | Treatment n (%) | Control n (%) | Total n (%) | p-value |
|---|---|---|---|---|
| No Improvement | 33 (39.29) | 41 (53.95) | 74 (46.25) | 0.081 |
| Improvement | 51 (60.72) | 35 (46.05) | 86 (57.33) | |
| Total | 84 (100) | 76 (100) | 160 (100) | |

A binary logistic regression analysis (Table 42) was conducted to predict improvement of the NHLSD scores using various covariates as predictors as determined by clinical judgment. $R^2$ of 0.038 indicates 3.8% variability of the response data around its mean. Treatment group was a predictor of improvement in NHLSD scores. Exp (B) value was the odds ratio. Treatment group assignment represents the mean increase of 2.142 in response for one unit of change in the NHLSD scores while holding the other predictors in the model constant. Since the odds ratio is greater than 1 for the treatment group, it is indicative of higher odds of the NHLSD score

improving. The odds ratio for Nursing Home Site #2 is less than 1 which is indicative of lower odds of improvement of the NHLSD scores.

Table 42: Regression model for covariates affecting the improvement scores in the NHLSD

| Improvement in NHLSD scores ($R^2$=0.038) | Exp (B) / Odds Ratio *(p)* |
|---|---|
| Treatment group | 2.142 (0.029) |
| Nursing home Site # 2 | 0.181 (0.127) |

Table 43 describes the distribution of the sample size by treatment and control group for each of the items in the NHLSD tool at pre-randomization. A significance indicated by a p-value of 0.039 is present for “movement outside the unit throughout the facility” between groups. Non-significant differences have been reported for the other items. This result implies that at pre-randomization, subjects who received individually configured lightweight manual wheelchairs moved outside their respective nursing home units throughout the facility compared to subjects who received nursing home provided wheelchairs with relative adjustments.

Table 43: Comparison of different items in the NHLSD between the groups at pre-randomization

| **Pre Rand NHLSD Items** | Treatment | | | | | | Control | | | | | | p-value |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 n (%) | 1 | 2 | 3 | 4 | 5 | 0 | 1 | 2 | 3 | 4 | 5 | |
| **Movement around own room** | 4 (3.1) | 1 (0.8) | 0 (0.0) | 3 (2.4) | 43 (33.9) | 76 (59.8) | 6 (4.8) | 1 (0.8) | 2 (1.6) | 6 (4.8) | 5 (28.2) | 4 (59.7) | 0.519 |
| **Movement outside the room within the unit** | 6 (4.7) | 2 (1.6) | 2 (1.6) | 5 (3.9) | 51 (40.2) | 61 (48.0) | 2 (1.6) | 0 (0) | 2 (1.6) | 0 (8.1) | 43 (34.7) | 7 (54.0) | 0.253 |
| **Movement outside the unit throughout the facility** | 40 (31.5) | 33 (26) | 5 (3.9) | 14 (11) | 19 (15) | 16 (12.6) | 29 (23.4) | 36 (29) | 15 (12.1) | 22 (17.7) | 1 (8.9) | 1 (8.9) | 0.039 |
| **Movement outside the facility** | 97 (76.4) | 23 (18.1) | 4 (3.1) | 2 (1.6) | 0 (0) | 1 (0.8) | 95 (76.6) | 24 (19.4) | 2 (1.6) | 3 (2.4) | 0 (0) | 0 (0) | 0.759 |

Table 44: Comparison of different items in the NHLSD independence components between the groups at pre-randomization

| NHLSD Items (Independence components) | Treatment | | Control | | p-value |
|---|---|---|---|---|---|
| | Yes | No | Yes | No | |
| Independence during moving around own room | 69 (56.1) | 54 (43.9) | 65 (55.1) | 53 (44.9) | 0.897 |
| Independence during moving outside the room within the unit | 60 (49.6) | 61 (50.4) | 58 (47.5) | 64 (52.5) | 0.798 |
| Independence during moving outside the unit throughout the facility | 24 (27.6) | 63 (72.4) | 20 (21.1) | 75 (78.9) | 0.386 |
| Independence during moving outside the facility | 6 (20) | 24 (80) | 4 (13.8) | 25 (86.2) | 0.731 |

Table 44 describes the distribution of the sample size by treatment and control group for each of the independence components of each item in the NHLSD tool at pre-randomization. Non-significant differences have been reported in the independence component for all items. This implies that at pre-randomization, subjects with individually-configured lightweight manual wheelchairs did not perform any better or worse with respect to the independence components of the NHLSD scores in comparison to individuals who had nursing home-provided manual wheelchairs with related adjustments. Tables 43 & 44 together indicate that even though subjects with individually configured lightweight manual wheelchairs moved around more outside of their nursing home units throughout the facility in comparison to subjects who had nursing home-provided wheelchairs with related adjustments, there wasn't a difference in the independence of wheelchair propulsion between groups.

Table 45 describes the distribution of the sample size by treatment and control group for each of the items in the NHLSD tool at endpoint. Non-significant differences as indicated by the p-value have been reported for all the items. This result implies that at endpoint, subjects who received individually configured lightweight manual wheelchairs did not have better mobility using their wheelchairs compared to subjects who received nursing home-provided wheelchairs with relative adjustments. This can be explained as a result of various reasons associated with aging and that could not be controlled by wheelchair-related characteristics. The decline in the health of the patients was not accounted for. This played an important role in the independence levels of the individuals who reached endpoint. New diagnoses that may have developed between equipment issue and endpoint weren't accounted for which could have played an important role in the wheelchair propulsion of the individual.

Table 45: Comparison of different items in the NHLSD scores between the groups at endpoint

| Endpoint NHLSD Items | Treatment | | | | | | Control | | | | | | p-value |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | 0 n (%) | 1 | 2 | 3 | 4 | 5 | 0 | 1 | 2 | 3 | 4 | 5 | |
| Movement around own room | 2 (2.4) | 0 (0) | 0 (0) | 4 (4.8) | 26 (31) | 52 (61.9) | 1 (1.3) | 2 (2.6) | 1 (1.3) | 2 (2.6) | 23 (30.3) | 47 (61.8) | 0.543 |
| Movement outside the room within the unit | 2 (2.4) | 1 (1.2) | 1 (1.2) | 2 (2.4) | 35 (41.7) | 43 (51.2) | 4 (5.3) | 1 (1.3) | 1 (1.3) | 5 (6.6) | 29 (38.2) | 36 (47.4) | 0.740 |
| Movement outside the unit throughout the facility | 18 (21.4) | 20 (23.8) | 10 (11.9) | 14 (16.7) | 16 (19.0) | 6 (7.1) | 20 (26.3) | 23 (30.3) | 8 (10.5) | 9 (11.8) | 10 (13.2) | 6 (7.9) | 0.759 |
| Movement outside the facility | 63 (75.0) | 17 (20.2) | 0 (0) | 2 (2.4) | 2 (2.4) | 0 (0) | 63 (82.9) | 8 (10.5) | 2 (2.6) | 2 (2.6) | 1 (1.3) | 0 (0) | 0.269 |

Table 46: Comparison of different items in the NHLSD independence components between the groups at endpoint

| NHLSD Items (Independence Components) | Treatment | | Control | | p-value |
|---|---|---|---|---|---|
| | Yes | No | Yes | No | |
| Independence during moving around own room | 47 (57.3) | 35 (42.7) | 38 (50.7) | 37 (49.3) | 0.427 |
| Independence during moving outside the room within the unit | 43 (52.4) | 39 (47.6) | 28 (38.9) | 44 (61.1) | 0.107 |
| Independence during moving outside the unit throughout the facility | 18 (27.3) | 48 (72.7) | 14 (25) | 42 (75) | 0.838 |
| Independence during moving outside the facility | 2 (9.5) | 19 (90.5) | 1 (7.7) | 12 (92.3) | 1.000 |

Table 46 describes the distribution of the sample size by treatment and control group for each of the independence components of each item in the NHLSD tool at endpoint. Non-significant differences as indicated by the p- value have been reported in the independence component for all items. This implies that at endpoint, subjects with individually-configured lightweight manual wheelchairs did not perform any better or worse with respect to the independence components of the NHLSD scores in comparison to individuals who had nursing home-provided manual wheelchairs with related adjustments. The subjects who received an individually configured manual wheelchair would be expected to have performed better due to the ease of propulsion associated with the lightweight manual wheelchairs in addition to the ease of propulsion for the wheelchair user and possibly enhanced comfort and motivation from getting a new wheelchair.

Table 47: Baseline characteristics of the sample classified by individuals whose NHLSD scores improved compared to those with no improvement

| | Total Sample | Improvement | No Improvement | p-value |
|---|---|---|---|---|
| **Parameter** | | **Mean (Standard Deviation)** | | |
| Age | 84.28 (8.970) | 85 (9.37) | 83.43 (8.46) | 0.272 |
| Length of stay in a nursing home at time of enrollment (in years) | 1.93 (2.07) | 1.73 (1.93) | 2.16 (2.22) | 0.192 |
| Number of medications (n=157) | 13.57 (5.550) | 13.65 (5.75) | 13.48 (5.35) | 0.844 |
| | **Frequency (Percentage)** | | | |
| GENDER | | | | |
| Female | 128 (80) | 71 (55.5) | 57 (44.5) | 0.431 |
| RACE | | | | |
| White | 145 (90.6) | 80 (55.2) | 65 (44.8) | 0.289 |
| Black | 15 (9.4) | 6 (40) | 9 (60) | 0.289 |
| DIAGNOSIS relating to | | | | |
| Heart | 103 (64.4) | 56 (54.4) | 47 (45.6) | 0.869 |
| Vascular system | 93 (58.1) | 52 (55.9) | 41 (44.1) | 0.525 |
| Hematopoietic system | 20 (12.5) | 9 (45) | 11 (55) | 0.475 |
| Respiratory system | 52 (32.5) | 27 (51.9) | 25 (48.1) | 0.866 |
| Eyes, Ears and Nose | 30 (18.8) | 15 (50) | 15 (50) | 0.688 |
| Upper Gastrointestinal system | 34 (21.3) | 17 (50) | 17 (50) | 0.700 |
| Lower Gastrointestinal system | 21 (13.1) | 13 (61.9) | 8 (38.1) | 0.487 |
| Liver system | 3 (1.9) | 0 (0) | 3 (100) | 0.097 |
| Renal system | 26 (16.3) | 11 (42.3) | 15 (57.7) | 0.282 |
| Genitourinary system | 34 (21.3) | 20 (58.8) | 14 (41.2) | 0.564 |
| Musculoskeletal/Integument | 96 (60) | 47 (49) | 49 (51) | 0.148 |
| Neurological system | 97 (60.6) | 49 (50.5) | 48 (49.5) | 0.334 |
| Endocrine, Metabolic, Breast | 42 (26.3) | 22 (52.4) | 20 (47.6) | 0.859 |
| Psychiatric | 99 (61.9) | 54 (54.5) | 45 (45.5) | 0.871 |
| Diabetes | 35 (21.9) | 22 (62.9) | 13 (37.1) | 0.253 |
| Other | 46 (28.7) | 28 (60.9) | 18 (39.1) | 0.295 |

| Table 47 (cont'd) | | | | | |
|---|---|---|---|---|---|
| INCONTINENCE | | | | | |
| | Urine N=118 | 115 (71.9) | 61 (53) | 54 (47) | 1.000 |
| | Feces N=118 | 104 (65) | 56 (53.8) | 48 (46.2) | 1.000 |
| Previous History of pressure ulcers N=141 | | 26 (16.3) | 17 (65.4) | 9 (34.6) | 0.196 |
| History of hip surgery | | 18 (11.3) | 10 (55.6) | 8 (44.4) | 1.000 |

Table 47 describes the baseline characteristics of the sample classified by the individuals whose NHLSD scores improved compared to those who had no improvement. There were no significant differences between groups as indicated by the p-values, of any of the baseline characteristics.

#### 5.3.6.3 WST

Table 48 describes results of the Chi square analysis of the WST skills scores by treatment group and individuals who had an improvement in the WST skills scores compared to those who did not show improvement. Individuals' were grouped as having improvement if the difference between their endpoint and day 14 WST Independence and Safety scores was $\geq 0$. The p-value of 0.083 indicated that there was a borderline significant difference between individuals who had improvement in WST skill scores compared to individuals who did not have improvement by treatment group assignment. This implies that subjects with individually configured lightweight manual wheelchairs had more improvement in wheelchair propulsion skills compared to individuals who received nursing home provided wheelchairs with related adjustments, though not significantly different.

Table 48: Representation of WST Skills scores between treatment groups of individuals who had an improvement in their scores and those who did not

| | Treatment n (%) | Control n (%) | Total n (%) | p-value |
|---|---|---|---|---|
| No Improvement | 13 (16.67) | 21 (28.77) | 34 (22.51) | 0.083 |
| Improvement | 65 (83.33) | 52 (71.23) | 117 (77.48) | |
| Total | 78 (100) | 73 (100) | 151 (100) | |

Table 49: Regression model for covariates affecting the improvement scores in the WST Skills

| Improvement in WST Skill scores ($R^2$=0.014) | Exp B/Odds Ratio *(p)* |
|---|---|
| Treatment group | 1.919 (0.146) |
| Diagnosis of Upper gastrointestinal system | 5.867 (0.032) |
| Use of WC for Ambulation | 13.337 (0.087) |
| Combativeness | 0.236 (0.035) |

A binary logistic regression analysis was conducted to predict improvement of the FEW-C independence scores using various covariates as predictors as determined by clinical judgment. $R^2$ of 0.014 indicates 1.4% variability of the response data around its mean. Diagnosis of upper gastrointestinal system issues and combativeness were predictors of improvement in WST skill scores. Treatment group and use of wheelchair for ambulation were borderline predictors of improvement in WST skill scores. Exp (B) value is the odds ratio. Since the odds ratio is greater than 1 for the treatment group, combativeness and being alert and oriented, this is indicative of higher odds for improvement of WST skill scores. Treatment group represents the mean increase of 1.919 in the response for one unit of change in the WST skill scores while holding the other predictors in the model constant. Diagnosis of upper gastrointestinal system issues represents the mean increase of 5.867 in the response for one unit of change in the WST skill scores while holding the other predictors in the model constant. Use of a wheelchair for as a primary means for ambulation vs. use of a walker or cane represents the mean increase of 13.337 in the response for one unit of change in the WST skill scores while holding the other predictors in the model constant. Presence of combativeness represents a mean increase of 0.236 in the response for one unit of change in the WST skill scores while holding the other predictors in the model constant. The odds ratio for combativeness is less than 1 which is indicative of lower odds of improvement in the WST skills scores. Since the odds ratio is greater than 1 for the treatment group, diagnosis

of upper gastrointestinal system issues, and use of wheelchair for ambulation, this is indicative of higher odds for improvement in WST skill scores.

Table 50 describes the baseline characteristics of the sample classified by the individuals whose WST skill scores improved compared to those who had no improvement. There were no significant differences between groups as indicated by the p-values, of any of the baseline characteristics.

Table 50: Baseline characteristics of the sample classified by the individuals whose WST skill scores improved compared to those who had no improvement

| | **Total Sample** | **Improvement** | **No Improvement** | **p-value** |
|---|---|---|---|---|
| **Parameter** | **Mean (Standard Deviation)** | | | |
| Age * | 84.32 (9.092) | 83.94 (9.317) | 85.65 (8.264) | 0.337 |
| Length of stay in a nursing home at time of enrollment (in years) * | 1.97 (2.091) | 1.91 (2.076) | 2.21 (2.157) | 0.464 |
| Number of medications (N=148) | 13.39 (5.428) | 13.36 (5.434) | 13.47 (5.490) | 0.917 |
| | **Frequency (Percentage)** | | | |
| GENDER* | | | | |
| Female | 120 (79.5) | 91 (75.8) | 29 (24.2) | 0.470 |
| RACE* | | | | |
| White | 138 (91.4) | 107 (77.5) | 31 (22.5) | 1.000 |
| Black | 13 (8.6) | 10 (76.9) | 3 (23.1) | 1.000 |
| DIAGNOSIS relating to * | | | | |
| Heart | 96 (63.6) | 77 (80.2) | 19 (19.8) | 0.316 |
| Vascular system | 90 (59.6) | 72 (80) | 18 (20) | 0.429 |
| Hematopoietic system | 17 (11.3) | 16 (94.1) | 1 (5.9) | 0.121 |
| Respiratory system | 49 (32.5) | 38 (77.6) | 11 (22.4) | 1.000 |
| Eyes, Ears and Nose | 28 (18.5) | 24 (85.7) | 4 (14.3) | 0.321 |
| Upper Gastrointestinal system | 34 (22.5) | 30 (88.2) | 4 (11.8) | 0.105 |
| Lower Gastrointestinal system | 21 (13.9) | 18 (85.7) | 3 (14.3) | 0.410 |
| Liver system | 3 (2) | 3 (100) | 0 (0) | 1.000 |
| Renal system | 24 (15.9) | 19 (79.2) | 5 (20.8) | 1.000 |
| Genitourinary system | 32 (21.2) | 25 (78.1) | 7 (21.9) | 1.000 |
| Musculoskeletal/Integument | 89 (58.9) | 71 (79.8) | 18 (20.2) | 0.435 |
| Neurological system | 92 (60.9) | 70 (76.1) | 22 (23.9) | 0.692 |
| Endocrine, Metabolic, Breast | 38 (25.2) | 31 (81.6) | 7 (18.4) | 0.654 |
| Psychiatric | 94 (62.3) | 73 (77.7) | 21 (22.3) | 1.000 |
| Diabetes | 33 (21.9) | 28 (84.8) | 5 (15.2) | 0.347 |
| Other | 43 (28.5) | 35 (81.4) | 8 (18.6) | 0.524 |

| Table 50 (cont'd) | | | | |
|---|---|---|---|---|
| INCONTINENCE | | | | |
| Urine*** | 109 (72.2) | 83 (76.1) | 26 (23.9) | 1.000 |
| Feces*** | 98 (64.9) | 76 (77.6) | 22 (22.4) | 0.735 |
| Previous History of pressure ulcers ** | 24 (15.9) | 18 (75) | 6 (25) | 0.794 |
| History of hip surgery * | 16 (10.6) | 13 (81.3) | 3 (18.8) | 1.000 |

*N=151

**N=134

***N=112

Table 51: Representation of WST Safety scores between treatment groups of individuals who had an improvement in their scores and those who did not

| | Treatment n (%) | Control n (%) | Total n (%) | p-value |
|---|---|---|---|---|
| No Improvement | 21 (42) | 29 (58) | 50 (33.11) | 0.120 |
| Improvement | 57 (56.4) | 44 (43.6) | 101 (66.88) | |
| Total | 78 (51.7) | 73 (48.3) | 151 | |

Table 51 describes results of the Chi square analysis of the WST safety scores by treatment group and individuals who had an improvement in the WST skills scores compared to those who did not have an improvement. The p-value of 0.120 indicated that there was no significant difference between individuals who had an improvement in WST safety scores compared to individuals who did not have an improvement in WST safety scores by treatment group assignment.

Table 52: Regression model for covariates affecting the improvement scores in WST Safety

| Improvement in WST Safety scores ($R^2$=0.014) | Exp B/ Odds Ratio *(p)* |
|---|---|
| Treatment group | 1.852 (0.136) |
| BMI | 1.112 (0.048) |
| Length of Stay in the nursing home | 0.744 (0.003) |
| Diagnosis of Musculoskeletal conditions | 2.862 (0.016) |
| Diagnosis of Psychiatric Illnesses | 2.060 (0.088) |
| Nursing home 7 | 0.083 (0.079) |
| Nursing home 18 | 0.212 (0.057) |

A binary logistic regression analysis was conducted to predict improvement of the WST safety scores using various covariates as predictors as determined by clinical judgment. $R^2$ of 0.014 indicates 1.4% variability of the response data around its mean. Treatment group was a borderline predictor of improvement in WST safety scores. Exp (B) value is the odds ratio. Treatment group represents a mean increase of 1.852 in the response for one unit of change in

the WST safety scores while holding the other predictors in the model constant. Body mass index represents a mean increase of 1.112 in the response for one unit of change in the WST safety scores while holding the other predictors in the model constant. Length of stay in a nursing home represents a mean increase of 0.744 in the response for one unit of change in the WST safety scores while holding the other predictors in the model constant. Diagnoses of musculoskeletal conditions represents the mean increase of 2.862 in the response for one unit of change in the WST safety scores while holding the other predictors in the model constant. Diagnoses of psychiatric illnesses represents the mean increase of 2.060 in the response for one unit of change in the WST safety scores while holding the other predictors in the model constant. For Nursing Home Site #7 a mean increase of 0.083 in the response for one unit of change in the WST safety scores was noted while holding the other predictors in the model constant. Nursing Home Site #18 showed a mean increase of 0.212 in the response for one unit of change in the WST safety scores while holding the other predictors in the model constant. Since the odds ratio is greater than 1 for treatment group, BMI, diagnosis of musculoskeletal conditions and diagnosis of psychiatric illnesses, it is indicative of higher odds for improvement in the WST safety scores. The odds ratio for length of stay in the nursing home, Nursing Home # 7 and Nursing Home # 18, is less than 1 which is indicative of lower odds of improvement of the WST safety scores.

Table 53: Baseline characteristics of the sample classified by the individuals whose WST safety scores improved compared to those who had no improvement

| | Total Sample | Improvement | No Improvement | p-value |
|---|---|---|---|---|
| **Parameter** | | **Mean (Standard Deviation)** | | |
| Age * | 84.32 (9.092) | 84.41 (8.596) | 84.16 (10.110) | 0.876 |
| Length of stay in a nursing home at time of enrollment (in years) * | 1.97 (2.091) | 1.82 (1.982) | 2.28 (2.286) | 0.206 |
| Number of medications (N=148) | 13.39 (5.428) | 13.43 (4.990) | 13.29 (6.275) | 0.876 |
| | | **Frequency (Percentage)** | | |
| GENDER* | | | | |
| Female | 120 (79.5) | 79 (65.8) | 41 (34.2) | 0.672 |
| RACE* | | | | |
| White | 138 (91.4) | 91 (65.9) | 47 (34.1) | 0.546 |
| Black | 13 (8.6) | 10 (76.9) | 3 (23.1) | 0.546 |
| DIAGNOSIS relating to * | | | | |
| Heart | 96 (63.6) | 68 (70.8) | 28 (29.2) | 0.209 |
| Vascular system | 90 (59.6) | 64 (71.1) | 26 (28.9) | 0.218 |
| Hematopoietic system | 17 (11.3) | 11 (64.7) | 6 (35.3) | 1.000 |
| Respiratory system | 49 (32.5) | 36 (73.5) | 13 (26.5) | 0.271 |
| Eyes, Ears and Nose | 28 (18.5) | 19 (67.9) | 9 (32.1) | 1.000 |
| Upper Gastrointestinal system | 34 (22.5) | 26 (76.5) | 8 (23.5) | 0.217 |
| Lower Gastrointestinal system | 21 (13.9) | 17 (81) | 4 (19) | 0.211 |
| Liver system | 3 (2) | 2 (66.7) | 1 (33.3) | 1.000 |
| Renal system | 24 (15.9) | 18 (75) | 6 (25) | 0.479 |
| Genitourinary system | 32 (21.2) | 26 (81.3) | 6 (18.8) | 0.059 |
| Musculoskeletal/Integument | 89 (58.9) | 65 (73) | 24 (27) | 0.078 |
| Neurological system | 92 (60.9) | 62 (67.4) | 30 (32.6) | 1.000 |
| Endocrine, Metabolic, Breast | 38 (25.2) | 25 (65.8) | 13 (34.2) | 1.000 |
| Psychiatric | 94 (62.3) | 68 (72.3) | 26 (27.7) | 0.076 |
| Diabetes | 33 (21.9) | 21 (63.6) | 12 (36.4) | 0.679 |
| Other | 43 (28.5) | 25 (58.1) | 18 (41.9) | 0.181 |

| Table 53 (cont'd) | | | | |
|---|---|---|---|---|
| INCONTINENCE | | | | |
| Urine*** | 109 (72.2) | 73 (67) | 36 (33) | 0.265 |
| Feces*** | 98 (64.9) | 64 (65.3) | 34 (34.7) | 0.769 |
| Previous History of pressure ulcers ** | 24 (15.9) | 13 (54.2) | 11 (45.8) | 0.236 |
| History of hip surgery * | 16 (10.6) | 10 (62.5) | 6 (37.5) | 0.780 |

*N=151

**N=134

***N=112

Table 53 describes the baseline characteristics of the sample classified by the individuals whose WST safety scores improved compared to those who had no improvement. There were no significant differences between groups as indicated by the p-values, of any of the baseline characteristics.

Table 54: Comparison of different items in the WST scores between the groups at post-randomization

| WST Independence | | | | | | | |
|---|---|---|---|---|---|---|---|
| Post-Randomization WST scores | Treatment | | | Control | | | p-value |
| | Pass | Fail | Not tested | Pass | Fail | Not tested | |
| Rolls forward 10 m | 93 (76.9) | 21 (17.4) | 7 (5.8) | 80 (70.2) | 28 (24.6) | 6 (5.3) | 0.397 |
| Rolls backwards 5 m | 82 (67.8) | 30 (24.8) | 9 (7.4) | 66 (57.9) | 39 (34.2) | 9 (7.9) | 0.260 |
| Turns 90 while moving forwards | 85 (70.2) | 28 (23.1) | 8 (6.6) | 66 (57.9) | 39 (34.2) | 9 (7.9) | 0.132 |
| Turns 90 while moving backwards | 75 (62.0) | 37 (30.6) | 9 (7.4) | 59 (51.8) | 46 (40.4) | 9 (7.9) | 0.262 |
| Turns 180 in place | 70 (57.9) | 42 (34.7) | 9 (7.4) | 54 (46.4) | 50 (43.9) | 10 (8.8) | 0.272 |
| Gets through hinged doors in both directions | 52 (43.0) | 59 (48.8) | 10 (8.3) | 44 (38.6) | 60 (52.6) | 10 (8.8) | 0.792 |
| WST Safety | | | | | | | |
| Rolls forward 10 m | 89 (73.6) | 25 (20.7) | 7 (5.8) | 75 (65.8) | 33 (28.9) | 6 (5.3) | 0.338 |
| Rolls backwards 5 m | 52 (43.0) | 60 (49.6) | 9 (7.4) | 47 (41.2) | 58 (50.9) | 9 (7.9) | 0.962 |

Table 54 describes the distribution of the sample size by treatment and control group for each of the items in the WST scores at post-randomization. Non-significant differences as indicated by the p-value have been reported for all items. The number/percentage of treatment group individuals that passed every item of the WST was greater than the number/percentage of

control group individuals passing every item; that is the treatment group overall had better results for skills and safety at post-randomization.

Table 55: Comparison of different items in the WST scores between the groups at endpoint

| WST Independence | | | | | | | |
|---|---|---|---|---|---|---|---|
| Endpoint WST scores | Treatment | | | Control | | | p-value |
| | Pass | Fail | Not tested | Pass | Fail | Not tested | |
| Rolls forward 10 m | 67 (79.8) | 13 (15.5) | 4 (4.8) | 53 (69.7) | 20 (26.3) | 3 (3.9) | 0.238 |
| Rolls backwards 5 m | 61 (72.6) | 19 (22.6) | 4 (4.8) | 47 (61.8) | 24 (31.6) | 5 (6.6) | 0.348 |
| Turns 90 while moving forwards | 58 (69.0) | 21 (25.0) | 5 (6.0) | 46 (60.5) | 24 (31.6) | 6 (7.9) | 0.528 |
| Turns 90 while moving backwards | 54 (64.3) | 23 (27.4) | 7 (8.3) | 45 (59.2) | 25 (32.9) | 6 (7.9) | 0.748 |
| Turns 180 in place | 52 (61.9) | 27 (32.1) | 5 (6.0) | 42 (55.3) | 28 (36.8) | 6 (7.9) | 0.679 |
| Gets through hinged doors in both directions | 41 (48.8) | 36 (42.9) | 7 (8.3) | 29 (38.2) | 40 (52.6) | 7 (9.2) | 0.392 |
| WST Safety | | | | | | | |
| Rolls forward 10 m | 64 (76.2) | 16 (19.0) | 4 (4.8) | 51 (67.1) | 22 (28.9) | 3 (3.9) | 0.339 |
| Rolls backwards 5 m | 40 (47.6) | 40 (47.6) | 4 (4.8) | 33 (43.4) | 38 (50.0) | 5 (6.6) | 0.805 |

Table 55 describes the distribution of the sample size by treatment and control group for each of the items in the WST scores at post-randomization. Non-significant differences as indicated by the p-value have been reported for all the items. The number/percentage of treatment group individuals that passed every item of the WST was greater than the number/percentage of control group individuals passing every item; that is the treatment group overall had better results for skills and safety at endpoint.

## 5.4 DISCUSSION

Functional improvement was noted in nursing home residents provided with individually-configured wheelchairs and skin protection cushions compared those to subjects provided skin protection cushions. Nursing home residents using individually-configured wheelchairs had improved functional abilities with respect to using wheelchair brakes, ability to transfer in and out of the wheelchairs, ability to reach side to side and forward in comparison to subjects using nursing home provided wheelchairs. This was a secondary analysis of a study aimed at preventing pressure ulcers in nursing home residents using lightweight manual wheelchairs. This study is the first clinical trial to use the FEW-C as an outcome measure in the nursing home population. Scores changed between pre-randomization and the endpoint in FEW-C independence and safety; which implies that individuals were more independent and safe while they transferred in and out of their wheelchairs, used their wheelchair brakes, and in leaning side to side and forward. Even though changes were observed in both the treatment and control groups, the treatment group showed greater changes than the control group which could be attributable to better wheelchair fit.

The analysis demonstrated close to significant differences in the NHLSD scores collected at pre-randomization and at the completion of the study. This observation implies that the individually-configured wheelchairs and skin protection cushions may have positively influenced the mobility patterns compared to the provision of a skin protection cushions with related adjustment to facility wheelchairs.

Differences between the independence components of the change in FEW-C scores between pre- randomization and study completion were also close to significant (see Table 31).

Better FEW-C scores suggest that the individuals who received custom fit light-weight manual wheelchairs may have had better and more independent functioning abilities six months after provision of equipment compared to subjects who received nursing home provided wheelchairs. In the subjects who were followed for 6 months there was a steep rise in the curve between pre-randomization day and Day 14 indicating learning after which learning plateaued between the Day 14 and the end of the study period. Wheelchair training provided on the day of equipment provision and on days 7 and 14 after equipment was given may have led to the acquisition of wheelchair skills early in the follow-up period. After day 14, training was revised if needed only on completion of the study. The FEW-C safety component was different between the pre-randomization vs. endpoint. Subjects in both groups who completed the six-month follow-up showed improvement in safe functioning in their wheelchair after Day 14. The delay suggests a longer period of adaptation is needed.

Presence of a psychiatric illness and an alert and oriented state of the subjects were found to be predictors of the FEW-C independence scores (see Table 33). Subjects who are alert and oriented may be able to assimilate and process information better than disoriented individuals.

A musculoskeletal condition diagnosis or presence of combativeness were predictors of improvement in the FEW-C safety score (see Table 37). These could be the potential factors affecting safety because they lead to increased immobility causing the person to be in less hazardous situations with being mobile while using their wheelchair.

Even though there are no comparable studies that have followed wheelchair users over 6 months, one study has investigated the effect of different wheelchair parts on the functional ability of wheelchair users. Koontz et al. (2010) investigated the differences in various axle positions in a manual wheelchair that affected functioning and maneuverability outcomes. The

results suggested that individuals have different needs that should be considered while prescribing a wheelchair (Koontz, Brindle, Kankipati, Feathers, & Cooper, 2010). Koontz et al. (2010) discussed the use of different types of wheelchairs like manual, power assist chair and power chairs with respect to the structure of the environment to help enhance independence (Koontz et al., 2010). They concluded that ultra-light wheelchairs require the least amount of space for maneuverability due to the minimal turning radius associated with moving the chair in comparison to power assist and power wheelchairs (Koontz et al., 2010).

The results of the WST imply that there were no differences between groups in propelling the wheelchair. A near significant difference was observed between the NHLSD scores at pre-randomization and endpoint ($p=0.09$) (see Table 44 & 45). This may be due to the physical and psychological deconditioning effects of aging. No differences observed in the WST scores between the two groups were not different could be due to various reasons. The characteristics of the geriatric population and various debilitating conditions, along with the resistance and difficulty associated with learning new tasks could be the main reasons between the 2 groups. Garber et al. (2002) studied the association between level of disability and increased wheelchair use. Improvements were noted in disability and reduced dependence on a wheelchair with appropriate wheelchair modifications, training and use (Garber, Bunzel, & Monga, 2002). Garber et al. (2002) concluded that appropriate wheelchair training, modifications and use help reduce dependence levels thus reducing disability levels in wheelchair users (Garber et al., 2002). Another reason that there may not have been differences between the two groups in functioning levels and maneuverability levels could be the limited amount of opportunity for residents to independently propel themselves. It was commonly observed that it was easier for the nursing home staff to push the residents in the wheelchairs rather than have them propel their

wheelchairs independently. It may be more efficient for the nursing home staff to push the residents around in their wheelchair than to have the residents propelling the chairs at slow speeds. This ultimately may have caused weakness due to disuse of the muscle groups that require the residents to propel themselves. It may also have resulted in decreased motivation for residents to propel themselves around their rooms or the unit. There are no studies that have examined the attitude of nursing home staff members towards wheelchair users. Hjelle & Vik (2011) examined the effect of intrapersonal and environmental factors affecting the social participation of wheelchair users (Hjelle & Vik, 2011). The nursing home staff could be considered as a part of the intrapersonal connection as well as the social environment in long term care. Hjelle & Vik (2011) focused on the importance of identification of intrapersonal and environmental factors which operate together to enhance or limit the social participation of people with disabilities (Hjelle & Vik, 2011).

The provision of training to use the wheelchair and provision of various adaptions to the wheelchair (e.g. brake extensions, adjustable tension backrests, etc.) which affected function and mobility in this research protocol were not reflective of the current practice trends in the nursing homes. With the growing number of individuals using a wheelchair, a need exists for more structure in documenting and tracking the functional status of wheelchair users. Objective ways to document functional outcomes are important in order to follow the improvement/deterioration status of various clients. It also enhances interdisciplinary communication. The parent study showed increased functional outcomes in individually configured wheelchairs with lower attrition in the individually configured wheelchair group compared to the nursing home provided wheelchair group.

A study by Mortenson, Miller & Auger (2007) examined the various objective outcome measures that can be used to select an appropriate wheelchair for an individual affecting participation and function (William B Mortenson, Miller, & Auger, 2008). This helps with identifying problem areas which, when addressed, can help improve dependence in activities of daily living and quality of life. Based on the results of this study, there exists a need for residents to use their chairs but also for nursing home staff members to be trained to allow the residents to use their chair and function safely.

### 5.4.1 Limitations

The study sample was primarily female and isn't representative of the entire nursing home population. The process of training an individual to propel a wheelchair is not reflective of the current trend of practice in nursing homes. Due to the study inclusion criteria, only individuals with a total Braden score of 18 and activity-mobility score $\leq 5$ were included in the study. The abilities of the residents to exhibit safer and more independent wheelchair functioning were seen. There was imbalance in the randomization groups based of the baseline scores of FEW-C at pre-randomization in the item of reaching side to side. At pre-randomization, subjects who received individually configured lightweight manual wheelchairs moved outside their respective nursing home units throughout the facility compared to subjects who received nursing home provided wheelchairs with relative adjustments (Table 42). The effect of wheelchair fit diminished at the endpoint of the study which was not what was expected keeping in mind the intervention goals. The difference in the maneuvering abilities between the two groups would be what we'd want to see after the intervention. The inclusion criteria of our study is also not representative of the nursing home wheelchair using population as all the study participants were at a high risk of

developing pressure ulcers based on the Braden total scores of ≤18 and had limited mobility as demonstrated by the Braden Activity -Mobility total components of ≤6.

# 6.0 CONCLUSION

The general aims of this dissertation were to:

1. To assess the effect of wheelchair fit on function, propulsion and mobility.
2. To evaluate the role of custom fit manual wheelchairs on fall risk of full time nursing home wheelchair users.
3. To assess the association of the Braden Risk Assessment Scales and Functioning Everyday with a Wheelchair score.

These aims were assessed using the parent study which was a randomized clinical trial from the National Institutes of Health grant titled, "An RCT on wheeled mobility for preventing pressure ulcers" (Grant number: 2R01HD041490). The outcome measures used to assess these aims were the Braden Risk Assessment Scale, Functioning Everyday with a Wheelchair Scale, Nursing Home Lifespace Diameter, and the Wheelchair Skills Test. The falls report, which was collected on a weekly basis, was also used for the analysis of the aims.

Regression analyses were completed for Aim 1. Significant p-values were observed for three out of the four analyses. Understanding the relationship between the Braden scores and the FEW-C scores is important as it will help with catering to the clients overall needs rather than system specific needs. If a nurse observes a lower Braden total and/or Braden Activity-Mobility score, a referral can be made to a therapist to assess the seating system. It is recommended that clinicians, both nursing and rehabilitation (physical & occupational therapists & assistants), understand the relationship between these scores to help address the client's needs with respect to assessing both wheelchair functioning and pressure ulcer risk.

The analysis of Aim 2, which assessed the relationship of individually configured lightweight manual wheelchairs on fall risk, did not demonstrate statistically significant differences for wheelchair related falls between the individuals with individually configured

lightweight manual wheelchairs and individuals with misfit nursing home chairs. Wheelchair fit is important when studying wheelchair-related falls because poorly fitting wheelchairs may result in poor posture (e.g., poor accommodation of spinal deformities, posterior pelvic rotation, pelvic obliquity, etc.) that will result in poor body mechanics and lower functioning levels. This, in turn, leads to risky behaviors and/or increased fall risk. The incidence of wheelchair-related falls in the treatment group were lower than the control group as anticipated before the analyses. Even though the result was not statistically significant, further data collection and analyses is needed to prove statistical and clinical significance. The small sample size was a limitation for the analysis of this aim. The results from the analysis of this aim can be used as pilot information to design a future study.

The analysis for Aim 3 demonstrated close to significant differences in NHLSD scores collected at Pre-Rand and Endpoint. This implies that the custom fit manual lightweight wheelchairs had an effect on the mobility patterns compared to poorly fit nursing home chairs. There were significant differences also between the independence components of the FEW-C scores at pre-randomization vs. endpoint and pre-randomization vs. Day 14. This implies that the individuals who received the individually configured, fit lightweight manual wheelchairs had better independence functioning abilities than individuals who received nursing home provided wheelchairs. The FEW-C safety component exhibited significant differences between pre-randomization vs. endpoint. The individuals in the study sample took beyond Day 14 to safely function in their wheelchair.

There were limitations to the analyses of the above-mentioned aims. The sample was primarily female and isn't representative of the entire nursing home population. Only individuals with a total Braden score of 18 and activity-mobility score ≤5 were invited to participate. The

abilities of the residents to exhibit safer and more independent wheelchair functioning were seen. This inclusion criterion is not representative of the nursing home wheelchair using population as a whole. In the real world, all practicing therapists are not cognizant of outcome measures such as the WST, FEW-C and the NHLSD. It is important for other professionals to understand these scales and promote inter-professional communication.

# APPENDIX A

## CLASSIFICATION OF WHEELCHAIRS

Medicare is administered and is regulated by the Heath Care Finance Administration (HCFA). With the trending advances in electronic health records, the wheelchairs have been assigned the "K codes" by the HCFA. The HCFA categorizes wheelchairs in various classes based on adjustability of wheels and castors, weight, etc. The various classes allow for varying levels of individual adjustability to the user's body. The following codes are assigned to wheelchairs-

I) Standard (K0001): The wheelchairs in this category are called standard wheelchairs. These chairs have steel frames and weigh are ≥ 36 pounds. The seat to floor height of these chairs is 19 to 21 inches. The wheelchairs in this group are not adjustable and not designed for everyday use but for transportation purposes.

II) Standard Hemi (K0002): The chairs in this category have similar frame characteristics as those in K0001. However, the seat to floor height of these chairs is lower (17 to 18 inches) than that of the K0001.

III) Lightweight (K0003): The chairs in this group weigh less than 36 pounds with an average of 28 pounds. Wheelchairs under this category are more modifiable than the wheelchairs in K0001 and K0002.

IV) High strength light weight (K0004): The wheelchairs in this category weigh average of 26 pounds. It is easier to adjust the seat height and the frames are more adjustable than

the wheelchairs in any of the above categories. The main feature that highlights the adjustability of the wheelchairs in this class is the modifiable axle position.

V) Ultralight weight (K0005): The frames of these chairs weigh as low as 17 to 18 pounds. The highlight of this class of wheelchairs is the ability to adjust the seat angle due to the axle adjustability. This category of wheelchairs offers maximum adjustability for castor adjustment and modifications.

# APPENDIX B

## FORMS AND THE ASSOCIATED TIMELINE

| Form name (Acronym) | Time point for administration (Responsible Team) | Purpose | Appendix |
|---|---|---|---|
| Braden Risk Assessment Scale (BRA) | Pre-Randomization/ Screening (Skin Team) | Document latest Braden Scores | D |
| Skin Inspection (SI) | | Document skin status and pressure ulcers (if any) | N |
| Eligibility Checklist (EC) | | Summarize eligibility criteria | E |
| Final Eligibility Verification (FEV) | | Summarizes the screening process to assure appropriate residents are entered into the study. | H |
| Functioning Everyday with a Wheelchair-Capacity (FEW-C) | Pre-Randomization (Seat team) | Document function before equipment issue | I |
| Nursing home Life-Space Diameter (NHLSD) | | Document mobility in wheelchair before equipment issue | P |
| Randomization | Randomization (Seat team) | Document randomization as completed by assessing clinician | L |
| Subject Baseline Data (SBD) | Post-Randomization (Seat team) | Obtain from residents chart latest medical records | O |
| Equipment Issue (EI) | | Document characteristics of equipment issued | G |
| Seating Needs assessment (SNA) | | Document the characteristics of the resident's posture | M |
| Wheelchair Skills Test (WST) | | Document the training and the skills associated with the new equipment | T |
| Bed (BED) | | Document bed and mattress details | C |
| Minimum Data Set (MDS) | | - | K |
| Skin Inspection (SI) | Weekly follow ups (Skin Team) | Document skin status and pressure ulcers (if any) | N |
| Braden Risk Assessment Scale (BRA) | | Document latest Braden Scores | D |
| Weekly Monitoring Form (WM1) | | Summarize the SI & Braden forms | Q |
| Wheelchair and Cushion Adjustment (WCA) | Weekly follow ups (Seat Team) | Document adjustments made to the wheelchair and/or cushion | S |

| | | | |
|---|---|---|---|
| Weekly Monitoring Form: Seat Team | | Document important parameters of the resident related to positioning | R |
| Endpoint (END) | Endpoint follow up (Skin/Seat Team) | Document reason for reaching endpoint and any other significant details related to reaching endpoint. | F |
| Interface Pressure Form (IP) | Day 14 follow up and endpoint follow up (Seat Team) | Document the computer interpretation of the pressure mapping data. | J |
| Wheelchair skills test (WST) | | Document the wheelchair skills test administration | T |
| Nursing home Life Space Diameter (NHLSD) | | Document mobility in wheelchair after equipment issue | P |
| Functioning every day with a wheelchair (FEW-C) | | Document mobility in wheelchair before equipment issue | H |
| Minimum Data Set (MDS) | | | K |

## APPENDIX C

## BED

| | | |
|---|---|---|
| Initial Verification: _ _ / _ _ / _ _ _ _ | Initials: _____ | Subject ID: __ __ - __ __ __ - __ __ __ __ __ |
| Entered: _ _ / _ _ / _ _ _ _ | Initials: _____ | Visit: ❑ Post-Rand ❑ 1 week post |
| Verified at EDC: _ _ / _ _ / _ _ _ _ | Initials: _____ | **Form Version: 01/01/2011** |

### Bed Form (BED)

Date __ __ / __ __ / __ __ __ __ Time ___ ___ : ___ ___ (military time)

**Bed:**

Type: _____ _____

Make: _____

Serial number: _____

**Mattress:**

Type: _____

Make: _____

Serial number_____

FILE FORM IN SUBJECT FOLDER

Research Staff signature(s): _____ Date: __ __ / __ __ / __ __ __ __

_____ Date: __ __ / __ __ / __ __ __ __

# APPENDIX D

## BRADEN RISK ASSESSMENT SCALE

| | | |
|---|---|---|
| Initial Verification: _ _ / _ _ / _ _ _ _ | Initials: _____ | Subject ID __ __ - __ __ __ - __ __ __ __ __ |
| Entered: _ _ / _ _ / _ _ _ _ | Initials: _____ | Week: _____ |
| Verified at EDC: _ _ / _ _ / _ _ _ _ | Initials: _____ | **Form Version: 01/01/2011** |

## Braden Risk Assessment Scale (BRA)

Date: __ __ / __ __ / __ __ __ __ Time __ __ : __ __

| **Sensory Perception** | **1. Completely Limited** | **2. Very Limited** | **3. Slightly Limited** | **4. No Impairment** | *Indicate Appropriate Numbers Below* |
|---|---|---|---|---|---|
| ability to respond meaningfully to pressure-related discomfort | Unresponsive (does not moan, flinch, or grasp) to painful stimuli, due to diminished level of consciousness or sedation OR limited ability to feel pain over most of body | Responds only to painful stimuli. Cannot communicate discomfort except by moaning or restlessness OR has a sensory impairment which limits the ability to feel pain or discomfort over ½ of body. | Responds to verbal commands, but cannot always communicate discomfort or the need to be turned OR has some sensory impairment which limits ability to feel pain or discomfort in 1 or 2 extremities. | Responds to verbal commands. Has no sensory deficit which would limit ability to feel or voice pain or discomfort. | |
| **Moisture** | **1. Constantly Moist** | **2. Very Moist** | **3. Occasionally Moist** | **4. Rarely Moist** | |
| degree to which skin is exposed to moisture | Skin is kept moist almost constantly by perspiration, urine, etc. Dampness is detected every time patient is moved or turned. | Skin is often, but not always moist. Linen must be changed at least once a shift. | Skin is occasionally moist, requiring an extra linen change approximately once a day. | Skin is usually dry, linen only requires changing at routine intervals | |
| **Activity** | **1. Bedfast** | **2. Chairfast** | **3. Walks Occasionally** | **4. Walks Frequently** | |
| degree of physical activity | Confined to bed. | Ability to walk severely limited or non-existent. Cannot bear own weight and/or must be assisted into chair or wheelchair. | Walks occasionally during day, but for very short distances, with or without assistance. Spends majority of each shift in bed or chair | Walks outside room at least twice a day and inside room at least once every two hours during waking hours | |
| **Mobility** | **1. Completely Immobile** | **2. Very Limited** | **3. Slightly Limited** | **4. No Limitations** | |
| ability to change and control body position | Does not make even slight changes in body or extremity position without assistance | Makes occasional slight changes in body or extremity position but unable to make frequent or significant changes independently. | Makes frequent though slight changes in body or extremity position independently. | Makes major and frequent changes in position without assistance. | |
| **Nutrition** | **1. Very Poor** | **2. Probably Inadequate** | **3. Adequate** | **4. Excellent** | |
| usual food intake pattern | Never eats a complete meal. Rarely eats more than 1/3 of any food offered. Eats 2 servings or less of protein (meat or dairy products) per day. Takes fluids poorly. Does not take a liquid dietary supplement OR is NPO and/or maintained on clear liquids or IV's for more than 5 days. | Rarely eats a complete meal and generally eats only about ½ of any food offered. Protein intake includes only 3 servings of meat or dairy products per day. Occasionally will take a dietary supplement. OR receives less than optimum amount of liquid diet or tube feeding | Eats over half of most meals. Eats a total of 4 servings of protein (meat, dairy products per day. Occasionally will refuse a meal, but will usually take a supplement when offered OR is on a tube feeding or TPN regimen which probably meets most of nutritional needs | Eats most of every meal. Never refuses a meal. Usually eats a total of 4 or more servings of meat and dairy products. Occasionally eats between meals. Does not require supplementation. | |
| **Friction and Shear** | **1. Problem** | **2. Potential Problem** | **3. No Apparent Problem** | | |
| | Requires moderate to maximum assistance in moving. Complete lifting without sliding against sheets is impossible. Frequently slides down in bed or chair, requiring frequent repositioning w/maximum assistance. Spasticity, contractures or agitation leads to almost constant friction | Moves feebly or requires minimum assistance. During a move skin probably slides to some extent against sheets, chair, restraints or other devices. Maintains relatively good position in chair or bed most of the time but occasionally slides down. | Moves in bed and in chair independently and has sufficient muscle strength to lift up completely during move. Maintains good position in bed or chair. | | |
| | | | | **Activity/Mobility Score:** | |
| Research Staff signature:_____ Date: __ __ / __ __ / __ __ __ __ | | | | **Total Score:** | |

# APPENDIX E

## ELLIGIBILITY CHECKLIST

| | | |
|---|---|---|
| Initial Verification: _ _ / _ _ / _ _ _ _ | Initials: _____ | Screening ID __ __ - __ __ __ __ __ |
| Entered: _ _ / _ _ / _ _ _ _ | Initials: _____ | |
| Verified at EDC: _ _ / _ _ / _ _ _ _ | Initials: _____ | **Form Version: 06/20/2011** |

## Stage I - Eligibility Checklist (EC) - Screening

Date __ __ / __ __ / __ __ __ __ Time ___ ___ : ___ ___ (military time)

**Inclusion Criteria:**

| | | | |
|---|---|---|---|
| ❑ Yes | ❑ No | ❑ Not Assessed | Male or female LTC resident 60 years of age or older |
| ❑ Yes | ❑ No | ❑ Not Assessed | A Braden score of less than or equal to 18 |
| ❑ Yes | ❑ No | ❑ Not Assessed | A combined Braden Activity and Mobility Subscale score less than or equal to 5 |
| ❑ Yes | ❑ No | ❑ Not Assessed | A tolerance for total daily wheelchair sitting time of greater than or equal to 6 hours (not continuous) |
| ❑ Yes | ❑ No | ❑ Not Assessed | Current use of a manual wheelchair |
| ❑ Yes | ❑ No | ❑ Not Assessed | Ability to accommodate seating and positioning needs with the wheelchair selected for use in this study |
| ❑ Yes | ❑ No | ❑ Not Assessed | Informed written consent |

**Exclusion Criteria:**

| | | | |
|---|---|---|---|
| ❑ Yes | ❑ No | ❑ Not Assessed | Body weight exceeding 250 lbs. (wheelchair weight limit) |
| ❑ Yes | ❑ No | ❑ Not Assessed | Hip width exceeding 20 in. (wheelchair width limit) |
| ❑ Yes | ❑ No | ❑ Not Assessed | Wheelchair seating requirements for additional head support, seat depth > 20 inches, elevated leg rests or severe orthopedic deformities of the pelvis, lower extremities or back that exceed the accommodating capability of the Breezy wheelchair |
| ❑ Yes | ❑ No | ❑ Not Assessed | Current use of any cushioning material(s) other than a standard cushion, a folded pad, or a pillow (standard cushion as defined by HCPCS code for Standard Cushions, i.e., non-skin protection cushion) |
| ❑ Yes | ❑ No | ❑ Not Assessed | Current use of a HCPCS code K0005 wheelchair |

**If <u>all</u> inclusion criteria are answered YES and <u>all</u> exclusion criteria are answered NO, the resident is eligible for Skin Inspection.**

❑ Yes ❑ No Eligible for Skin Inspection (Stage II Screening)?

Comments:

_____

_____

_____

# APPENDIX F

# ENDPOINT (END)

| | | |
|---|---|---|
| Initial Verification: _ _ / _ _ / _ _ _ _ | Initials: _____ | Subject ID __ __ - __ __ __ - __ __ __ __ __ |
| Entered: _ _ / _ _ / _ _ _ _ | Initials: _____ | |
| Verified at EDC: _ _ / _ _ / _ _ _ _ | Initials: _____ | **Form Version: 01/27/2012** |

## Endpoint Form (END)

Date __ __ / __ __ / __ __ __ __

1. Date Endpoint Reached: __ __ / __ __ / __ __ __ __
2. Number of Study Weeks Completed: ____ ____
3. Number of Study Days Completed: ____ ____ ____
4. Endpoint Type
   - ❑ Development of Seat Surface Pressure Ulcer
   - ❑ 26 weeks since initiation of seating intervention
   - ❑ Discharged from long-term care facility
   - ❑ Subject/ family requested withdrawal
     - ❑ Subject's equipment available (endpoint data collected)
     - ❑ Subject's equipment not available (no endpoint data)
   - ❑ Study team withdrew subject
     - ❑ Subject's equipment available (endpoint data collected)
     - ❑ Subject's equipment not available (no endpoint data)
   - ❑ Death
   - ❑ Other, specify: _____
5. LTCF staff notified that subject has reached study endpoint? ❑ Yes ❑ No
6. Endpoint seating evaluation completed? ❑ Yes ❑ No

   Indicate reason:
   - ❑ Subject is deceased
   - ❑ Subject left facility before evaluation could be completed
   - ❑ Subject declined endpoint seating evaluation
   - ❑ Other, specify: _____
7. Were MDS data available (other than the Post-Rand MDS)? ❑ Yes ❑ No
8. Other comments? ❑ Yes ❑ No

   If yes: _____

   _____

FILE FORM IN SUBJECT FOLDER

Research Staff signature(s): _____ Date: __ __ / __ __ / __ __ __ __

_____ Date: __ __ / __ __ / __ __ __ __

# APPENDIX G

## EQUIPMENT ISSUE (EI)

| | | |
|---|---|---|
| Initial Verification: _ _ / _ _ / _ _ _ _ | Initials: _____ | Subject ID _ _ _ - _ _ _ _ - _ _ _ _ _ _ |
| Entered: _ _ / _ _ / _ _ _ _ | Initials: _____ | Visit: ❑ Post-Rand ❑ Week _____ |
| Verified at EDC: _ _ / _ _ / _ _ _ _ | Initials: _____ | **Form Version: 07/20/2012** |

## Equipment Issued Form (EI)

Date _ _ / _ _ / _ _ _ _ Time _ _ : _ _ (military time)

| Component | Specifications | Comments |
|---|---|---|
| Wheelchair:<br>❑ Treatment group (Lightweight manual)<br>❑ Control group<br>make_____<br>model_____<br>❑ No Equipment Issued | Width x Depth:<br>❑ 16" x 16"<br>❑ 18" x 16"<br>❑ 20" x 16"<br>❑ Other: _____ x _____ | |
| Cushion: | Type:<br>❑ Roho Quattro<br>❑ Vicare<br>❑ Jay 3<br>Size:<br>❑ 16" x 16"<br>❑ 18" x 16"<br>❑ 20" x 16"<br>❑ 20" x 18" | |
| Reason(s) for cushion selection: | No Yes<br>❑ ❑ Patient's preference<br>❑ ❑ Clinician's preference<br>Based on:<br>❑ Best pressure distribution<br>❑ Best postural support | |
| Back Support: | Type:<br>❑ Standard flat<br>❑ Adjustable tension<br>Characteristics:<br>❑ Low (below axilla)<br>❑ Mid (at axilla level)<br>❑ High (above axilla) | |
| Armrests: | Desk Length:<br>❑ Right<br>❑ Left<br>Full Length:<br>❑ Right<br>❑ Left | |
| Leg rests:<br>❑ Issued →<br>❑ not issued | Non-elevating:<br>❑ Right<br>❑ Left<br>Elevating:<br>❑ Right<br>❑ Left | |
| Anti-tippers: | ❑ Issued ❑ Not Issued | |
| Solid Seat Insert: | ❑ Issued ❑ Not Issued | |
| Cushion Owner's Manual: | ❑ Issued ❑ Not Issued | |
| Other: | ❑ No ❑ Yes | If yes, please describe: |

# APPENDIX H

## FINAL ELLIGIBILITY VERIFICATION (FEV)

| | | |
|---|---|---|
| Initial Verification: __/__/____ | Initials: _____ | Screening ID ___-_____ |
| Entered: __/__/____ | Initials: _____ | |
| Verified at EDC: __/__/____ | Initials: _____ | **Form Version: 08/29/2013** |

## Final Eligibility Verification (FEV)

Date __ __ / __ __ / __ __ __ __ Time __ __ : __ __ (military time)

**Stage I Screen** (See Stage I – Eligibility Checklist Screening Form and Braden Scale Form for details)

a) Stage I screen completed by (initials) _____ on (date) __ __ / __ __ / __ __ __ __

b) Subject passed Stage I Screen?

❑ Yes, continue screening process ❑ No, subject excluded from study

**Stage II Screen** (See Stage II – Skin Inspection Screening Form for details)

a) Stage II screen completed by (initials) _____ on (date) __ __ / __ __ / __ __ __ __

b) Subject passed Stage II Screen?

❑ Yes, continue screening process ❑ No, subject excluded from study

**Stage III Screen** (See Stage III – Seating Needs Visual Assessment)

a) Stage III screen completed by (initials) _____ on (date) __ __ / __ __ / __ __ __ __

b) Subject passed Stage III Screen?

❑ Yes, continue screening process ❑ No, subject excluded from study

**Stage IV Screen** (Pressure Ulcer Status - search of medical records)

a) Search of records completed by (initials) _____ on (date) __ __ / __ __ / __ __ __ __

b) Subject pressure ulcer free per medical records?

❑ Yes ❑ No, subject excluded from study

Subject eligible for study

*Sign below when all screening procedures have been completed.*

Research Coordinator: _____ Date: __ __ / __ __ / __ __ __ __

Signature

# APPENDIX I

## FUNCTIONING EVERYDAY WITH A WHEELCHAIR CAPACITY (FEW-C)

Initial Verification: __/__/____ Initials: _____ Subject ID ___-___-___-_____

Entered: __/__/____ Initials: _____ Visit: ❑ Day14 ❑ Endpoint

Verified at EDC: __/__/____ Initials: _____ **Form Version: 01/01/2011**

## Functioning Everyday with a Wheelchair (FEWC)

Date __ __ / __ __ / __ __ __ __ Time ___ ___ : ___ ___ (military time)

**Assistive Technology Devices (ATDs) used during FEW-C tasks:**

No Yes

❑ ❑ Cane
❑ ❑ Reacher
❑ ❑ Walker
❑ ❑ AAC device
❑ ❑ Other, specify:_____

**Total # of ATDs used:** _____

| Subtasks | FEW-C Subtasks | INDEPENDENCE DATA | | | | | | SAFETY DATA | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | NA<br>4 - No Assist | VA<br>3 - Verbal Assist | V*A<br>2 - Visual Assist | PA<br>1 - Physical Assist | UN<br>0 - Unable | | SP<br>3 - Safe practices | MR<br>2 - Minor risk - no assist | PH<br>1 - Risk - Potential harm | SR<br>0 - Severe risk - prevent harm |
| 1. On/Off and Brakes | Turns wheelchair/scooter on and off or locks and unlocks brakes on wheelchair adequately (does not bump into or scrape body parts on surrounding surfaces, maintains balance, no unplanned movements) and efficiently (within 1 try, does not struggle, controlled manner).<br>**"PLEASE SHOW ME HOW YOU LOCK THE BRAKES ON THE WHEELCHAIR AND THEN UNLOCK THEM"** | NA<br>❑ | VA<br>❑ | V*A<br>❑ | PA<br>❑ | UN<br>❑ | | SP<br>❑ | MR<br>❑ | RI<br>❑ | SR<br>❑ |
| 2. WC Transfer | Positions wheelchair/scooter adequately (secures wheelchair/scooter for transfer) and with ease (does not struggle, within 1 try, controlled manner) and transfers from wheelchair/scooter to identified surface adequately (does not bump into or scrape body parts on surrounding surfaces, does not plop down onto surface) and efficiently (does not struggle, within 1 try, controlled manner, no unplanned stops).<br>**"PLEASE SHOW ME HOW YOU TRANSFER FROM YOUR WHEELCHAIR TO YOUR BED"** | NA<br>❑ | VA<br>❑ | V*A<br>❑ | PA<br>❑ | UN<br>❑ | | SP<br>❑ | MR<br>❑ | RI<br>❑ | SR<br>❑ |
| 3. Reach Forward | Retrieves item from in front of self by reaching forward adequately (stabilizes self and reaches forward beyond fingertips to pick up the tape measure) and efficiently (without dropping, within 1 try, does not struggle).<br>**"PLEASE SHOW ME HOW YOU REACH FORWARD IN YOUR WHEELCHAIR. PLEASE HAND ME THE TAPE MEASURE"** | NA<br>❑ | VA<br>❑ | V*A<br>❑ | PA<br>❑ | UN<br>❑ | | SP<br>❑ | MR<br>❑ | RI<br>❑ | SR<br>❑ |

Subject ID __ __ - __ __ __ - __ __ __ __ __

| | | NA | VA | V*A | PA | UN | | SP | MR | PH | SR |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 4 - No Assist | 3 - Verbal Assist | 2 - Visual Assist | 1 - Physical Assist | 0 - Unable | | 3 - Safe practices | 2 - Minor risk - no assist | 1 - Risk - Potential harm | 0 - Severe risk - prevent harm |
| **Subtasks** | **FEW-C Subtasks** | **INDEPENDENCE DATA** | | | | | | **SAFETY DATA** | | | |
| **4. Reach Side to Side** | Retrieves item from hand of the assessor (to the left or right) and hands it to assessor on the opposite side adequately (holds and places securely, does not over-reach) and efficiently (without dropping, within 1 try, does not struggle).<br>**"PLEASE TAKE THIS TAPE MEASURE FROM MY HAND AND GIVE IT BACK TO ME WHEN I MOVE TO THE OTHER SIDE OF YOUR WHEELCHAIR"**<br>Ss position during item retrieval **[CHECK ONE]:**<br>❑ **Right side of Ss wheelchair to Left side**<br>❑ **Left side of Ss wheelchair to Right side** | NA | VA | V*A | PA | UN | | SP | MR | RI | SR |
| | | ❑ | ❑ | ❑ | ❑ | ❑ | | ❑ | ❑ | ❑ | ❑ |
| **5. Personal Hygiene** | Positions wheelchair and retrieves and applies soap to hands, rinses hands with water, and dries hands while seated in wheelchair/ scooter adequately (reaches all items, does not spill on self/floor, does not bump into or scrape body parts on surrounding surfaces, maintains balance) and efficiently (does not drop items, does not struggle, controlled manner).<br>**"PLEASE SHOW ME HOW YOU WASH AND DRY YOUR HANDS AT THE SINK."** | NA | VA | V*A | PA | UN | | SP | MR | RI | SR |
| | | ❑ | ❑ | ❑ | ❑ | ❑ | | ❑ | ❑ | ❑ | ❑ |

FILE FORM IN SUBJECT FOLDER

Research Staff signature(s): _____ Date: __ __ / __ __ / __ __ __ __

_____ Date: __ __ / __ __ / __ __ __ __

# APPENDIX J

## INTER PRESSURE FORM

| | | |
|---|---|---|
| Initial Verification: _ _ / _ _ / _ _ _ _ | Initials: _____ | Subject ID: _ _ - _ _ _ - _ _ _ _ _ |
| Entered: _ _ / _ _ / _ _ _ _ | Initials: _____ | Visit: ❑ Day14 ❑ Endpoint |
| Verified at EDC: _ _ / _ _ / _ _ _ _ | Initials: _____ | **Form Version: 12/20/2011** |

## Interface Pressure Form (IP)

Date _ _ / _ _ / _ _ _ _

Time _____ : _____ (military time)

1. Left Ischial Tuberosity FSA cell number: _ _ _
2. Right Ischial Tuberosity FSA cell number: _ _ _
3. Sacrum FSA cell number: _ _ _
4. Peak Pressure: _ _ _
5. Peak Pressure Index: _ _ _
6. TOP 4 Pressure Index: _ _ _
7. Resident uses padding in addition to provided cushion? ❑ Yes (complete IPPAD) ❑ No

   7.a. If yes, was an IPPAD (Interface Pressure Form for Additional Padding) completed? ❑ Yes ❑ No

**Peak pressure:** The highest pressure reading obtained for the cushion

**Peak Pressure Index (PPI):** The average for a group of sensors in a 2,500 $mm^2$ data window is moved over the entire dataset. The PPI is the highest recorded average in a given area.

**Note:** A 50 mm by 50 mm square or 50 mm diameter circular area are examples of appropriate data window sizes. For example, if using an sensor array with a sensor size of approximately 100 $mm^2$ (e.g., Tekscan, Xsensor), 25 sensor values (a 5 by 5 array) are averaged and if using an sensor array with a sensor size of approximately 645 $mm^2$ (e.g., FSA), 4 sensor values (a 2 by 2 array) are averaged.

**Average of Top 4:** The average of the four highest pressure readings in the entire dataset

FILE FORM IN SUBJECT FOLDER

Research Staff signature(s): _____ Date: _ _ / _ _ / _ _ _ _

_____ Date: _ _ / _ _ / _ _ _ _

# APPENDIX K

## MINIMUM DATA SET COVER SHEET

## Minimum Data Set (MDS sections C, D, E, and G) - Cover Sheet

Initial Verification: __ __ / __ __ / __ __ __ __ Initials: _____

Entered: __ __ / __ __ / __ __ __ __ Initials: _____

Verified at EDC: __ __ / __ __ / __ __ __ __ Initials: _____

Subject ID __ __ - __ __ __ - __ __ __ __ __

Visit: ❑ Post-Rand ❑ Endpoint

Date of MDS data update: __ __ / __ __ / __ __ __

| A0310. (A10.) Type of Assessment / Tracking | |
|---|---|
| Enter ☐☐ Code | a. **Federal OBRA Reason for Assessment / Tracking**<br>01. **Admission** assessment (required by day 14)<br>02. **Quarterly** review assessment<br>03. **Annual** assessment<br>04. **Significant change in status** assessment<br>05. **Significant correction** to **prior Comprehensive / full** assessment<br>06. **Significant correction** to **prior quarterly** assessment<br>99. **Not OBRA required** assessment / tracking |

**FILE FORM IN SUBJECT FOLDER.**

Research Staff signature(s): _____ Date: __ __ / __ __ / __ __ __ __

_____ Date: __ __ / __ __ / __ __ __ __

Please fax this cover sheet with the subject de-identified MDS Sections C, D, E, & G to the EDC at 412-624-3710

# APPENDIX L

# RANDOMIZATION

**RCT WC2 – Telephone Randomization Worksheet**
**Telephone Randomization System**

| **Site Codes:** | | | | |
|---|---|---|---|---|
| 01 – Monroeville | 05 – Bethel Park | 09 – McMurray | 13 – Asbury Heights | 17 – Seneca Place |
| 02 – North Hills | 06 – Heartland | 10 – Scott Township | 14 – Friendship Ridge | 18 – Cranberry Place |
| 03 – Greentree | 07 – Shadyside | 11 – McKeesport | 15 – Ross Township | 19 – Sherwood Oak |
| 04 – Whitehall | 08 – Sky Vue Terrace | 12 – Glen Hazel | 16 – Heritage s | 20 – Lutheran Home |

SECTION I

**Complete the following questions prior to dialing into the WC2 telephone randomization system (1-866-639-7205)**

1. Confirm patient is eligible for randomization. *[confirm with Final Eligibility Verification form]*
2. Date of randomization: ☐☐☐☐☐☐☐☐ (mm/dd/yyyy)
3. Site Code: ☐☐
4. First three letters of patient's Last Name: ☐☐☐
5. First two letters of patient's First Name: ☐☐

Screening ID
☐☐ - ☐☐☐ - ☐☐
(site code) (first 3 letters of last name) (first 2 letters of first name)

SECTION II

**Follow the System Prompts and Record the information provided by the WC2 telephone randomization system**

1. Enter your 5 digit **User ID** *[you should have received your User ID from data center]*
2. Enter your 4 digit **Passcode** *[you should have received Passcode from data center]*
3. Enter your 2 digit **Site Code** *[Listed on top of this form]*
4. Enter the **First three letters of patient's Last Name** *[as entered above]*
5. Enter **First two letters of patient's First Name** *[as entered above]*
6. If entered Screening ID was previously randomized, the system will announce the previous assignment
7. Confirm you want to randomize the subject
8. Record the Subject ID when it is given → SUBJECT ID: ☐☐ - ☐☐☐ - ☐☐☐☐☐
9. Record the Randomization assignment when given → RANDOMIZATION: ☐ Treatment ☐ Control
10. Confirm Randomization *[Make sure you have the correct Subject ID and Randomization recorded above]*
11. Randomization email will be sent to user

SECTION III

**If you are in need of assistance please contact John Gianakas at (412)624-5926 or gianakasj@edc.pitt.edu.**
**If John is unavailable please contact Deborah Martin at (412)624-4416, or Kim Beringer at (412)624-3759.**

**Keypad Response Rules**

1) Press (#) for instructions for entering characters
   a) continue pressing the key associated with the letter you wish to enter until you hear the letter, and then press (#)
   **Example:** Press the 2 key three times to enter the letter "C" followed by the pound sign (#)
2) Press ( *) to pause the survey

*23 May 2011*

# APPENDIX M

## SEATING NEEDS ASSESSMENT (SNA)

| | | |
|---|---|---|
| Initial Verification: _ _ / _ _ / _ _ _ _ | Initials: _____ | Subject ID __ __ - __ __ __ - __ __ __ __ __ |
| Entered: _ _ / _ _ / _ _ _ _ | Initials: _____ | Visit: Post-Rand |
| Verified at EDC _ _ / _ _ / _ _ _ _ | Initials: _____ | **Form Version: 07/15/2011** |

## Seating Needs Assessment (SNA)

Date __ __ / __ __ / __ __ __ __ Time ___ ___ : ___ ___ (military time)

Able to complete SNA? ❑ Yes ❑ No

| | | | | |
|---|---|---|---|---|
| **SENSATION** | ❑ Normal | ❑ Diminished / Questionable | ❑ Absent | |
| **PAIN** | ❑ None | ❑ Intermittent | ❑ Constant | *If Intermittent or Constant:* Interferes with Fxn? ❑ Yes ❑ No |
| **ABNL REFLEXES** | ❑ Integrated | ❑ Present | ❑ Dominant | |
| **MUSCLE TONE** | Normal: ❑ Yes ❑ No *(if Yes: UE, LE and Trunk are N/A)* | UE: ❑ Yes ❑ No *If Yes:* ❑ hi ❑ lo ❑ flex ❑ ext | LE: ❑ Yes ❑ No *If Yes:* ❑ hi ❑ lo ❑ flex ❑ ext | Trunk: ❑ Yes ❑ No *If Yes:* ❑ hi ❑ lo ❑ flex ❑ ext ❑ variable |
| **STRENGTH** | ❑ Normal | ❑ Reduced | ❑ Absent | |
| **SCOLIOSIS** | ❑ Neutral | ❑ Flex deformity | ❑ Fixed deformity | *If Flex or Fixed deformity:* ❑ Thoracic *or* ❑ Lumbar ❑ Mild ❑ Mod ❑ Severe |
| **KYPHOSIS** | ❑ Neutral | ❑ Flex deformity | ❑ Fixed deformity | *If Flex or Fixed deformity:* ❑ Mild ❑ Mod ❑ Severe |
| **LORDOSIS** | ❑ Neutral | ❑ Flex deformity | ❑ Fixed deformity | *If Flex or Fixed deformity:* ❑ Mild ❑ Mod ❑ Severe |
| **PELVIC TILT** | ❑ Neutral | ❑ Flex deformity | ❑ Fixed deformity | *If Flex or Fixed deformity:* ❑ Ant *or* ❑ Post ❑ Mild ❑ Mod ❑ Severe |
| **PELVIC RTN** | ❑ Neutral | ❑ Flex deformity | ❑ Fixed deformity | |
| **PELVIC OBLIQ** | ❑ Neutral | ❑ Flex deformity | ❑ Fixed deformity | |
| **COMMUNICATN** | ❑ Indep. w/o device | ❑ Assisted | ❑ Dependent | |
| **FEEDING** | ❑ Independent | ❑ Assisted | ❑ Dependent | *If Dependent:* ❑ Oral ❑ G-tube ❑ Neither |
| **DRESSING** | ❑ Independent | ❑ Assisted | ❑ Dependent | |
| **HYGIENE** | ❑ Independent | ❑ Assisted | ❑ Dependent | |
| **SITTING BALANCE** | ❑ Independent | ❑ Limited | ❑ Dependent | |
| **TRANSFERS** | ❑ Independent | ❑Assisted | ❑ Dependent | |
| **AMBULATION** | ❑ Indep. w/o device | ❑ Assisted | ❑ Dependent/none | |
| **WC PROPULSN** | ❑ Independent | ❑ Assisted | ❑ Dependent | *If Independent or Assisted* ❑ Arm ❑ Foot or ❑ Both |
| **COGNITION** | ❑ A&O x 3 Follow > 2 step cd | ❑ A&O x 2 Follows 2 step cmd | ❑ A&O x 1 Follows 1 step cmd | Confused: ❑ Yes ❑ No ST Memory Loss ❑ Yes ❑ No |
| **BEHAVIOR/ JUDGEMENT** | ❑ Age appropriate | ❑ Safety risk: self | ❑ Safety risk: others | |
| **THERAPY: current** | PT: ❑ Yes ❑ No | OT: ❑ Yes ❑ No | SPEECH: ❑ Yes ❑ No | |

Problems:

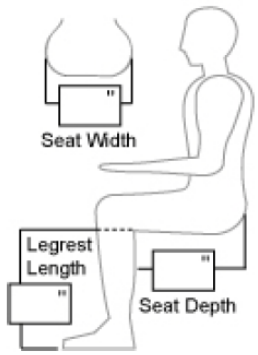
_____

_____

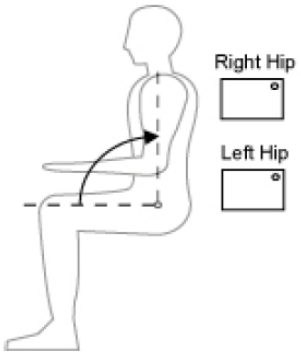
Subject ID __ __ - __ __ __ - __ __ __ __ __

Body Measurements:

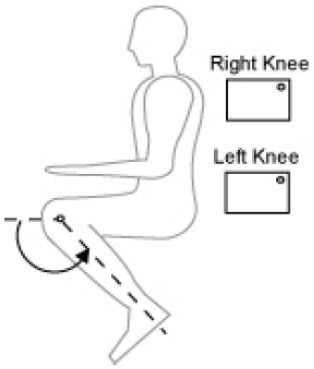
Linear Measures



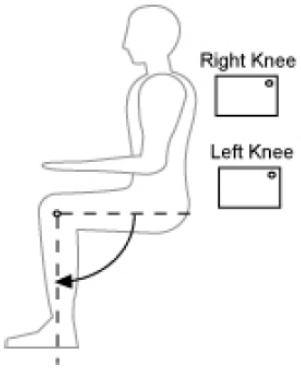

Hip Flexion Angle




Knee Flexion Angle




Knee Extension Angle




FILE FORM IN SUBJECT FOLDER.

Research Staff signature(s): _____ Date: __ __ / __ __ / __ __ __ __

_____ Date: __ __ / __ __ / __ __ __ __

# APPENDIX N

## SKIN INSPECTION

Initial Verification: _ _ / _ _ / _ _ _ _ Initials: _____ Subject ID _ _ - _ _ _ - _ _ _ _ _

Entered: _ _ / _ _ / _ _ _ _ Initials: _____ Week _____

Verified at EDC: _ _ / _ _ / _ _ _ _ Initials: _____ **Form Version: 01/01/2011**

## Skin Inspection (SI) – Weekly

Date _ _ / _ _ / _ _ _ _ Time _ _ : _ _ (military time)

1. Indicate skin status below. "Seated surface" locations are marked with an asterisk (*). "Pelvic" locations are listed in *italics*. For possible pressure ulcers and stage I pressure ulcers, check all applicable indicators.

**KEY**: **LTCF** = Long term care facility; **BE** = Blanchable Erythema **UBE** = Unblanchable erythema; **Blue/Purp** =Blue or purple skin discoloration; **Temp** = Temperature different from contralateral side or adjacent skin; **Consist** = Firm or boggy tissue consistency compared to contralateral side or adjacent skin; **Sens** = Sensation change (pain, itching, etc.); **N/A** = Not applicable

**Right Ischial Tuberosity***

❑ Not Assessed
❑ **No Ulcer**
❑ ***Pressure Ulcer*** → Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable ❑ Deep Tissue injury
Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No

❑ **Possible Pressure Ulcer**, Recheck within 24 Hours

Check all that apply at initial check: ❑ UBE ❑ BE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens

Recheck Date: _ _ / _ _ / _ _ _ _ Time: _ _ : _ _ (military time)

*Pressure Ulcer Present on recheck*? ❑ Yes ❑ No

Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable ❑ Deep Tissue injury
Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No

Comments:

**Left Ischial Tuberosity***

❑ Not Assessed
❑ **No Ulcer**
❑ ***Pressure Ulcer*** → Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable ❑ Deep Tissue injury
Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No

❑ **Possible Pressure Ulcer**, Recheck within 24 Hours

Check all that apply at initial check: ❑ UBE ❑ BE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Recheck Date: __ __ / __ __ / __ __ __ __ Time: __ __ : __ __(military time)
*Pressure Ulcer Present on recheck*? ❑ Yes ❑ No
Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable ❑ Deep Tissue injury
Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No

Comments:

**Sacrum***

❑ Not Assessed
❑ **No Ulcer**
❑ ***Pressure Ulcer*** → Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable ❑ Deep Tissue injury
Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No

❑ **Possible Pressure Ulcer**, Recheck within 24 Hours

Check all that apply at initial check: ❑ UBE ❑ BE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Recheck Date: __ __ / __ __ / __ __ __ __ Time: __ __ : __ __(military time)
*Pressure Ulcer Present on recheck*? ❑ Yes ❑ No
Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable ❑ Deep Tissue injury
Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No

Comments:

***Coccyx****

❑ Not Assessed
❑ **No Ulcer**
❑ ***Pressure Ulcer*** → Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable ❑ Deep Tissue injury
Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No

❑ **Possible Pressure Ulcer**, Recheck within 24 Hours

Check all that apply at initial check: ❑ UBE ❑ BE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Recheck Date: __ __ / __ __ / __ __ __ __ Time: __ __: __ __(military time)
*Pressure Ulcer Present on recheck*? ❑ Yes ❑ No
Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable ❑ Deep Tissue injury
Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No

Comments:

***Right Greater Trochanter***

❑ Not Assessed
❑ **No Ulcer**
❑ ***Pressure Ulcer*** → Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable ❑ Deep Tissue injury
Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No

❑ **Possible Pressure Ulcer**, Recheck within 24 Hours

Check all that apply at initial check: ❑ UBE ❑ BE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Recheck Date: __ __ / __ __ / __ __ __ __ Time: __ __: __ __(military time)
*Pressure Ulcer Present on recheck*? ❑ Yes ❑ No
Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable ❑ Deep Tissue injury
Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No

Comments:

***Left Greater Trochanter***

❑ Not Assessed
❑ **No Ulcer**
❑ ***Pressure Ulcer***

Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable ❑ Deep Tissue injury

Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens

Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No

❑ **Possible Pressure Ulcer**, Recheck within 24 Hours

Check all that apply at initial check: ❑ UBE ❑ BE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens

Recheck Date: __ __ / __ __ / __ __ __ __ Time: __ __: __ __(military time)

*Pressure Ulcer Present on recheck*? ❑ Yes ❑ No

Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable ❑ Deep Tissue injury

Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens

Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No

Comments:

**Right Heel**

❑ Not Assessed
❑ **No Ulcer**
❑ ***Pressure Ulcer***

Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable ❑ Deep Tissue injury

Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens

Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No

❑ **Possible Pressure Ulcer**, Recheck within 24 Hours

Check all that apply at initial check: ❑ UBE ❑ BE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens

Recheck Date: __ __ / __ __ / __ __ __ __ Time: __ __: __ __(military time)

*Pressure Ulcer Present on recheck*? ❑ Yes ❑ No

Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable ❑ Deep Tissue injury

Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens

Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No

Comments:

**Left Heel**

❑ Not Assessed
❑ **No Ulcer**
❑ ***Pressure Ulcer*** → Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable ❑ Deep Tissue injury
Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No

❑ **Possible Pressure Ulcer**, Recheck within 24 Hours

Check all that apply at initial check: ❑ UBE ❑ BE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Recheck Date: __ __ / __ __ / __ __ __ __ Time: __ __: __ __(military time)
*Pressure Ulcer Present on recheck*? ❑ Yes ❑ No
Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable ❑ Deep Tissue injury
Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No

Comments:

**Other (optional):**

❑ Not Assessed
❑ **No Ulcer**
❑ ***Pressure Ulcer*** → Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable ❑ Deep Tissue injury
Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No

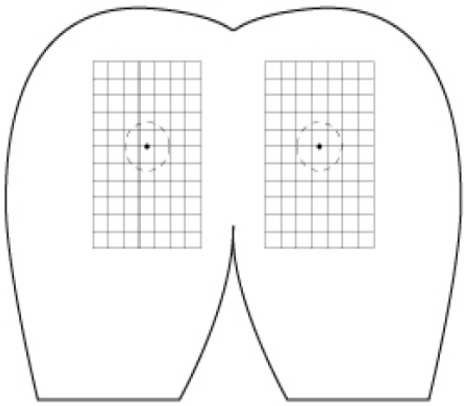
❑ **Possible Pressure Ulcer**, Recheck within 24 Hours

Check all that apply at initial check: ❑ UBE ❑ BE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Recheck Date: __ __ / __ __ / __ __ __ __ Time: __ __: __ __(military time)
*Pressure Ulcer Present on recheck*? ❑ Yes ❑ No
Stage: ❑ I ❑ II ❑ III ❑ IV ❑ Unstageable ❑ Deep Tissue injury
Check all that apply: ❑ UBE ❑ Blue/Purp ❑ Temp ❑ Consist ❑ Sens
Pressure ulcer presence confirmed by LTCF staff? ❑ Yes ❑ No

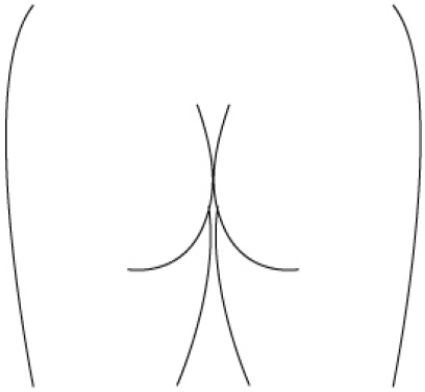
Comments:

2. Sketch the location and approximate size of confirmed or possible pressure ulcers below.

SEATED VIEW



PRONE VIEW



****Recheck all possible pressure ulcers before completing items below****

3. Is a pressure ulcer present at any seated surface site (marked with an asterisk)?

❑ ***Yes, subject has reached study endpoint***

LTCF staff notified of patient's skin status?

❑ Yes ❑ No

Was result of inspection recorded on Weekly Assessment Form?

❑ Yes ❑ No

Was Endpoint form completed?

❑ Yes ❑ No

❑ No, subject continues in study

Was result of inspection recorded on Weekly Assessment Form?

❑ Yes ❑ No

FILE FORM IN SUBJECT FOLDER

Research Staff signature(s): _____ Date: __ __ / __ __ / __ __ __ __

_____ Date: __ __ / __ __ / __ __ __ __

# APPENDIX O

## SUBJECT BASELINE DATA

| | | |
|---|---|---|
| Initial Verification: _ _ / _ _ / _ _ _ _ | Initials: _____ | Subject ID __ __ - __ __ __ - __ __ __ __ __ |
| Entered: _ _ / _ _ / _ _ _ _ | Initials: _____ | Visit: Post-Rand |
| Verified at EDC: _ _ / _ _ / _ _ _ _ | Initials: _____ | **Form Version: 07/15/2011** |

## Subject Baseline Data (SBD)

Date __ __ / __ __ / __ __ __ __

1. Date of Birth: __ __ / __ __ / __ __ __ __

2. Sex: ❑ Male ❑ Female

3. Race (check all that apply):

   ❑ White or Caucasian
   ❑ Black or African-American
   ❑ Asian
   ❑ American Indian or Alaska Native
   ❑ Native Hawaiian or other Pacific Islander
   ❑ Other (specify)_____

3.1 Ethnicity: ❑ Hispanic ❑ Non-Hispanic

4. Measurements

   Height: ____ ft. ____ in

   Weight ___ ___ ___ . ___ ___ lbs

5. Nursing Home Admission Date __ __ / __ __ / __ __ __ __ Time : ____ : ____ ❑ time not available
   **(military time)**

6. Primary Diagnosis(es) (why hospitalized):

   ❑ Heart
   ❑ Vascular
   ❑ Hematopoietic
   ❑ Respiratory
   ❑ Eyes, Ears, Nose, Throat and Larynx
   ❑ Upper Gastrointestinal
   ❑ Lower Gastrointestinal
   ❑ Liver
   ❑ Renal
   ❑ Genitourinary
   ❑ Musculoskeletal/Integument
   ❑ Neurological
   ❑ Endocrine/Metabolic and Breast
   ❑ Psychiatric Illness
   ❑ Diabetes
   ❑ Other (specify): _____

7. Incontinent?

❑ Yes ❑ No

↓

If yes,

| | |
|---|---|
| Urine: | ❑ Yes ❑ No |
| Feces: | ❑ Yes ❑ No |

7.1. Does the patient wear a disposable adult undergarment?

❑ Yes ❑ No

7.2 Is the patient catheterized?

❑ Yes ❑ No

8. Previous history of pressure ulcers? ❑ Yes ❑ No ❑ Unknown

↓

8.1 Is PU location known? ❑ Yes ❑ No

↓

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| ❑ Yes | ❑ No | Ischials | → If yes: | Number: _____ | Location: | ❑ Right | ❑ Left | ❑ Both |
| ❑ Yes | ❑ No | Sacrum | → If yes: | Number: _____ | | | | |
| ❑ Yes | ❑ No | Coccyx | → If yes: | Number: _____ | | | | |
| ❑ Yes | ❑ No | Heel | → If yes: | Number: _____ | Location: | ❑ Right | ❑ Left | ❑ Both |
| ❑ Yes | ❑ No | Malleolus | → If yes: | Number: _____ | Location: | ❑ Right | ❑ Left | ❑ Both |
| ❑ Yes | ❑ No | Knee | → If yes: | Number: _____ | Location: | ❑ Right | ❑ Left | ❑ Both |
| ❑ Yes | ❑ No | Trochanter | → If yes: | Number: _____ | Location: | ❑ Right | ❑ Left | ❑ Both |
| ❑ Yes | ❑ No | Spinous process | → If yes: | Number: _____ | | | | |
| ❑ Yes | ❑ No | Elbow | → If yes: | Number: _____ | Location: | ❑ Right | ❑ Left | ❑ Both |
| ❑ Yes | ❑ No | Scapula | → If yes: | Number: _____ | Location: | ❑ Right | ❑ Left | ❑ Both |
| ❑ Yes | ❑ No | Head | → If yes: | Number: _____ | | | | |

9. Number of medications currently administered: ____ ____

10. Means of mobility used most often within nursing home (check one):

❑ Ambulation
❑ Manual wheelchair
❑ Other (specify): _____

11. Ambulation

a. Distance: ❑ 0 ft **(skip to Q12)**
❑ <= 10ft
❑ > 10ft

Uses Device? ❑ Yes ❑ No
↓ (check all that apply)
❑ Wheeled Walker
❑ Standard Walker
❑ Crutches
❑ Cane
❑ Other, specify _____
_____

b. Assistance with ambulation:
❑ None
❑ Supervision
❑ Minimal
❑ Moderate
❑ Maximum

❑ 1 person
❑ 2 persons
❑ > 2 persons

12. Weight Bearing (WB) Status (check one per extremity)

| Extremity | Full (FWB) | As Tolerated (WBAT) | Partial (PWB) | Non-WB (NWB) | Not Specified in Chart (NIC) |
|---|---|---|---|---|---|
| Right Lower | ❑ | ❑ | ❑ ___% body wt. | ❑ | ❑ |
| Left Lower | ❑ | ❑ | ❑ ___% body wt. | ❑ | ❑ |
| Right Upper | ❑ | ❑ | ❑ ___% body wt. | ❑ | ❑ |
| Left Upper | ❑ | ❑ | ❑ ___% body wt. | ❑ | ❑ |

13. Transfers

a. Sit ↔ Stand (Movement from a seated position at edge of bed or wheelchair to a standing position and vice versa.)

i. Assistance (check one)

❑ None
❑ Supervision
❑ Minimal
❑ Moderate
❑ Maximum
❑ Unable to do
❑ Mechanical lift

❑ 1 person
❑ 2 persons
❑ > 2 persons

b. Bed ↔ Chair (Movement from a seated position in a wheelchair to a seated position at the edge of the bed and vice versa.)

i. Assistance (check one)

- ❑ None
- ❑ Supervision
- ❑ Minimal
- ❑ Moderate
- ❑ Maximum
- ❑ Mechanical lift

(Minimal, Moderate, Maximum →)
- ❑ 1 person
- ❑ 2 persons
- ❑ > 2 persons

ii. Technique (check one)

- ❑ Stand turn →
- ❑ Stand pivot
- ❑ Lateral scoot without sliding board
- ❑ Lateral scoot with sliding board
- ❑ Dependent pivot
- ❑ Mechanical lift

Specify Assistive Device (check all that apply)
- ❑ Wheeled Walker
- ❑ Standard Walker
- ❑ Crutches
- ❑ Cane
- ❑ Other, specify _____
- ❑ No Device Used

c. Sit ↔ Supine (Movement from a seated position at the edge of the bed to a supine position in bed and vice versa.)

i. Assistance (check one)

- ❑ None
- ❑ Supervision
- ❑ Minimal
- ❑ Moderate
- ❑ Maximum

(Supervision, Minimal, Moderate, Maximum →)
- ❑ 1 person
- ❑ 2 persons
- ❑ > 2 persons

14. History of hip surgery?

❑ Yes ↓ ❑ No

a. Surgery on right side? ❑ Yes ↓ ❑ No

Type (check all that apply):
- ❑ Hip replacement, date: __ __ / __ __ / __ __ __ __
- ❑ Fixation following fracture, date: __ __ / __ __ / __ __ __ __
- ❑ Other, specify: _____

Precautions (check all that apply):
- ❑ No hip adduction past midline
- ❑ No hip flexion beyond 90 degrees
- ❑ No internal rotation past neutral
- ❑ Other hip precautions (specify): _____
- ❑ No known precautions

b. Surgery on left side? ❑ Yes ↓ ❑ No

Type (check all that apply):
- ❑ Hip replacement, date: __ __ / __ __ / __ __ __ __
- ❑ Fixation following fracture, date: __ __ / __ __ / __ __ __ __
- ❑ Other, specify: _____

Precautions (check all that apply):
- ❑ No hip adduction past midline
- ❑ No hip flexion beyond 90 degrees
- ❑ No internal rotation past neutral
- ❑ Other hip precautions (specify): _____
- ❑ No known precautions

15. Other Precautions (check all that apply)

- ❑ Latex allergy
- ❑ Aspiration precautions
- ❑ Anticoagulant therapy
- ❑ Osteoporosis
- ❑ Other (specify): _____
- ❑ No other known precautions

Subject ID __ __ - __ __ __ - __ __ __ __ __

16. Is the patient alert and oriented to self?

❑ Yes ❑ No

17. Does the patient have a history of agitation and combativeness?

❑ Yes ❑ No

FILE FORM IN SUBJECT FOLDER

Research Staff signature(s): _____ Date: __ __ / __ __ / __ __ __ __

_____ Date: __ __ / __ __ / __ __ __ __

# APPENDIX P

## NURSING HOME LIFE-SPACE DIAMETER (NHLSD)

| | | |
|---|---|---|
| Initial Verification: _ _ / _ _ / _ _ _ _ | Initials: _____ | Subject ID __ __ - __ __ __ - __ __ __ __ __ |
| Entered: _ _ / _ _ / _ _ _ _ | Initials: _____ | Visit: Endpoint |
| Verified at EDC: _ _ / _ _ / _ _ _ _ | Initials: _____ | **Form Version: 01/01/2011** |

## The Nursing Home Life-Space Diameter Measure (NHLSD)

Date __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

_____NHLSD1. *[d1]=1*

Within the last 2 weeks, how often has the resident moved **around within his/her own room?** *[f1]*

❑ 5. > 3 times a day ❑ 2. At least weekly
❑ 4. 1-3 times a day ❑ 1. Less than weekly
❑ 3. > 2 times a week ❑ 0. Never

**Was movement in the room without human assistance?** ❑ No ❑ YES **
*If* YES, *multiply (d1 x f1)* ***X 2*** *for NHLSD1 score. If no, multiply (d1 x f1) for NHLSD1 score.*

_____NHLSD2. *[d2]=2*

Within the last 2 weeks, how often has the resident moved **outside the room, within the unit?** *[f2]*

❑ 5. > 3 times a day ❑ 2. At least weekly
❑ 4. 1-3 times a day ❑ 1. Less than weekly
❑ 3. > 2 times a week ❑ 0. Never

**Was movement outside the room, within the unit, without human assistance?** ❑ No ❑ YES **
*If* YES, *multiply (d2 x f2)* ***X 2*** *for NHLSD2 score. If no, multiply (d2 x f2) for NHLSD2 score.*

_____NHLSD3. *[d3]=3*

Within the last 2 weeks, how often has the resident moved **outside the unit, throughout the facility?** *[f3]*

❑ 5. > 3 times a day ❑ 2. At least weekly
❑ 4. 1-3 times a day ❑ 1. Less than weekly
❑ 3. > 2 times a week ❑ 0. Never

**Was movement outside the unit, throughout the facility, without human assistance?** ❑ No ❑ YES **
*If* YES, *multiply (d3 x f3)* ***X 2*** *for NHLSD3 score. If no, multiply (d3 x f3) for NHLSD3 score.*

_____NHLSD4. *[d4]=4*

Within the last 2 weeks, how often has the resident moved **outside the facility (i.e., left the facility)** *[f4]*

❑ 5. > 3 times a day ❑ 2. At least weekly
❑ 4. 1-3 times a day ❑ 1. Less than weekly
❑ 3. > 2 times a week ❑ 0. Never

**Was movement outside the facility without human assistance?** ❑ No ❑ YES **
*If* YES, *multiply (d4 x f4)* ***X 2*** *for NHLSD4 score. If no, multiply (d4 x f4) for NHLSD4 score.*

_____**NHLSD Total Score** *(NHLSD1 + NHLSD2 + NHLSD3 + NHLSD4)*

** "Independence of movement can be incorporated into score by multiplying by 2 if movement without human assistance."

# APPENDIX Q

## WEEKLY MONITORING FORM 1 (WM1)

| | | |
|---|---|---|
| Initial Verification: _ _/ _ _/ _ _ _ _ | Initials: _____ | Subject ID _ _ _ - _ _ _ _ - _ _ _ _ _ _ |
| Entered: _ _/ _ _/ _ _ _ _ | Initials: _____ | Week: _____ |
| Verified at EDC: _ _/ _ _/ _ _ _ _ | Initials: _____ | **Form Version: 11/04/2013** |

## Weekly Monitoring Form (WM1) – Skin Team

Date _ _ / _ _ / _ _ _ _

1. Braden Scale Score Assessed?

   ❑ Yes, enter data from Braden Scale Risk Assessment

   Total of Activity and Mobility Subscales: _____
   Overall score (all subscales): _____

   ❑ No, indicate reason for missed assessment (check one)
   - ❑ Subject unavailable for medical reasons (illness, testing, hospitalization, etc.)
   - ❑ Subject unavailable for non-medical reasons (family visit, etc.)
   - ❑ Subject declined assessment
   - ❑ Research staff unavailable
   - ❑ ~~Subject not using study equipment~~ (INACTIVE)
   - ❑ Other, specify: _____

2. Skin Inspection Performed?

   ❑ Yes, enter data from weekly Skin Inspection form below (check one)
   - ❑ Seated surface pressure ulcer (PU) present, subject exits study, complete endpoint form
   - ❑ No pelvic or seated surface PU present, subject continues in study
   - ❑ Pelvic PU present, subject continues in study, continue to monitor
   - ❑ Both seated surface and pelvic PU present, subject exits study, complete endpoint form
   - ❑ Other, specify: _____

   ❑ No, indicate reason for missed assessment below (check one)
   - ❑ Subject unavailable for medical reasons (illness, testing, hospitalization, etc.)
   - ❑ Subject unavailable for non-medical reasons (family visit, etc.)
   - ❑ Subject declined skin inspection
   - ❑ Research staff unavailable
   - ❑ ~~Subject not using study equipment~~ (INACTIVE)
   - ❑ Other, specify: _____
   - ❑ Subject out of bed

   → Indicate the patient's status according to LTCF staff (check one)
   - ❑ LTCF staff indicates No Ulcers
   - ❑ LTCF staff indicates Ulcer
   - ❑ LTCF staff was not aware of patient's status
   - ❑ LTCF staff was unavailable or was not approached
   - ❑ Other, specify: _____

   → ❑ Check here if endpoint SI **and last attempt** (i.e., no further attempts for skin inspection will be made)

3. Sitting Time:

a. Did LTCF staff report exceptions to 6-hour minimum sitting time (check)?

❑ Yes ❑ No ❑ Not sampled this week

Reason given (check all that apply):

- ❑ Illness requiring bed rest
- ❑ Hospitalization
- ❑ Medical testing/Special Procedures
- ❑ Off-campus for non-medical reasons (i.e. family visit)
- ❑ Other, specify: _____

b. Number of sitting time sampling events this week (check one): ❑ 0 ❑ 1 ❑ 2 ❑ 3

Hours of sitting time at sampling event 1: ____ hours
❑ Sampling day, data missing
❑ N/A: Not a sampling day

Hours of sitting time at sampling event 2: ____ hours
❑ Sampling day, data missing
❑ N/A: Not a sampling day

Hours of sitting time at sampling event 3: ____ hours
❑ Sampling day, data missing
❑ N/A: Not a sampling day

4. Did LTCF staff report a change in the subject's medical or functional status?

❑ Yes ❑ No

If yes, describe: _____

_____

_____

5. Other comments?

❑ Yes ❑ No

If yes: _____

_____

FILE FORM IN SUBJECT FOLDER

Research Staff signature(s): _____ Date: __ __ / __ __ / __ __ __ __

_____ Date: __ __ / __ __ / __ __ __ __

# APPENDIX R

## WEEKLY MONITORING FORM-SEATING TEAM (WM2)

| | | |
|---|---|---|
| Initial Verification: _ _ / _ _ / _ _ _ _ | Initials: _____ | Subject ID __ __ - __ __ __ - __ __ __ __ __ |
| Entered: _ _ / _ _ / _ _ _ _ | Initials: _____ | Week: _____ |
| Verified at EDC: _ _ / _ _ / _ _ _ _ | Initials: _____ | **Form Version: 01/13/2014** |

## Weekly Monitoring Form (WM2) – Seating Team

Date __ __ / __ __ / __ __ __ __

1. a) Was subject assessed?
   - ❑ Yes
   - ❑ No, indicate reason for missed assessment (check one)
     - ❑ Subject unavailable for medical reasons (illness, testing, hospitalization, etc.)
     - ❑ Subject unavailable for non-medical reasons (family visit, etc.)
     - ❑ Subject declined assessment
     - ❑ Research staff unavailable
     - ❑ Other, specify: _____

   b) Was subject using study equipment?
   - ❑ Yes
   - ❑ No, indicate missing equipment (check one)
     - ❑ Cushion
     - ❑ Wheelchair
     - ❑ Wheelchair and Cushion

2. Is the patient wearing a disposable adult undergarment?
   ❑ Yes ❑ No ❑ Not Assessed

3. Is the patient catheterized?
   ❑ Yes ❑ No ❑ Not Assessed

4. On this date, was the patient alert and oriented to self?
   ❑ Yes ❑ No ❑ Not Assessed

5. On this date, was the patient easily agitated or combative?
   ❑ Yes ❑ No ❑ Not Assessed

6. Falls? ❑ Yes ❑ No

How many? _____

| Fall | Date of fall | How did it happen | Please describe circumstances (e.g. fell while transferring from wheelchair to toilet) | Level of Injury | Serious AE |
|---|---|---|---|---|---|
| 1 | __ __ / __ __ / __ __ __ __ | | | | ❑ No ❑ Yes |
| 2 | __ __ / __ __ / __ __ __ __ | | | | ❑ No ❑ Yes |
| 3 | __ __ / __ __ / __ __ __ __ | | | | ❑ No ❑ Yes |
| 4 | __ __ / __ __ / __ __ __ __ | | | | ❑ No ❑ Yes |
| 5 | __ __ / __ __ / __ __ __ __ | | | | ❑ No ❑ Yes |

**How did the fall happen?**

1. During wheelchair transfer
2. During wheelchair use other than transferring
3. Other

**Level of Injury:**

1. No injury – no evidence of any injury is noted on the physical assessment by the nurse or primary care clinician; no complaints of pain or injury by the resident; no change in the resident's behavior is noted after the fall.
2. Injury (except major) - skin tears, abrasions, lacerations, superficial bruises, hematomas and sprains; or any fall-related injury that causes the resident to complain of pain.
3. Major injury - bone fractures, joint dislocations, closed head injuries with altered consciousness, subdural hematoma.

7. Other adverse event? ❑ Yes ❑ No

How many? _____

| Event | Date of adverse event | Specify | Serious AE |
|---|---|---|---|
| 1 | __ __ / __ __ / __ __ __ __ | | ❑ No ❑ Yes |
| 2 | __ __ / __ __ / __ __ __ __ | | ❑ No ❑ Yes |

8. Other comments? ❑ Yes ❑ No

If yes: _____

_____

FILE FORM IN SUBJECT FOLDER

Research Staff signature(s): _____ Date: __ __ / __ __ / __ __ __ __

_____ Date: __ __ / __ __ / __ __ __ __

# APPENDIX S

## WHEELCHAIR CUSHION ADJUSTMENT

| | | | |
|---|---|---|---|
| Initial Verification: _ _ / _ _ / _ _ _ _ | | Initials: _____ | Subject ID _ _ - _ _ _ - _ _ _ _ _ |
| Entered: | _ _ / _ _ / _ _ _ _ | Initials: _____ | Week _____ |
| Verified at EDC | _ _ / _ _ / _ _ _ _ | Initials: _____ | **Form Version: 07/20/2012** |

## Wheelchair and Cushion Adjustments Form (WCA)

Date _ _ / _ _ / _ _ _ _ (mm/dd/yyyy)

Did you make any adjustments to the wheelchair or cushion?

❑ Yes ❑ No (form complete) ❑ Not Assessed (form complete)

**Wheelchair**

Participant received new wheelchair?

- ❑ No (continue to Backrest)
- ❑ Yes, indicate reason for new wheelchair (Complete EI form)
  - ❑ Fit
  - ❑ Damage
  - ❑ Other, specify _____

**Backrest**

- ❑ Adding an adjustable backrest
- ❑ Adjusting and aligning the AT backrest
- ❑ Changing the push handle's cane height
- ❑ Other_____

**Armrest**

- ❑ Changing the height
- ❑ Adjusting the screws
- ❑ Adding an arm extension
- ❑ Customizing an armrest (fit a lap tray, attached restraint device)
- ❑ Replacing an armrest
- ❑ Other_____

**Seat**

- ❑ Adding a drop seat
- ❑ Changing the seat height and/or angle
  - ❑ Adjusting the axle position
  - ❑ Adjusting the drop seat
- ❑ Adding Velcro
- ❑ Other_____

**Footrest**

❑ Changing to elevating footrest
❑ Adjusting the height
❑ Replacing the footrest
❑ Other_____

**Brakes**

❑ Adjusting the right/left break
❑ Replacing the right/left brake
❑ Adding an extension brake
❑ Other_____

**Cushion**

❑ Corrected cushion orientation (e.g. backwards, sideways, upside down)
❑ Reset the cushion per initial set-up (maintenance)
❑ Adjusted the cushion per changing needs
❑ Damaged and need to be changed

❑ New cushion →

| Type: | Size: |
|---|---|
| ❑ Roho Quattro | ❑ 16" x 16" |
| ❑ Vicare | ❑ 18" x 16" |
| ❑ Jay 3 | ❑ 20" x 16" |
| | ❑ 20" x 18" |

❑ Other_____

**Others**

❑ Adding Oxygen tank holder
❑ Adding a tray
❑ Quick release wheels locked
❑ Aide/Nursing staff educated about equipment use
→ Comments:_____

❑ Other_____

FILE FORM IN SUBJECT FOLDER

Research Staff signature(s): _____ Date: __ __/__ __/__ __ __ __

_____ Date: __ __/__ __/__ __ __ __

# APPENDIX T

## WHEELCHAIR SKILLS TEST (WST)

| | | |
|---|---|---|
| Initial Verification: _ _ / _ _ / _ _ _ _ | Initials: _____ | Subject ID __ __ - __ __ __ - __ __ __ __ __ |
| Entered: _ _ / _ _ / _ _ _ _ | Initials: _____ | Visit: ❑ Post-Rand ❑ Day7 ❑ Day14 ❑ Endpoint |
| Verified at EDC: _ _ / _ _ / _ _ _ _ | Initials: _____ | **Form Version: 06/14/2011** |

## Wheelchair Skills Test (WST)

Date: __ __ / __ __ / __ __ __ __ (mm/dd/yyyy)

Time start: ___ ___ : ___ ___ (military time)

Time finish: ___ ___ : ___ ___ (military time)

**Scoring Guide**
✓ = pass × = fail
NT = not tested (easier skill has been failed)

| | Individual Skills | Skill ✓ | Skill × | Safety ✓ | Safety × | Safety NT | Comments |
|---|---|---|---|---|---|---|---|
| 1. | Rolls forward 10m | ❑ | ❑ | ❑ | ❑ | ❑ | |
| 2. | Rolls backward 5m | ❑ | ❑ | ❑ | ❑ | ❑ | |
| 3. | Turns 90° while moving forward L&R | ❑ | ❑ | ❑ | ❑ | ❑ | |
| 4. | Turns 90° while moving backward L&R | ❑ | ❑ | ❑ | ❑ | ❑ | |
| 5. | Turns 180°in place | ❑ | ❑ | ❑ | ❑ | ❑ | |
| 6. | Gets through hinged door in both directions | ❑ | ❑ | ❑ | ❑ | ❑ | |
| | **Total Scores** | | | | | | |

Additional comments: _____

FILE FORM IN SUBJECT FOLDER

Research Staff signature(s): _____ Date: __ __ / __ __ / __ __ __ __

_____ Date: __ __ / __ __ / __ __ __ __

## BIBLIOGRAPHY


Aizen, E., Shugaev, I., & Lenger, R. (2007). Risk factors and characteristics of falls during inpatient rehabilitation of elderly patients. *Archives of gerontology and geriatrics, 44*(1), 1-12.

Al-Aama, T. (2011). Falls in the elderly Spectrum and prevention. *Canadian Family Physician, 57*(7), 771-776.

Axelson, P., Minkel, J., Chesney, D., & Thomas, P. (1994). *A guide to wheelchair selection: how to use the ANSI/RESNA wheelchair standards to buy a wheelchair*: Paralyzed Veterans of America.

Berg, K., Hines, M., & Allen, S. (2002). Wheelchair users at home: few home modifications and many injurious falls. *American journal of public health, 92*(1), 48-48.

Bergstrom, N., Braden, B. J., Laguzza, A., & Holman, V. (1987). The Braden scale for predicting pressure sore risk. *Nursing research, 36*(4), 205-210.

Best, K., Miller, W. C., Routhier, F., Eng, J. J., & Goldsmith, C. (2014). Feasibility of the Wheelchair Self-Efficacy Enhanced for Use (WheelSeeU) training program: study protocol for a randomized controlled trial. *Canadian journal of occupational therapy. Revue canadienne d'ergotherapie, 81*(5), 308.

Blake, A., Morgan, K., Bendall, M., Dallosso, H., Ebrahim, S., Arie, T., . . . Bassey, E. (1988). Falls by elderly people at home: prevalence and associated factors. *Age and ageing, 17*(6), 365-372.

Boninger, M. L., Cooper, R. A., Baldwin, M. A., Shimada, S. D., & Koontz, A. (1999). Wheelchair pushrim kinetics: body weight and median nerve function. *Archives of physical medicine and rehabilitation, 80*(8), 910-915.

Boswell-Ruys, C., Harvey, L., Delbaere, K., & Lord, S. R. (2010). A Falls Concern Scale for people with spinal cord injury (SCI-FCS). *Spinal cord, 48*(9), 704-709.

Brienza, D., Kelsey, S., Karg, P., Allegretti, A., Olson, M., Schmeler, M., . . . Holm, M. (2010). A randomized clinical trial on preventing pressure ulcers with wheelchair seat cushions. *Journal of the American Geriatrics Society, 58*(12), 2308-2314.

Brown, P. J., Roose, S. P., Fieo, R., Liu, X., Rantanen, T., Sneed, J. R., . . . Avlund, K. (2014). Frailty and depression in older adults: a high-risk clinical population. *The American Journal of Geriatric Psychiatry, 22*(11), 1083-1095.

Calder, C. J., & Kirby, R. L. (1990). Fatal wheelchair-related accidents in the United States. *American Journal of Physical Medicine & Rehabilitation, 69*(4), 184-190.

Campbell, A. J., Reinken, J., Allan, B., & Martinez, G. (1981). Falls in old age: a study of frequency and related clinical factors. *Age and ageing, 10*(4), 264-270.

Chen, W.-Y., Jang, Y., Wang, J.-D., Huang, W.-N., Chang, C.-C., Mao, H.-F., & Wang, Y.-H. (2011). Wheelchair-related accidents: relationship with wheelchair-using behavior in active community wheelchair users. *Archives of physical medicine and rehabilitation, 92*(6), 892-898.

Costello, E., & Edelstein, J. E. (2008). Update on falls prevention for community-dwelling older adults: review of single and multifactorial intervention programs. *J Rehabil Res Dev, 45*(8), 1135-1152.

Cuddigan, J., Berlowitz, D. R., & Ayello, E. A. (2001). Pressure ulcers in America: prevalence, incidence, and implications for the future. *Advances in skin & wound care, 14*(4), 208.

Daechsel, D., & BSR, O. (1988). Clinical trial of foam cushions in the prevention of decubitis ulcers in elderly patients. *Journal of rehabilitation research and development, 25*(2).

Davis, J., Robertson, M., Ashe, M., Liu-Ambrose, T., Khan, K., & Marra, C. (2010). International comparison of cost of falls in older adults living in the community: a systematic review. *Osteoporosis international, 21*(8), 1295-1306.

Downton, J., & Andrews, K. (1991). Prevalence, characteristics and factors associated with falls among the elderly living at home. *Aging Clinical and Experimental Research, 3*(3), 219-228.

Finlayson, M. L., Peterson, E. W., & Asano, M. (2013). A cross-sectional study examining multiple mobility device use and fall status among middle-aged and older adults with multiple sclerosis. *Disability and Rehabilitation: Assistive Technology, 9*(1), 12-16.

Finlayson, M. L., Peterson, E. W., & Cho, C. C. (2006). Risk factors for falling among people aged 45 to 90 years with multiple sclerosis. *Archives of physical medicine and rehabilitation, 87*(9), 1274-1279.

Fonad, E., Wahlin, T. B. R., Winblad, B., Emami, A., & Sandmark, H. (2008). Falls and fall risk among nursing home residents. *Journal of clinical nursing, 17*(1), 126-134.

French, D. D., Werner, D. C., Campbell, R. R., Powell-Cope, G. M., Nelson, A. L., Rubenstein, L. Z., . . . Spehar, A. M. (2007). A multivariate fall risk assessment model for VHA nursing homes using the minimum data set. *Journal of the American Medical Directors Association, 8*(2), 115-122.

Friedman, S. M., Williamson, J. D., Lee, B. H., Ankrom, M. A., Ryan, S. D., & Denman, S. J. (1995). Increased fall rates in nursing home residents after relocation to a new facility. *Journal of the American Geriatrics Society*.

Fries, B. E., Morris, J. N., Skarupski, K. A., Blaum, C. S., Galecki, A., Bookstein, F., & Ribbe, M. (2000). Accelerated dysfunction among the very oldest-old in nursing homes. *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences, 55*(6), M336-M341.

Fuller, G. F. (2000). Falls in the elderly. *American family physician, 61*(7), 2159-2168, 2173-2154.

Garber, S. L., Bunzel, R., & Monga, T. N. (2002). Wheelchair utilization and satisfaction following cerebral vascular accident. *Journal of rehabilitation research and development, 39*(4), 521.

Gardner, K. (2011). Outcome Measures in Patient Care.

Gavin-Dreschnack, D., Nelson, A., Fitzgerald, S., Harrow, J., Sanchez-Anguiano, A., Ahmed, S., & Powell-Cope, G. (2005). Wheelchair-related falls: current evidence and directions for improved quality care. *Journal of nursing care quality, 20*(2), 119-127.

Gell, N. M., Wallace, R. B., Lacroix, A. Z., Mroz, T. M., & Patel, K. V. (2015). Mobility device use in older adults and incidence of falls and worry about falling: Findings from the 2011–2012 National Health and Aging Trends Study. *Journal of the American Geriatrics Society, 63*(5), 853-859.

Giesbrecht, E. M., Mortenson, W. B., & Miller, W. C. (2012). Prevalence and Facility Level Correlates of Need for Wheelchair Seating Assessment among Long-Term Care Residents. *Gerontology, 58*(4), 378-384.

Gorecki, C., Brown, J. M., Nelson, E. A., Briggs, M., Schoonhoven, L., Dealey, C., . . . Nixon, J. (2009). Impact of pressure ulcers on quality of life in older patients: a systematic review. *Journal of the American Geriatrics Society, 57*(7), 1175-1183.

Grams, A., & Albee, G. W. (1995). Primary prevention in the service of aging. *Promoting successful and productive aging*(16), 5.

Greer, N., Brasure, M., & Wilt, T. J. (2012). Wheeled mobility (wheelchair) service delivery.

Gresham, G., Granger, C., Linn, R., & Kulas, M. (1999). Status of functional outcomes for stroke survivors. *Physical medicine and rehabilitation clinics of North America, 10*(4), 957-966.

Handfield-Jones, R. (1989). Falls in the elderly: a practical approach. *Canadian Family Physician, 35*, 637.

Hanson, K., Neuman, T., & Voris, M. (2003). *Understanding the health-care needs and experiences of people with disabilities: Findings from a 2003 survey*: Henry J. Kaiser Family Foundation.

Hegeman, J., Kok, R., Van der Mast, R., & Giltay, E. (2012). Phenomenology of depression in older compared with younger adults: meta-analysis. *The British Journal of Psychiatry, 200*(4), 275-281.

Hjelle, K. M., & Vik, K. (2011). The ups and downs of social participation: experiences of wheelchair users in Norway. *Disability and rehabilitation, 33*(25-26), 2479-2489.

Hofmann, M. T., Bankes, P. F., Javed, A., & Selhat, M. (2003). Decreasing the incidence of falls in the nursing home in a cost-conscious environment: A pilot study. *Journal of the American Medical Directors Association, 4*(2), 95-97.

Jensen, J., Lundin-Olsson, L., Nyberg, L., & Gustafson, Y. (2002). Fall and injury prevention in older people living in residential care facilities: a cluster randomized trial. *Annals of internal medicine, 136*(10), 733-741.

Jørgensen, V., Forslund, E. B., Franzén, E., Opheim, A., Seiger, Å., Ståhle, A., . . . Roaldsen, K. S. (2016). Factors Associated with Recurrent Falls in Individuals with Traumatic Spinal Cord Injury–a Multi-Center Study. *Archives of physical medicine and rehabilitation*.

Kalula, S. Z., De Villiers, L., Ross, K., & Ferreira, M. (2006). Management of older patients presenting after a fall-an accident and emergency department audit: original article. *South African Medical Journal, 96*(8), p. 718-721.

Kirby, R. L. (1997). Principles of wheelchair design and prescription. *Principles of neurologic rehabilitation. New York: McGraw-Hill*, 465-481.

Kirby, R. L., Ackroyd-Stolarz, S. A., Brown, M. G., Kirkland, S. A., & MacLeod, D. A. (1994). Wheelchair-related accidents caused by tips and falls among noninstitutionalized users of manually propelled wheelchairs in Nova Scotia. *American Journal of Physical Medicine & Rehabilitation, 73*(5), 319-330.

Kirby, R. L., & Smith, C. (2001). Fall during a wheelchair transfer: a case of mismatched brakes. *American Journal of Physical Medicine & Rehabilitation, 80*(4), 302-304.

Kirby, R. L., Swuste, J., Dupuis, D. J., MacLeod, D. A., & Monroe, R. (2002). The Wheelchair Skills Test: a pilot study of a new outcome measure. *Archives of physical medicine and rehabilitation, 83*(1), 10-18.

Kon, K., Hayakawa, Y., Shimizu, S., Nosaka, T., Tsuruga, T., Matsubara, H., . . . Ino, T. (2015). Development of an algorithm to predict comfort of wheelchair fit based on clinical measures. *Journal of physical therapy science, 27*(9), 2813.

Koontz, A. M., Brindle, E. D., Kankipati, P., Feathers, D., & Cooper, R. A. (2010). Design features that affect the maneuverability of wheelchairs and scooters. *Archives of physical medicine and rehabilitation, 91*(5), 759-764.

Lake, E. T., & Cheung, R. B. (2006). Are patient falls and pressure ulcers sensitive to nurse staffing? *Western Journal of Nursing Research, 28*(6), 654-677.

Lewicki, L. J., Mion, L., Splane, K. G., Samstag, D., & Secic, M. (1997). Patient risk factors for pressure ulcers during cardiac surgery. *AORN journal, 65*(5), 933-942.

Lindquist, N. J., Loudon, P. E., Magis, T. F., Rispin, J. E., Kirby, R. L., & Manns, P. J. (2010). Reliability of the performance and safety scores of the wheelchair skills test version 4.1 for manual wheelchair users. *Archives of physical medicine and rehabilitation, 91*(11), 1752-1757.

Lord, S. R., Tiedemann, A., Chapman, K., Munro, B., Murray, S. M., Ther, G. R., & Sherrington, C. (2005). The effect of an individualized fall prevention program on fall risk and falls in

older people: a randomized, controlled trial. *Journal of the American Geriatrics Society, 53*(8), 1296-1304.

Majmudar, S., Wu, J., & Paganoni, S. (2014). Rehabilitation in amyotrophic lateral sclerosis: Why it matters. *Muscle & nerve, 50*(1), 4-13.

Masud, T., & Morris, R. O. (2001). Epidemiology of falls. *Age and ageing, 30*(suppl 4), 3-7.

Medicare, C. f., & Services, M. (2013). Nursing home data compendium: 2010 edition.

Mikołajewska, E. (2012). The most common problems in wheelchair selection–own observations. *Journal of Health Sciences, 2*(1), 89-93.

Mikołajewska, E. (2013). Wheelchair-related falls–a review. *International Journal on Disability and Human Development, 12*(3), 259-266.

Mills, T. L., Holm, M. B., & Schmeler, M. (2007). Test-retest reliability and cross validation of the functioning everyday with a wheelchair instrument. *Assistive Technology, 19*(2), 61-77.

Mortenson, W. B., Demers, L., Fuhrer, M. J., Jutai, J. W., Lenker, J., & DeRuyter, F. (2012). How assistive technology use by individuals with disabilities impacts their caregivers: A systematic review of the research evidence. *American Journal of Physical Medicine & Rehabilitation, 91*(11), 984-998.

Mortenson, W. B., Miller, W. C., & Auger, C. (2008). Issues for the selection of wheelchair-specific activity and participation outcome measures: a review. *Archives of physical medicine and rehabilitation, 89*(6), 1177-1186.

Mulrow, C. D., Gerety, M. B., Kanten, D., Cornell, J. E., DeNino, L. A., Chiodo, L., . . . Solis, R. M. (1994). A randomized trial of physical rehabilitation for very frail nursing home residents. *Jama, 271*(7), 519-524.

Nelson, A. L., Groer, S., Palacios, P., Mitchell, D., Sabharwal, S., Kirby, R. L., . . . Powell-Cope, G. (2010). Wheelchair-related falls in veterans with spinal cord injury residing in the community: a prospective cohort study. *Archives of physical medicine and rehabilitation, 91*(8), 1166-1173.

Okunribido, O. O. (2013). Patient Safety During Assistant Propelled Wheelchair Transfers: The Effect of the Seat Cushion on Risk of Falling. *Assistive Technology, 25*(1), 1-8.

Organization, W. H. (2008). *Guidelines on the provision of manual wheelchairs in less resourced settings*.

Pancorbo-Hidalgo, P. L., Garcia -Fernandez, F. P., Lopez-Medina, I. M., & Alvarez-Nieto, C. (2006). Risk assessment scales for pressure ulcer prevention: a systematic review. *Journal of advanced nursing, 54*(1), 94-110.

Paniagua, M. A., Malphurs, J. E., & Phelan, E. A. (2006). Older patients presenting to a county hospital ED after a fall: missed opportunities for prevention. *The American journal of emergency medicine, 24*(4), 413-417.

Park-Lee, E., & Caffrey, C. (2009). Pressure ulcers among nursing home residents: United States, 2004. *NCHS data brief*(14), 1-8.

Peel, C., Baker, P. S., Roth, D. L., Brown, C. J., Bodner, E. V., & Allman, R. M. (2005). Assessing mobility in older adults: the UAB Study of Aging Life-Space Assessment. *Physical Therapy, 85*(10), 1008-1019.

Prudham, D., & Evans, J. G. (1981). Factors associated with falls in the elderly: a community study. *Age and ageing, 10*(3), 141-146.

Ray, W. A., Taylor, J. A., Meador, K. G., Thapa, P. B., Brown, A. K., Kajihara, H. K., . . . Griffin, M. R. (1997). A randomized trial of a consultation service to reduce falls in nursing homes. *Jama, 278*(7), 557-562.

Reddy, M., Gill, S. S., & Rochon, P. A. (2006). Preventing pressure ulcers: a systematic review. *Jama, 296*(8), 974-984.

Rubenstein, L. Z., Josephson, K. R., & Robbins, A. S. (1994). Falls in the nursing home. *Annals of internal medicine, 121*(6), 442-451.

Russell, M. A., Hill, K. D., Day, L. M., Blackberry, I., Schwartz, J., Giummarra, M. J., . . . Dharmage, S. C. (2010). A randomized controlled trial of a multifactorial falls prevention intervention for older fallers presenting to emergency departments. *Journal of the American Geriatrics Society, 58*(12), 2265-2274.

Salter, A., Khan, K. M., Donaldson, M., Davis, J., Buchanan, J., Abu-Laban, R. B., . . . McKay, H. A. (2006). Community-dwelling seniors who present to the emergency department with a fall do not receive Guideline care and their fall risk profile worsens significantly: a 6-month prospective study. *Osteoporosis international, 17*(5), 672-683.

Schein, R. M., Schmeler, M. R., Holm, M. B., Pramuka, M., Saptono, A., & Brienza, D. M. (2011). Telerehabilitation assessment using the Functioning Everyday with a Wheelchair-Capacity instrument. *Journal of rehabilitation research and development, 48*(2), 115-124.

Schmeler, M. R. (2006). *Wheelchair functional outcomes measures & functioning everyday with a wheelchair tools.* Paper presented at the Canadian Seating and Mobility Conference.

Smith, D. M. (1995). Pressure ulcers in the nursing home. *Annals of internal medicine, 123*(6), 433-438.

Smith, R. O. (1996). Measuring the outcomes of assistive technology: challenge and innovation. *Assistive Technology, 8*(2), 71-81.

Spaniolas, K., Cheng, J., Gestring, M., Sangosanya, A., Stassen, N., & Bankey, P. (2010). Ground level falls are associated with significant mortality in elderly patients.(2010). *Journal of Trauma: Injury, Infection and Critical Care, 69*(4), 821-825.

Taylor, M. E., Delbaere, K., Lord, S. R., Mikolaizak, A. S., Brodaty, H., & Close, J. C. (2014). Neuropsychological, physical, and functional mobility measures associated with falls in cognitively impaired older adults. *The Journals of Gerontology Series A: Biological Sciences and Medical Sciences, 69*(8), 987-995.

Teasell, R., McRae, M., Foley, N., & Bhardwaj, A. (2002). The incidence and consequences of falls in stroke patients during inpatient rehabilitation: factors associated with high risk. *Archives of physical medicine and rehabilitation, 83*(3), 329-333.

Tinetti, M. E., & Ginter, S. F. (1990). The Nursing Home Life-space diameter *Journal of the American Geriatrics Society, 38*(12), 1311-1315.

Tinetti, M. E., Liu, W.-L., & Claus, E. B. (1993). Predictors and prognosis of inability to get up after falls among elderly persons. *Jama, 269*(1), 65-70.

Tinetti, M. E., Speechley, M., & Ginter, S. F. (1988). Risk factors for falls among elderly persons living in the community. *New England journal of medicine, 319*(26), 1701-1707.

Wood-Dauphinee, S., Opzoomer, M., Williams, J., Marchand, B., & Spitzer, W. (1988). Assessment of global function: The Reintegration to Normal Living Index. *Archives of physical medicine and rehabilitation, 69*(8), 583-590.

Xiang, H., Chany, A., & Smith, G. A. (2006). Wheelchair related injuries treated in US emergency departments. *Injury prevention, 12*(1), 8-11.

Yang, Y., Feldman, F., Leung, P. M., Scott, V., & Robinovitch, S. N. (2015). Agreement between video footage and fall incident reports on the circumstances of falls in long-term care. *Journal of the American Medical Directors Association, 16*(5), 388-394.