THE IMPACT OF PHYSICAL VERSUS SOCIAL ACTIVITY ON THE PHYSICAL
AND COGNITIVE FUNCTIONING OF SENIORS WITH DEMENTIA

A Thesis

submitted to the Faculty of Graduate Studies and Research

in partial fulfillment of the requirements

for the Degree of

Master of Science

in Gerontology

University of Regina

By

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SUPERVISORY AND EXAMINING COMMITTEE

Jonathan Brody Harris, candidate for the degree of Master of Science in Gerontology, has presented a thesis titled, ***The Impact of Physical Versus Social Activity on the Physical and Cognitive Functioning of Seniors with Dementia***, in an oral examination held on March 8, 2012. The following committee members have found the thesis acceptable in form and content, and that the candidate demonstrated satisfactory knowledge of the subject material.

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Chair of Defense:	Dr. Rod Dolmage, Associate Dean, Faculty of Education

***Not present at defense**

ABSTRACT

Introduction: Physiological effects of aging combined with abnormal cognitive decline often lead to decreased functional independence among older adults with dementia.

Those who reside in long-term care (LTC) are even more prone to loss of functional independence as they are typically at a more advanced stage of dementia and require a higher level of care with activities of daily living relating to self-care.

Purpose: The purpose of this study was to determine if regular physical activity was effective at maintaining/improving physical and cognitive function in this population as compared to a comparable social activity intervention.

Methods: Sixteen older adults with dementia residing in a Regina LTC facility were randomly assigned to either a walking program (3 days per week), or a non-walking condition which involved a weekly group social visit with student volunteers for 12 weeks. Functional indicators assessed at baseline, after six weeks, and after 12 weeks were timed up-and-go, functional reach, and six-minute walk. Cognitive function was assessed using the Mini-Mental State Examination. Descriptive data, including age, education level, prescribed medications, and co-morbid health conditions were collected through chart audits. Mixed-model ANOVA was used to assess within and between group differences.

Results: No statistically significant differences were found between the two groups in timed up-and-go, functional reach, six-minute walk, or Mini-Mental State at any time point. However, at the individual level, differences were observed in percent change scores in timed-up-and-go, six-minute walk, and Mini Mental State from baseline to the end of the 12 weeks.

Conclusion: No differences were found in the effectiveness of a physical activity intervention as compared to a social activity intervention in the maintenance of physical and cognitive function in LTC residents with dementia. However, individual percent change scores showed a beneficial effect of physical activity for some participants.

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Last, I must extend my most sincere thanks to my supervisor, Dr. Shanthi Johnson. She has been an invaluable mentor throughout this process, and her passion for and commitment to the health of older adults is a constant source of inspiration.

Dedication

Without the endless love and support of my parents, John and Barbara Harris, this project could not have been completed. Also, this work is dedicated to Billy, Marjorie, Walter, Cyril, Pina, Percy, and all of the other individuals with dementia and their carepartners who have made an impact on my life to date.

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1. INTRODUCTION AND LITERATURE REVIEW

1.1 Population aging

Older adults (aged 65 years and older) are the fastest growing segment of the Canadian population (Statistics Canada, 2006). Saskatchewan's population currently has the highest proportion of older adults (14.9% in 2006) of any province in Canada (Statistics Canada, 2006). As the demographic post-Second World War baby boom generation enters old age in the coming years, this proportion will continue to rise not only in Saskatchewan but also nationwide. By the year 2031, all of the baby boom generation will have reached the age of 65 and 25% of Canada's population will be aged 65 and older (Statistics Canada, 2009). This unprecedented rate of population aging emphasizes the need to maintain health, quality of life, and overall function of the older population into late life.

Although a high proportion of Canadian older adults report living in good health well past the age of 65, more than 25% are limited in their ability to perform activities of daily living by chronic or age-related health conditions (Health Canada, 2002). Older adults also have much higher rates of health service utilization, prescription medication use, hospitalization and institutionalization than their younger counterparts (Health Canada and Interdepartmental Committee on Aging & Seniors Issues, 2002). As the proportion of older adults in the Canadian population continues to rise, so too will rates of age-related conditions such as dementia.

1.2 Dementia

Dementia is a syndrome caused by disease of the brain that leads to a progressive decline in cognitive functioning, including deficits in memory, learning, orientation,

language, comprehension, and judgement (Feldman et al., 2008). Although dementia does not exclusively affect older adults, those over 65 years of age represent the vast majority of diagnosed cases. While it is known that the brain begins to show natural structural decline around the age of 30 years (Raz, 2000), dementia is a specific pathology that is not associated with normal healthy aging.

Dementia is typically viewed as a single disease entity or divided into broad categories (Rockwood & Middleton, 2007). Alzheimer's Disease International and the Alzheimer's Society of Canada classify dementia into four separate disease states: Alzheimer disease, vascular dementia, frontotemporal dementia, and Lewy body dementia. These states represent four distinct pathologies that may present very similarly. However, the extent to which these diseases can be differentiated in older adults is minimal, and this uncertainty can lead to confusion regarding the best ways of treating and managing symptoms of dementia (Rockwood & Middleton, 2007).

The most common form of dementia, Alzheimer disease, is believed to be caused by two specific mechanisms affecting the processing of two key neuronal proteins, amyloid-precursor protein (APP) and tau protein. APP is an integral membrane protein found in the synapses of neurons that plays an important role in neuronal structure, function, and plasticity. Abnormal proteolytic cleavage of APP leads to the formation of a shorter protein called β -amyloid or $A\beta$ (Zheng & Koo, 2006). $A\beta$ has no known function in human biologic systems. It inhibits neural conduction and can initiate an inflammatory response that ultimately leads to neuronal apoptosis, or pre-programmed cell death (Zheng & Koo, 2006).

Much like APP, tau protein is important to the structure of neurons. Tau is primarily responsible for the structure of microtubules, tiny vessels through which nutrients and intracellular organelles are transported within the neuron. When tau is hyperphosphorylated, meaning that phosphate groups are added to all available active sites, it collapses into its primary structure, leading to the formation of neurofibrillary tangles. These tangles affect the structural integrity of the protein and prevent nutrients from passing through, leading eventually to neuronal death (Tang-Wai, Josephs, & Peterson, 2007).

Vascular dementia (also sometimes called multi-infarct dementia) is a broad term used to describe any dementia caused specifically by a dysfunction of the vascular system. It is most often caused by tissue hypoxia occurring as a result of a stroke (Alzheimer Society of Canada, 2009). However, in rare cases, vascular dementia may be caused by small vessel disease that inhibits microcirculation in the grey matter, causing cell death and degradation in this area of the brain (Kalaria & Ballard, 1999). Either mechanism may lead to permanent lesions in the brain, inhibiting circulation and causing the breakdown of smooth muscle within blood vessels, leading to neuronal death (Kalaria & Ballard, 1999).

Lewy body dementia, a less common but highly debilitating form, is caused by intracytoplasmic formations (Lewy bodies) that are composed of altered neurofilaments such as ubiquitin. Although it is not known how or why Lewy bodies form, it is known that, much like A β and tau, they have a profound neurotoxic effect (Kalra, Bergeron, & Lang, 1996).

Diagnosing these various forms of dementia is difficult to do in vivo. A formal assessment to diagnose dementia includes collecting an extensive history, rigorous physical assessment, and a battery of cognitive and neuropsychological testing (Feldman et al., 2008). Neuroimaging using computed tomography (CT) or magnetic resonance imaging (MRI) scan may also be used depending on availability of the technology. These techniques involve non-invasive scans that are used to create images of the brain and can be useful in identifying brain atrophy characteristic of dementia. Other screening measures, such as positron emission tomography (PET) scans, analysis of cerebrospinal fluid for biomarkers, and genotyping/genetic counselling exist but are not yet readily available and are currently unlikely to be recommended by family physicians (Feldman et al., 2008).

The most recent World Alzheimer Report (Alzheimer's Disease International, 2009) estimated that over 35 million people worldwide would be living with dementia in 2010. This represents a substantial increase from a previous estimate of 24.2 million in 2001 from an Alzheimer's Disease International-commissioned delphi study (Ferri et al., 2005). Available evidence suggests that the worldwide prevalence of dementia will double every 20 years until the year 2050. Among North American older adults, the prevalence of dementia has been reported to double with each 5.5 year increase in age after 65 years (Alzheimer's Disease International, 2009). Although this unprecedented increase is fuelled primarily by higher than average rates of population aging in the developing world, developed nations such as Canada are also expected to see a significant upswing in dementia prevalence (Alzheimer's Disease International, 2009).

A study commissioned by the Alzheimer Society of Canada, entitled “Rising Tide: The Impact of Dementia on Canadian Society” estimates that half a million Canadians currently are currently living with dementia, with this number expected to rise to 1.1 million within a generation. This means the prevalence of dementia has nearly doubled since the initial estimate from the 1991 Canadian Study on Health and Aging (CSHA), and will increase four-fold by the year 2038. Dementia is more prevalent in females than males, and it is estimated that 72% of all individuals with dementia in Canada are women (Alzheimer Society of Canada, 2009), a proportion that is unlikely to change much given that women have longer life expectancy, thus a greater likelihood of developing dementia.

Dementia is a condition that greatly impacts quality of life for those affected and also one that presents a significant burden to health care systems around the world. According to the World Health Organization, dementia is the second highest contributor of years lived with disability worldwide, contributing over 7.4 million years of dependence and disability among sufferers. This number is higher than the contributions of cardiovascular disease, cancer, and diabetes (Mathers, Fat, Boerma, World Health Organization, & Joint United Nations Programme on HIV/AIDS, 2008). Dementia is estimated to cost \$315 billion per year internationally, with the vast majority of this cost being absorbed by developed nations (Wimo, Winblad, & Jonsson, 2007). The last definitive estimate of the cost of dementia in Canada, based on 1991 data from the CSHA, showed that just under \$4 billion was spent annually on the condition at the time (Ostbye & Crosse, 1994). The Rising Tide study estimates that the total direct and indirect economic cost of dementia in Canada in 2008 was roughly \$10 billion, with an

additional \$5 billion cost for lost productivity of those providing informal or unpaid care. This \$15 billion cost is expected to rise to nearly \$153 billion by 2038 as the prevalence of dementia rises due to population aging (Alzheimer Society of Canada, 2010).

1.3 Dementia and physical function

While dementia care into late life represents a significant economic burden, it is important to remember the impact that this illness can have on the quality of life of older adults. One such factor that leads to increased institutionalization and reduced quality of life among those with dementia is difficulties with movement and motor control that often arise as symptoms. These difficulties magnify the normal age-related conditions that can negatively affect physical function. After the age of 45, static and dynamic muscle strength begin to deteriorate, with a loss of about five percent function every year. (van Doorn et al., 2003). This effect is most pronounced in type II (fast-twitch) muscle fibres in the legs (van Doorn et al., 2003). Total body muscle mass can also decrease up to 50% as we age through muscular atrophy and sarcopenia occurring between the ages of 50 and 80 years (Faulkner, Larkin, Claflin, & Brooks, 2007). Those with dementia are particularly susceptible to muscle disuse atrophy (Mechling, 2008), potentially as a result of inactivity and inadequate dietary intake. Maximal aerobic capacity also declines naturally with age (Mazzeo et al, 1998). In a study of over 6000 healthy community dwelling older adults over the age of 70 years, 26% could not climb even one set of stairs without stopping, 31% could not lift 10 lbs (the approximate weight of one bag of groceries) and 36% reported having trouble walking several city blocks (Clark, Stump, Hui, & Wolinsky, 1998).

In addition to these physiologic changes, motor performance is specifically affected by dementia pathologies. Gait can be particularly affected, including stride length and walking speed. It is believed that while walking requires only limited attentional resources in younger, healthy people, older adults require full cortical control of gait (Dubost et al., 2008). This means that walking requires cognitive ability and attention in older populations. Rhythmic and dual-task motor skills can also be affected (Beauchet et al., 2008), which can make it more difficult to take part in physical activity.

These motor symptoms are caused by changes in brain structure and function due to the pathology of dementia. Important centres in the brain that are involved in the control of voluntary movement are the frontal and temporal lobes as well as the hippocampus. The hippocampus also plays an important role in procedural memory, which is important for more complex motor skills. Dementia causes shrinkage and dysfunction of all three of these important brain structures, and it is hypothesized that this leads to associated motor dysfunction (Beauchet et al., 2008). Dementia also affects neurotransmitter production and function, which increases excitability in the motor cortex of the brain, an important site for the initiation of locomotion (Francis, Palmer, Snape, & Wilcock, 1999). This increased motor excitability may lead to the psychomotor agitation that is a common symptom of the disease (Cummings & Cole, 2002).

In combination, these physiologic and neurologic changes lead to a variety of issues with movement for those with dementia. Thus, this population may have difficulty adapting not only to changes in strength and endurance, but also in the way in which they are able to process, perform, and learn new motor skills. There is a variety of existing evidence to suggest that cognitive impairment associated with dementia and other

geriatric cognitive disorders is directly related to deficits in physical function regardless of the stage or severity of these conditions. A number of epidemiologic studies have shown that impaired cognitive function, even when not a product of a dementia, is a strong predictor of limitations with physical function (Freid, Ettinger, Ling, Newman, & Gardin, 1994; Grenier, Snowdon, & Schmitt, 1996; Moritz, Kasl, & Berkman, 1995). Impaired physical function has also been shown to be a predictor of the development of Alzheimer disease and other dementias in later life (Wang, Larson, Bowen, & van Belle, 2006). One study by Petterson, Olsson, and Wahlund (2005) found that people with even very mild diagnosed dementia had poorer performance on mobility and dual task procedures than individuals with cognitive impairment but no dementia (CIND) and those with no cognitive impairment at all. This study also found that balance was the only indicator of physical function that was a statistically significant correlate of physical activity level (Petterson et al., 2005). These findings indicate that even mild degrees of clinically significant cognitive impairment may be associated with limitations in physical functioning.

These deficits with physical function which may arise as a result of cognitive impairment can also translate into difficulties performing activities of daily living (ADLs). ADL abilities are not only important determinants of quality of life in aging populations, but also clinically meaningful predictors of overall executive function (Rockwood, 2007). Of course, these issues with physical function and ADL ability may lead to older adults with dementia participating in less meaningful daily physical activity. All of these changes, including this decreased activity level, may contribute to the two-to-threefold increase in falls (van Doorn et al., 2003) in those with dementia.

As previously noted, a variety of physiologic and neurologic factors can make it difficult for individuals with dementia to safely participate in adequate daily physical activity. However, physical activity has many benefits for this population. A wide variety of existing evidence shows that being physically active can both prevent dementia and have a positive impact on cognitive health. Being physically active throughout the aging process has been shown to reduce dementia incidence (Abbott et al., 2004). There are two proposed mechanisms by which this reduction is believed to occur. Barnes, Whitmer, and Yaffe (2007) point out in a recent review that obesity, diabetes, and vascular risks such as hypertension and cardiovascular disease, all independent risk factors for dementia, are decreased by engaging in regular physical activity of sufficient intensity. This same review also points to a more direct mechanism which supports the possibility that physical activity enhances neuronal function within the brain. It has been shown that acute exercise causes up-regulation of a neurotrophin called brain-derived neurotrophic factor (BDNF) that stimulates the growth and proliferation of new nerve cells within the brain (Vaynman & Gomez-Pinilla, 2005). This increase in BDNF could stimulate plastic change within the brain and perhaps even reverse some of the natural deterioration of brain structures and neuronal function as a part of neurodegenerative conditions like dementia. The effectiveness of regular physical activity at improving cognition in those already with dementia has not yet been widely investigated, but there is a growing body of literature suggesting it may have positive effects (Yu, Kolanowski, Strumpf, & Eslinger, 2006).

Rockwood and Middleton (2007) suggest that existing evidence infers a dose-response relationship between physical activity and cognitive function, especially in

previously sedentary individuals. However, much if not all of the existing research is epidemiologic in nature and investigates only the influence of activity level on development of dementia or cognitive impairment in later life. Only a few intervention studies have specifically investigated the effects of an exercise intervention on the cognition of those already experiencing symptoms of AD or a related dementia. One study (Palleschi et al., 1996) showed improvements for a group of older males with dementia of the Alzheimer type (DAT) on a battery of psychometric tests including the Folstein Mini-Mental State Exam (MMSE) after three months of aerobic training three times per week for 20 minutes with cycle ergometres. Results from a randomized controlled trial indicated that an individually designed exercise program done for 30 minutes, three times per week for the same time period resulted in maintenance or improvement of performance in the Clock Drawing test, another widely used psychometric test for those with dementia residing in nursing homes (Stevens & Killeen, 2006).

There is also evidence to suggest that physical activity may have a positive effect on physical function in aging populations. In normal healthy aging individuals, regular physical activity has been shown to improve measures of physical fitness such as muscular strength and endurance, aerobic capacity, flexibility, and balance. Smaller beneficial effects also exist for markers of physical disability and physical function (Manini & Pahor, 2009).

1.4 Literature Review

Comparatively less is known about the effect of physical activity on fitness and physical function in older adults affected by dementia than in cognitively healthy older

adults. A recent Cochrane review (Forbes et al., 2008) identified only two randomized controlled trials that measured physical function as an outcome as part of a broader investigation of physical activity for those with dementia, and concluded that supporting evidence for a positive effect was insufficient. An earlier meta-analysis on the topic (Heyn, Abreu, & Ottenbacher, 2004) included 30 studies conducted from 1970 to 2004, twelve of which examined one or more functional indicators. The authors found a positive effect on physical fitness and function as a result of taking part in regular activity. However, many of the included studies focused more on health-related indicators of physical fitness and did not assess physical function independently. Thus, further research is needed into the effect of regular physical activity on physical function in older adults with dementia.

Given the gap between these two existing reviews (Forbes et al., 2008; Heyn, Abreu, & Ottenbacher, 2004), a further systematic review was conducted (Harris & Johnson, 2010). This review examined studies of adults with dementia published from January 1995 to September 2010 that directly assessed physical function before and after a physical activity program. A systematic search of articles was conducted in four major online databases of peer-reviewed literature: Medline/PubMed, SportDiscus, PsycInfo, and the Cochrane Library. Seventeen studies were identified that examined the impact of physical activity interventions on direct indicators of physical function. Indicators of physical function refer to measurements of one's capacity to complete activities instrumental to caring for oneself and others on a daily basis (Connelly, 2008).

In older adults with dementia, functional indicators are preferable to raw indicators of physical fitness (such as maximal strength or aerobic capacity). This is

because functional indicators are tied directly to daily activities that contribute to quality of life and independence, and deficits in physical function may be related to cognitive deficits as much as physical changes associated with aging (Rockwood, 2007).

The most common indicators of physical function used in the included studies and what they measured are shown in Appendix A. Common measures of physical function used included tests of balance, timed walking speed, and independence in functional activities (Connelly, 2008). In this review, the most commonly used functional indicators were the Timed Up and Go (TUG) test (Podsiadlo & Richardson, 1991), the Katz activities of daily living (KADL) scale (Katz, Ford, Moskowitz, Jackson, & Jaffe, 1963), the Tinetti balance scale (Tinetti, 1986), the six-minute walk test (Guyatt et al., 1985) and the functional reach test (Duncan, Weiner, Chandler, & Studenski, 1990). The TUG, a test of basic functional mobility, measures one's ability to independently and efficiently transfer from a seated position to walking. The KADL scale assesses one's independence in six fundamental areas of self-care: bathing, dressing, toileting, transferring (from sitting/lying to standing), continence and feeding. The six-minute walk test is a quick, submaximal test of functional aerobic fitness, with a greater distance walked believed to indicate a greater level of aerobic fitness. The Tinetti scale and the functional reach test are both measures of balance. However, the Tinetti scale assesses both static and dynamic balance, while functional reach measures only dynamic standing balance.

The vast majority of the included studies (14/17, ~82%) showed that taking part in the exercise intervention led to statistically significant within-subject improvements in at least one of the targeted indicators of physical function. A summary of the results of the included studies is shown in Appendix B. One study (Brill et al, 1995) reported

improvements in strength and balance, although these improvements were not quantified. For most studies with statistically significant results, improvement meant that those taking part in the intervention actually experienced gains in specific performance measures. For other studies (Rolland et al, 2007; Tappen et al, 2000), this statistically significant difference reflected reduced decline as compared to a control or alternative treatment group. This reduced decline implies that while participants did not show improvements in physical function, their performances declined less over time compared to their peers who were not taking part in the same intervention. It is important to note that both studies which investigated reduced decline were conducted in long-term care settings where participants were typically more advanced in age (mean >83 years of age) and included individuals classified as having severe dementia (mean Mini-Mental Status Exam scores <11).

Among the functional outcomes that showed statistically significant improvement were balance, muscular strength and endurance, functional mobility, independence in ADLs, flexibility, gait and gait speed, and aerobic capacity and endurance. While most of these indicators are related to falls and fall-related injuries (Kannus, Sievänen, Palvanen, Järvinen, & Parkkari, 2005), the single study that included reducing falls and fractures as a secondary outcome (Rolland et al., 2007) found no statistically significant difference between either over 12 months in the group receiving the exercise intervention compared to those receiving routine care.

The nature of the interventions varied considerably. Most integrated a combination of aerobic, strength, and balance training (Rolland et al., 2007; Rolland et al., 2000; Santana-Sosa, Barriopedro, Lopez-Mojares, Perez, & Lucia, 2008). Many

specifically trained muscular strength and endurance of the lower body, targeting hip, knee, and ankle flexors and extensors. Others focused solely on activities like walking or stationary biking (Tappen et al., 2000; Rolland et al., 2000). Both approaches showed positive effects on physical function. However, for those with severe cognitive impairment as a result of dementia, simpler activities like walking may be preferable due to relative safety and ease of delivery.

Interventions that were most effective at improving indicators of physical function were those performed regularly (three times weekly or more) in groups for a period of at least 12 weeks. Successful interventions were also typically structured and supervised by qualified professionals in the field of rehabilitation, such as physiotherapists or occupational therapists. While some less structured programs (Francese, Sorel, & Butler, 1997) and individualized interventions (Christofolini et al., 2008; Teri et al., 1998) did show positive results, these types of programs tended to have poorer adherence as compared to structured group interventions.

Of the 17 studies, eight were conducted in long-term care settings. All eight long-term care studies showed positive results. The long-term care setting offered many positive attributes for delivering an exercise intervention. Studies conducted in long-term care had higher rates of adherence and were longer in length than those conducted in adult day programs, acute care facilities, or the community. Long-term care residents are on-site at all times and typically stay at the facility for an extended period. Thus, researchers and rehabilitation professionals have access to them for more often and for a longer period of time. The inherent group socialization involved with bringing residents

of long-term care community together to participate in a physical activity program may also enhance adherence.

Delivering exercise interventions in long-term care facilities presented specific challenges. Older adults who reside in long-term care facilities tend to require a high level of care and supervision as compared to community dwelling elders (Berta, Laporte, & Valdmanis, 2005). This is especially true of those with dementia living in long-term care. The higher relative care and supervision level adds to the need for supervision for the safe and effective delivery of physical activity programs in long-term care, although this can be both time and labour-intensive.

A recurring issue throughout most of the studies was the measure of exercise intensity. Many authors did not report how intensity was measured, and a number of others mentioned that exercises were performed at progressive intensities with little detail provided on how the principles of progression were applied (Christofolletti et al., 2008; Francese et al., 1997; Rolland et al., 2000; Toulotte, Fabre, Dangremont, Lensel, & Thévenon, 2003). In most cases where intensity was taken into consideration, it was not quantified. Strength training was typically termed to be progression as tolerated (Binder, 1995), while aerobic exercise, if quantified, was to be performed to moderate breathlessness (Rolland et al., 2007). While these measures are indirect indicators of intensity, physiologic measures or standardized tests such as the estimated one repetition maximum (1RM) for weight training would have ensured that comparable intensities were reached for all participants. However, using these measures adds to the considerable challenges in working with this population and may add additional safety concerns.

Two trials in this review used an indirect measure of intensity, known as the talk test, with some success (Arkin & Morrow-Holwell, 1999; Arkin, 2003). The talk test rates intensity by one's ability to speak comfortably while taking part in exercise. Participants are asked to rate difficulty with speech while taking part in the activity as not difficult, a bit difficult, or very difficult. If speech is not at all difficult, then the individual is likely not reaching an intensity at which cardiorespiratory training effects will be seen. Conversely, if speech is very difficult and each word is laboured, the individual may be reaching a state of fatigue or over-exertion that could be dangerous, particularly in the older adult population. Ideally, speech should be noticeably more difficult than at rest, indicating that the individual is in a cardiorespiratory training zone (Persinger, Foster, Gibson, Fater, & Porcari, 2004).

A recurring issue with trials in this review was adherence. Up to 25% drop-out was seen in some studies (Salazar & Hageman, 2003; Tappen, Roach, Applegate, & Stowell, 2000; Teri et al., 1998). Three studies did not formally report adherence. In those studies that did measure adherence, the way in which it was measured was inconsistent. Eleven studies measured adherence only as whether or not the participant completed the study, while three studies looked at the number of exercise sessions attended by participants who stayed in the study until completion. Participant drop-out was of particular issue for the studies conducted in acute and adult day settings, as any change in care level could have been cause for a participant to leave the facility or be dropped from the study. Adherence was highest in studies where the intervention was conducted in group settings (Francese et al., 1997, Toulotte et al., 2003) and when the intervention involved a broad range of activities. Longer studies tended to have poorer

adherence. For example, Rolland et al. (2007) used a 12 month intervention, which was the longest of study reviewed and an exceptionally long intervention compared to most intervention studies in long-term care settings. While 82% of the 134 participants completed pre- and post-tests on the performance measures, only 13 of these (19.4%) had what the authors classed as high adherence, meaning they had attended at least two-thirds of all exercise sessions. That participation tended to be infrequent may have had profound effects on whether or not training effects were seen.

Intervention length was also an issue. Twelve weeks is the most widely used intervention length for both strength and aerobic training in older adults, with training adaptations not thought to be seen in this population until around the eighth week (Johnson & Vandervoort, 2008). Indeed, the vast majority of studies in this review showing statistically significant effects took place over a time period of at least 12 weeks. While longer interventions may be favourable in showing the effects of chronic physical activity on the progressive symptoms of dementia, the few longer trials (six to 12 months in length) included for review suffered from poor adherence and retention (Christoforetti et al., 2008; Rolland et al., 2007).

In terms of research design, no existing study has included a control group that receives attention comparable to the group taking part in the physical activity intervention. Most of the included studies use physical activity programs that take place either in a group or under direct supervision, meaning that participants are engaged in meaningful social activity in addition to physical activity. For this reason, it is difficult to determine whether changes in cognitive or physical function are attributable to the

increase in physical activity or the inherent increase in social activity and social connectedness.

Although there are a number of recent studies of high quality that have been identified in this review, methodologies and intervention types have varied among past studies. Future research that integrates the positive aspects of existing evidence would be a step in the right direction for designing a program that can easily and safely be implemented as part of care plans for older adults with dementia in a variety of settings.

1.5 Purpose

The purpose of this study was to assess the effect of a regular, 12 week supervised walking program on indicators of physical and cognitive function in adults 65 years of age and older with dementia residing in a long-term care facility in Regina, Saskatchewan.

1.6 Hypothesis

It was hypothesized that taking part in a regular walking program would improve both physical and cognitive function over the 12 week intervention period as compared to a control group that took part in a social activity program with no change in their daily physical activity level.

2. METHODS

2.1 Participants

Participants for this intervention were residents of the long-term care facility at Regina Pioneer Village. A-priori power analysis identified a necessary sample size of 42 to obtain statistical power of 0.80, a minimum effect size of 0.20, with statistical significance set at 0.05 and correlation of repeated measures at 0.5 for within-subjects effects in a repeated-measures design as calculated using G*Power 3.1 software (Faul, Erdfelder, Lang, & Buchner, 2007). Fifty-three residents aged 65 years and older were invited to participate. Of these 53, 23 consented and were included for chart audit and/or baseline assessment. Sixteen of the participants who consented met all inclusion criteria and were able to complete baseline assessments, and thus were deemed suitable for inclusion.

The primary inclusion criterion for this study was an existing clinical diagnosis of dementia (including Alzheimer disease, vascular, frontotemporal, Lewy Body, mixed, or undifferentiated dementia), and the ability to walk independently with or without the use of a mobility aid such as a cane or a rollator walker. Participants were excluded if they were receiving palliative care or have a progressive terminal illness that requires intensive medical treatment (e.g. cancer, congestive heart failure).

2.2 Procedures

2.2.1 Recruitment of participants

Facility administrators and nursing staff aided in identifying residents who met the inclusion criteria. Once potential participants were identified, an information letter and consent form was mailed to his/her proxy decision-maker. If the consent form was

returned, the potential participant was individually approached by the researcher to build rapport and comfort. Those who were receptive to taking part in the program after having the details and expectations fully explained to them were verbally invited to participate.

2.2.2 Recruitment of volunteers

Approximately 10 volunteers were recruited from the Faculty of Kinesiology and Health Studies at the University of Regina and the local community to assist in the project. Volunteers filled one of two important roles. Five volunteers were involved as activity leaders who took the lead role in the delivery of the walking program. An additional five volunteers made social visits to participants in the control group as part of the control condition, each visiting three to four residents once weekly. Each volunteer was asked to contribute anywhere from 1.5 to 3 hours per week for 12 weeks to this project. Prior to beginning their work, volunteers took part in a mandatory training session to inform them of their responsibilities and the research objectives. Volunteers were also required to provide a certified criminal record check and complete confidentiality training as required by the Regina Qu'Appelle Health Region.

2.2.3 Physical activity intervention

Participants were randomly assigned to one of two groups using a random number generator. The principle investigator and research assistant, who was responsible for all testing, were blinded to group assignment. Half of the participants were assigned to take part in a 12 week physical activity intervention which consisted of walking three days per week in the morning or early afternoon to negate the impact of sundowning, which is the tendency for dementia sufferers to be more agitated or show more behavioural

disturbances in the late afternoon and evening (Volicer, Harper, Manning, Goldstein, & Satlin, 2001). The walking program was led by groups of two volunteer activity leaders. Participants were divided into smaller groups of three to four and walked at a self-selected pace for 15 minutes or until they reached moderate breathlessness as measured by the talk test. They were asked to discontinue walking immediately and seek the attention of a nurse if they felt dizzy, short of breath, or experienced chest pain. Walking time was increased by five minutes bimonthly or as tolerated by each group. Activity leaders were asked to record total walking time for each session.

2.2.4 Social activity intervention

To negate the effect of social activity on indicators of physical function, a control group was included. This group had no change in their activity level from baseline, but received weekly 30 to 45 minute social visits from a student volunteer. These visits were informal but based around an activity that the facility's recreation staff had identified as something the participants enjoyed, such as reading, playing cards or board games, or conversing. These visits were conducted during the morning or afternoon hours to avoid the impact of sundowning on the residents.

2.3 Measures

Participants were tested at baseline, after six weeks, and after 12 weeks for a variety of indicators of physical and cognitive function. All tests were conducted by the researcher and/or a trained research assistant, both of whom were blind to group assignment. Background information about participants, including age, prescribed chronic use medication, clinical diagnoses relating to cognitive health and health profile

including any co-morbid conditions was obtained through a chart review prior to baseline testing.

2.3.1 Cognitive function

Participants were screened to confirm their diagnosis of dementia using the Mini-Mental State Exam (Folstein, Folstein, & McHugh, 1975). The Mini-Mental State Exam (MMSE) is the most commonly used measure of cognitive ability in studies related to physical activity and cognitive function (Harris & Johnson, 2010) and is easily interpreted by a variety of health professionals given its wide use. It assesses orientation, attention, immediate and short-term recall, language, and the ability to follow simple verbal and written commands, and is scored out of a possible 30 points (Folstein et al., 1975). Although MMSE cut-off scores for dementia vary in the existing literature, this study used the most commonly used and DSM-IV recommended cut-off score of less than 23 (American Psychiatric Association & American Psychiatric Association Task Force on DSM-IV, 2000). The MMSE has previously been shown to have excellent internal consistency ($\alpha = 0.90$) (Albert & Cohen, 1992) and good test-retest reliability ($r = 0.80$) (Uhlmann, Larson, & Buchner, 1987) in individuals with dementia. The MMSE also has adequate concurrent validity with the Revised Wechsler Adult Intelligence Scale (WAIS-R), a commonly used test of cognitive ability in adults (Hopp, Dixon, Grut, & Backman, 1997). Cognitive function was reassessed after weeks six and 12 of the intervention. Tests were conducted in the residents' rooms or a familiar common area, and were not conducted immediately after the resident had taken part in physical activity or social activity.

2.3.2 Physical function

Participants were tested at baseline, after 6 weeks and after twelve weeks on three measures of physical function: mobility, functional endurance, and balance. All assessments took place in a corridor and common area on the home nursing unit of each resident on a day when they had not taken part in any scheduled physical activity or social activity. The principal investigator and research assistant were trained by a senior faculty member with previous experience using the assessment tools in a research context. Mobility was assessed using the TUG test (Podsiadlo & Richardson, 1991). For this test, participants were asked to stand from a seated position in a chair with arms and walk three metres at a normal pace, then turn and return to the chair and sit down. This action was timed, with a score greater than 20 seconds indicating mobility impairment (Podsiadlo & Richardson, 1991).

Functional endurance was measured using the 6-minute walk test (Guyatt et al., 1985). In this test, participants were asked to walk as far as possible at a self-selected pace in the allotted six minutes. A loop inside the facility corridors was measured and a total number of laps completed counted and recorded. A greater distance walked, in metres, indicated greater functional endurance (Guyatt et al., 1985).

Balance was assessed using the functional reach test (Duncan et al., 1990). For this test, the participants were asked to stand beside the wall with arms extended. A measuring stick is placed against the wall at shoulder level and then the participant was asked to reach as far as possible. Two measurements were taken, one of the normal reach when the participant is standing comfortably with arms outstretched, and the second measuring the maximum reach while maintaining balance. The difference between these

two measures determined the functional reach. One practice trial was allowed. A score of less than 20 centimetres indicated impaired functional balance (Duncan et al., 1990).

2.3.3 Intensity

Intensity was measured using the talk test. The talk test rates difficulty with speech as a result of an increased ventilation rate. At an appropriate walking intensity, individuals should experience some difficulty with speech but not be so out of breath as to limit speech entirely. The talk test is an indirect measure of exercise intensity that has been shown to approximate optimal training heart rates and the ventilatory threshold in healthy younger adults, athletes, and those with stable cardiovascular disease (Persinger et al., 2004) and coronary artery disease (Brawner, Vanzant, Ehrman, Foster, Porcari, Kelso, et al., 2006).

Activity leaders were instructed to follow these protocols in their small groups, paying particular attention to those who may be having a great deal of difficulty speaking. Participants who were cognitively able were asked to assess their own difficulty with speech as they walk, while those with more severe cognitive deficits had their speech rated by the activity leader.

2.3.4 Compliance

Compliance was measured as a percentage of physical or social activity sessions attended out of the total number offered. Volunteer activity leaders were asked to complete a daily record of whether or not participants took part in the session, the duration of the exercise session, and, if applicable, the reason for termination of the session. If a participant was unavailable for a reason outside of his/her control (i.e.

doctor's appointment, family visit, facility outing), this was recorded but not included as a session offered.

2.4 Informed Consent and Ethical Approval

2.4.1 Informed consent - participants

Information letters and consent forms were mailed to the proxy decision maker of each participant identified by facility staff as meeting inclusion criteria. Once informed consent had been granted by the proxy decision maker, participants were approached by the principal investigator to explain the commitments, expectations, benefits, and risks posed by taking part in this research. Only after verbal consent had been obtained from the potential participant was he or she enrolled in the study and data collected from him or her.

2.4.2 Confidentiality - student volunteers

Volunteers were fully informed that they are assisting with a research project and asked to sign an informed consent document and confidentiality agreement stating that they would not share sensitive information about the participants or the research project with anyone outside the long-term care facility or project team. Volunteers were also required to complete training sessions led by the principal investigator and Dr. Shanthi Johnson, as well as confidentiality training required by the long-term care facility before beginning their work. As part of this confidentiality training, participants were also required to provide a criminal background check obtained from their local police station. Approval from the University of Regina Research Ethics Board and the Regina Qu'Appelle Health Region was sought and obtained before any data were collected.

2.5 Statistical Analyses

Data were entered into IBM SPSS Statistics Version 19 (Armonk, NY).

Descriptive statistics as well as compliance were calculated. Groups were compared for MMSE, TUG, FR, and 6MW score using a one-way ANOVA to ensure that the groups were equal at baseline. Mixed-model ANOVA was used to assess differences within and between groups in terms of the specified functional outcomes and cognitive state at baseline, six and 12 weeks. Effect sizes by group (partial η^2) for each variable were calculated for each time point. Effect sizes were quantified using Cohen's (1988) guidelines, with an effect size of 0.2 indicating a small effect, 0.5 indicating a medium effect, and 0.8 indicating a large effect. Intraclass correlations (ICC) were used to determine the test-retest reliability of all measures. ICC was used in lieu of Pearson's r because of the tendency of Pearson's r to overestimate reliability in small sample sizes (Weir, 2005). Individual percent change was calculated using guidelines for physical activity program evaluation, with the given formula: $[(\text{follow-up} - \text{baseline score}) \div \text{baseline score}] \div 100 = \text{individual change}$ (Lord et al., 1996; Myers, 1999).

Data were analyzed using the intent to treat model (Lachine, 2000). This model follows all participants until the end of the program regardless of their level of compliance. This means that data were included even for participants who were unable to complete the entire intervention. This model was adopted given that a level of dropout anticipated based on past research (Harris & Johnson, 2010).

3. RESULTS

3.1 Participants

Fifty-three residents were identified by facility staff as meeting inclusion criteria, and were invited to participate. Informed consent was obtained for 23 individuals (43.4%) and chart audits were conducted. Demographic and health characteristics of these participants are shown in Table 3.1. The majority of residents (69.6% female, 30.4% male) were over 80 years of age (82.6%) and had a diagnosis of undifferentiated dementia (60.9%), meaning the exact type of dementia they were experiencing was unknown. The participants were taking an average of five prescribed medications and had an average of three diagnosed co-morbid health conditions such as cardiovascular disease, diabetes, or arthritis. As shown in Table 3.2, 43% of the initially identified residents were diagnosed with hypertension, but often had multiple co-morbid conditions. Information regarding prescribed, chronic use medications is shown in Table 3.3. Medications that were used on a PRN (as needed) basis are not included in this table. In terms of prescribed medication, 87% of initially identified residents were taking anti-depressant or anti-psychotic medications. Of the 23 initially identified residents, three were excluded because chart audits showed that they did not meet inclusion criteria. Four other residents met inclusion criteria but were unable to meaningfully complete baseline assessments, and thus were excluded from the study.

Sixteen participants (6 males, 10 females, average age 83 years) completed baseline assessments and were included in the intervention, with equal numbers randomly assigned to either the physical activity or social activity groups. Of these participants, 44% had less than a high school education. The majority of the participants had a

diagnosis of undifferentiated dementia (68.8%) and complex health states with multiple co-morbid conditions (average number of comorbidities = 3.1, range 1 to 7). No statistically significant differences were found between the groups for any of the baseline tests (MMSE, TUG, FR, 6MW) or in age, number of prescribed medications, or number of co-morbid health conditions. Baseline characteristics by group are shown in Table 3.4.

Although there were no statistically significant differences between the two groups, functional impairment was apparent given baseline scores. The mean MMSE score among all participants was 12.4 ± 6.3 (range 0-22). As previously noted, any score below 23 indicates cognitive impairment, with lower scores indicating more severe impairment. There were also existing deficits in physical function among the participants in this study. The mean TUG score was 27.6 ± 16.4 seconds (range 11.5-76.7 seconds), with a time of greater than 20 seconds indicating impaired mobility. Sixty-three percent of participants in the physical activity group and 75% of the participants in the social activity group had scores higher than 20 seconds at baseline. A score of less than 20 cm indicates impaired balance using the FR test, and the mean score in this sample was 12.3 ± 9.1 cm (range 0-30 cm). Seventy-five percent of participants in the physical activity group and 88% of those in the social activity group had a reach that was less than 20 cm at baseline. In this study, the mean distance walked was 163.2 ± 85.6 m, much lower than has been found previously in healthy individuals. The baseline profile of both study groups clearly indicated the level of functional impairment present in many of the participants. There was also a high level of variability in function within groups as evidenced by the large standard deviations for all functional measures.

Table 3.1

Descriptive characteristics of consented and included participants

Characteristic	Consented (<i>n</i> = 23)	Included (<i>n</i> = 16)
Gender (% female)	69.6	62.5
Age (% $\geq$ 80 years)	82.6	87.5
Education (% less than high school)	26.0	44.0
Diagnosis (% undifferentiated dementia)	60.9	68.8
Number of co-morbid conditions (mean)	3.4	3.1
Number of prescribed medications (mean)	5.0	5.3

Table 3.2

Co-morbid health conditions of all consented participants

Condition	Consented Percentage (%) (n = 23)	Included Percentage (%) (n = 16)
Hypertension	43.5	43.8
Cancer (any type)	26.1	31.3
Osteoarthritis	26.1	18.8
Rheumatoid arthritis	26.1	25.0
Depression	21.7	25.0
Non-insulin dependent diabetes (NIDDM)	17.4	18.8
Cardiovascular disease	17.4	25.0
Macular degeneration	13.0	12.5
Osteoporosis	13.0	12.5
Anemia	8.7	12.5
Angina pectoralis	8.7	6.3
Coronary artery disease (CAD)	8.7	6.3
Past fracture	8.7	6.3
Past myocardial infarction	8.7	6.3
Urinary (including incontinence)	8.7	12.5
Aphasia	4.3	6.3
Bipolar disorder	4.3	6.3
Cataracts	4.3	0.0
Congestive heart failure	4.3	6.3
Deep vein thrombosis	4.3	6.3
Past cerebrovascular accident	4.3	6.3
Pulmonary embolism	4.3	6.3
Insulin dependent diabetes	4.3	6.3

Table 3.3

Prescribed/chronic use medications of all consented participants

Medication type	Consented	Included
	Percentage (%)	Percentage (%)
	(<i>n</i> = 23)	(<i>n</i> = 16)
Anti-depressant/anti-psychotic	87.0	87.5
Blood pressure	43.5	50.0
Calcium/Vitamin D supplements	34.8	31.3
Non-PRN NSAID	30.4	31.3
Diabetes (includes insulin)	26.1	31.3
Anti-coagulant	17.4	18.8
Sleeping/sedative	17.4	12.5
Statin	13.0	18.8
Ulcer	13.0	12.5
Beta-blocker	8.7	12.5
Osteoporosis/bisphosphonates	8.7	6.3
Urinary (includes prostate)	8.7	12.5
Thyroid	8.7	6.3
Anti-convulsant	4.3	6.3
Loop diuretic	4.3	6.3
Respiratory	4.3	6.3
Alzheimer disease/dementia	0.0	0.0

One participant began palliative care around the sixth week of the intervention and thus was excluded from further participation. Three participants sustained fractures unrelated to the intervention in the final two weeks of the intervention and thus completed only the MMSE during the post-testing. However, no participant voluntarily withdrew from the study. Study compliance was measured as percentage of sessions attended out of the total number of sessions offered. Compliance over the 12 weeks of the intervention was generally high (physical activity group mean 74%, social activity group mean 80%) with no statistically significant difference between groups.

3.2 Intervention effectiveness

Mixed-model ANOVAs with $p < 0.05$ were used to assess within- and between-subjects effects for the two groups (physical activity versus social activity) at all three time points. Table 3.5 displays the F -score, statistical significance level (p -value), effect size (partial eta squared), and observed power for each dependent variable (MMSE, TUG, FR, 6MW). Because of the small sample size, observed power was low for all measured variables, meaning that there was not sufficient power to detect statistically significant effects ($p < 0.05$) if they did exist. However, small effects, meaning that 20% or greater of the variance was explained by group assignment, were detected for both TUG (partial $\eta^2=0.23$) and FR (partial $\eta^2 = 0.21$) between the baseline and six-week test sessions, meaning that taking part in the physical activity program versus the social activity program may have explained some of the between-group variation during this time period. TUG time decreased slightly in the physical activity group and increased slightly in the social activity group from baseline to six weeks, while functional reach decreased in both groups over the same time period, more dramatically in the physical

activity group. Simple main effect contrasts showed that the TUG decrease from baseline to six weeks approached statistical significance, $t(7) = 1.986, p = 0.09$. No statistically significant results were found with regard to the interaction contrasts of treatment by time (Jaccard & Guilamo-Ramos, 2002). Negligible effect sizes were found for all variables when taking into account all three time points (baseline, six weeks, twelve weeks), and when comparing midpoint to end point and baseline to end point only. MMSE and 6MW also had negligible effect sizes from baseline to midpoint. Mean group changes in MMSE, TUG, FR, and 6MW over time are shown in Figures 1 to 4.

3.3 Individual change calculations

To account for individual variation in the magnitude of change in the measured variables from baseline to the 6- and 12-week follow-up, individual change calculations were performed for each study participant on each measured variable. Individual percent change was calculated using the formula outlined previously (Lord et al., 1996; Myers, 1999). The individual percent change scores were averaged to show the trends on each measured variable. Results from these analyses are shown in Table 3.6.

Although the small sample and variability in the baseline profiles of the participants resulted in large variation in the individual change scores, two of the four variables produced results that may be of clinical importance. TUG scores decreased by an average of 6% in the physical activity group and increased by an average of 19% in the social activity group. The findings indicate that the physical activity group showed a tendency toward maintenance or improvement while the social activity group saw a marked decline. 6MW scores in the physical activity group also increased by an average of 36%,

Table 3.4

Baseline characteristics of participants by group

	Physical activity group (n = 8)			Social activity group (n = 8)			<i>F</i>	df	<i>p</i>
	%	<i>M</i>	<i>SD</i>	%	<i>M</i>	<i>SD</i>			
Gender (% female)	75%			50%					
Education (% less than high school)	37.5%			50%					
Age		83.25	4.33		82.88	7.85	.014	14	.91
Medications (#)		5.00	1.41		5.50	2.33	.269	14	.61
Comorbidities (#)		3.13	1.36		3.75	2.25	.487	14	.50
MMSE		12.00	5.45		12.86	7.67	.064	13	.81
TUG (s) .24		32.18	20.64		21.42	4.56	1.542		12
FR (cm)		11.75	9.74		12.86	9.12	.051	13	.83
6MW (m)		180.34	113.70		143.28	34.20	.585	14	.460

Table 3.5

Mixed-model ANOVA results for all time points

Functional measure	df	<i>F</i>	<i>p</i>	Partial eta ²
MMSE				
<i>Time</i>	2	0.741	0.48	0.058
<i>Group</i>	1	0.000	0.98	0.000
<i>Group*Time</i>	2	0.796	0.46	0.062
TUG				
<i>Time</i>	2	1.359	0.48	0.187
<i>Group</i>	1	0.396	0.54	0.047
<i>Group*Time</i>	2	0.971	0.16	0.402
6MW				
<i>Time</i>	2	1.146	0.34	0.146
<i>Group</i>	1	0.273	0.61	0.037
<i>Group*Time</i>	2	0.082	0.92	0.012
FR				
<i>Time</i>	2	1.359	0.25	0.145
<i>Group</i>	1	0.396	0.54	0.047
<i>Group*Time</i>	2	0.971	0.40	0.108

Figure 3.1. Comparison of change in MMSE scores over time between physical activity and social activity groups.

Figure 3.2. Comparison of change in TUG scores over time between physical activity and social activity groups.

Figure 3.3. Comparison of change in FR scores over time between physical activity and social activity groups.

Figure 3.4. Comparison of change in 6MW scores over time between physical activity and social activity groups

Table 3.6

Mean individual percentage change of participants in each measured variable by group

	Physical activity group (<i>n</i> = 8)		Social activity group (<i>n</i> = 8)	
	<i>M</i>	<i>SD</i>	<i>M</i>	<i>SD</i>
MMSE (%)	-1.03	29.35	9.22	33.06
TUG (%)	-6.13	31.80	19.16	42.81
FR (%)	-2.10	60.08	-8.37	35.16
6MW (%)	36.29	80.87	6.17	29.60

Note: Positive percent change indicates improvement in MMSE, 6MW, FR. Negative percent change indicates improvement in TUG.

Table 3.7

Mean individual percentage change of participants in each measured variable at all time points

	<i>M</i>	<i>SD</i>	<i>Max</i>	<i>Min</i>
MMSE pre-mid (%)	5.1	28.3	-44.4	+42.9
MMSE pre-post (%)	2.9	29.9	-55.6	+50.0
MMSE mid-post (%)	9.7	42.2	-40.0	+133.3
TUG pre-mid (%)	-2.2	25.8	-31.8	+43.6
TUG pre-post (%)	5.4	37.6	-41.8	+74.5
TUG mid-post (%)	20.7	39.4	-42.2	+72.7
FR pre-mid (%)	12.9	66.8	-78.3	+140.0
FR pre-post (%)	-5.2	46.5	-41.2	+120.0
FR mid-post (%)	-0.8	49.8	-52.2	+100.0
6MW pre-mid (%)	33.8	83.6	-34.3	+264.3
6MW pre-post (%)	5.3	29.6	-29.2	+26.0
6MW mid-post (%)	-2.9	20.6	-22.5	+63.4

Note: Positive percent change indicates improvement in MMSE, 6MW, FR. Negative percent change indicates improvement in TUG.

functional endurance over the 12-week intervention period. In terms of MMSE score, the physical activity group had an average percent change of negative one percent (less than 1 point on the 30 point MMSE scale) and the social activity group an average change of 9.2% (less than 3 points on the 30 point MMSE scale), neither of which represents a clinically meaningful change. FR declined in both groups (2.1% in the physical activity group, 8.4% in the social activity group), but given the generally low scores at all time points, neither of these scores can be considered clinically meaningful.

3.4 Test-retest reliability

With the exception of MMSE, the measures used have not been validated or widely-used in populations with low cognitive function as a result of dementia. As such, test-retest reliability (intra-class correlation) was calculated to ensure that these tests were reliable in spite of the individual variation that may have occurred throughout the 12 weeks of the intervention. Results of this analysis are shown in Table 3.8.

MMSE, TUG, and 6MW were all found to have good test-retest reliability ($ICC \geq 0.7$, $p < 0.05$) in this sample at all time points (i.e. from 0-6 weeks, 6-12 weeks, and 0-12 weeks). FR scores from each time point did not correlate with any other time point and did not reach a higher ICC than 0.499, indicating that this measure is likely not reliable for use with this population.

Table 3.8

Test-retest reliability for all measures

Measure	0-12 weeks		6-12 weeks		0-6 weeks	
	ICC	<i>p</i>	ICC	<i>p</i>	ICC	<i>p</i>
MMSE	0.846	0.001*	0.857	0.001*	0.877	0.001*
TUG	0.817	0.001*	0.747	0.001*	0.855	0.001*
FR	0.365	0.032*	0.127	0.347	0.499	0.029*
6MW	0.769	0.001*	0.903	0.001*	0.687	0.001*

* denotes statistical significance

4. DISCUSSION

4.1 Study overview

The purpose of this study was to assess the effect of a regular, 12-week volunteer-supervised walking program on indicators of physical and cognitive function in adults aged 65 years and older with dementia residing in a long-term care facility. After participant and proxy decision-maker consent was received, participants were randomly assigned to either a physical activity ($n = 8$) or social activity ($n = 8$) group. Those in the physical activity group took part in a small group walking program for 15 minutes or more three times weekly, while those in the social activity group took part in a once-weekly group social visit for one hour with no change to their daily physical activity level. Chart audits were conducted for all included participants to determine dementia diagnosis, prescribed medications, co-morbid health conditions, and education level. Participants were tested at baseline, 6, and 12 weeks for physical function. Three parameters of physical function were assessed: functional mobility using the timed-up-and-go test, functional endurance using the six-minute walk test, and dynamic balance using the functional reach test. Cognitive function was assessed using the Mini-Mental State Examination.

4.2 Participant characteristics

Participants in this study had generally low cognitive function at baseline. While one would expect impaired cognitive function among residents of a facility designated for level 3 and 4 care, where residents require a higher level personal care, the level of cognitive function (mean baseline MMSE= 12.4 ± 6.3) in the sample was very low. Baseline physical function in the sample was also indicative of some impairment at

baseline. The mean TUG score was 28 seconds. A TUG time greater than 20 seconds indicates impaired functional mobility and 69% of participants had times above this cutoff. A FR score of less than 20 cm indicates impaired balance and the mean baseline FR score was well below this at 12 cm. Although 6MW scores are meant to be interpreted as either percent change or absolute change (American Thoracic Society, 2002), the mean baseline distance walked in this study (163 m) is low compared to the mean of 630 m from a past study of healthy older adults (Troosters, Crosselink, & Decramer, 1999). To date, no studies have attempted to establish standard 6MW cutoffs for individuals with dementia, but baseline scores for older adults in a cardiac rehabilitation program have been found to be greater than 500 m on average (Hamilton & Haennel, 2000).

Study participants also had complex health states, although this was to be expected given the multi-factorial nature of dementia and their advanced age (mean age 83 years). Participants had an average of 3.4 (range 1-9) co-morbid health conditions including but not limited to cardiovascular disease, cancer, depression, and arthritis. These co-morbid health conditions may have contributed to participants' poor physical function and their capacity for improvement in these indicators.

Participants in this study were also on a wide variety of prescribed chronic use medications (mean = 5.3 ± 1.9) as a result of their complex health states. This number does not include medications that are prescribed for PRN (as needed) use, so does not capture the use of non-steroidal anti-inflammatory drugs (NSAIDs), laxatives, or hypnotics that are not taken on a daily basis. The relatively large mean number of concurrent prescribed medications demonstrates that a number of participants may be

experiencing polypharmacy, which can be defined as the use of more prescription medications than are clinically indicated (Hajjar, Cafiero, & Hanlon, 2007).

While taking a high number of any medications concurrently can increase one's risk of a variety of health conditions (Agostini, Han, & Tinnitti, 2004), psychotropic medications, such as antidepressants and antipsychotics, are particularly dangerous for individuals with dementia. Recent evidence suggests that psychotropic medication use in this population can lead to a variety of adverse reactions and events, including injurious falls (Banerjee et al., 2011; Connelly, Law, Angus, & Prentice, 2010; Sterke, van Beeck, van der Velde, Ziere, Petrovic, Looman, & van der Cammen, 2011). In the present sample, 88% of participants were taking one or more psychotropic medications. This proportion contrasts sharply with the fact that no participant was prescribed an AD-specific drug, such as a cholinesterase inhibitor or memantine.

To summarize, many of the participants in this study were frail, severely cognitively impaired, had complex health states, and were taking a variety of prescribed medications. Some of these medications, such as psychotropics, were contraindicated for older adults with advanced dementia (Banerjee et al., 2011). While this does add to the difficulty of isolating the effect of a treatment such as physical activity, it is likely that this situation is typical among residents at advanced levels of care in LTC facilities. There will be individual variation among LTC clients, but recognizing the complexity associated with these clients' health states is crucial to conducting effective research in this setting.

4.3 Intervention

This is believed to be the first Canadian study to evaluate the impact of physical activity on physical and cognitive function in a LTC population with dementia. As discussed earlier, this study also had strong compliance and limited participant dropout, which had been issues in previous studies (Harris & Johnson, 2010). This study used a variety of measures that are widely used and easily interpreted and administered regardless of whether or not one has expertise in administering psychometric tests or conducting physical assessments.

Another strength of the current study was the calculation of individual change scores in addition to the comparison of group means. Existing evidence suggests that group level comparisons may not be sufficient to reflect individual variation in very frail individuals (Jacob Johnson, Myers, Scholey, Cyarto, & Ecclestone, 2003). The calculation of individual percent change gives important insight on the effects of the intervention at the individual level and may be a more useful tool for assessing the effectiveness of an intervention.

As noted in the literature review, this study was unique in that it was designed to ensure that similar attention was paid to the control group, rather than having a true non-treatment control group. A recent systematic review placed this as an issue of primary importance in assessing the methodological quality of trials investigating the impact of exercise on physical and cognitive function among those with dementia (Littbrand, Stenvall, & Rosendahl, 2011). Littbrand et al. also found that no existing study had addressed the issue of paying sufficient attention to control participants, likely indicating that this is the first study in this field to have a social activity comparison group.

The small effect sizes in TUG and FR, along with the general trends toward improvement in individual percent change TUG and SMW, are important results that suggest a potential impact of physical activity on physical function in older adults with dementia. Since there seemed to be no effect on cognitive function, this may suggest that the natural progression of dementia pathologies outstrip any potential cognitive gains from this sort of intervention, particularly at advanced stages.

While this research provides valuable insight into the rehabilitative potential of LTC residents with dementia, there were also limitations. The small sample size ($n=16$) of this study obviously limits the generalizability of the study. There were a variety of reasons for the small sample size as outlined in the results section. Prior to the beginning of data collection, the facility administrator was asked to provide a comprehensive list of all residents meeting inclusion criteria. The task of compiling this list was passed on to individual unit nurse managers, who provided a list of residents on their unit who met the specified criteria. This process yielded a list of 53 residents who were then invited to participate before they could be assessed to confirm that they did meet the inclusion criteria. Of these 53, informed consent was obtained from proxy decision-makers for 23 residents, at which point chart audits and initial assessments were conducted. The proxy-decision makers of the remaining 30 potential participants either did not respond to the invitation even after reminder letters were sent (11) or declined to provide consent (9).

Although all of these 23 residents should have been eligible to participate, this was unfortunately not the case. A combination of staff error in identifying residents who met inclusion criteria and changes in residents' health status from the time the list was initially compiled until after consent forms had been received led to the necessary

exclusion of seven potential participants for whom informed consent had been given. Of these seven residents, one was not diagnosed with dementia and the others were either unable to communicate verbally, non-ambulatory, or otherwise unable to complete the baseline assessment. While this recruitment process was likely the best way of ensuring the residents' privacy, it was certainly less than ideal in obtaining an accurate estimate of how many residents would be eligible to participate.

While there was no formal participant dropout in this study and all missing data were due to unrelated injuries or changes in health status beyond researcher and participant control, this issue with recruitment underscores the many foreseen and unforeseen logistical issues in recruiting and retaining older adults with dementia. In the systematic review (Harris & Johnson, 2010), 35% (7 of 20) of included studies had a sample size below 20 participants, and 75% (15 of 20) had a sample size below 30 participants (range 5-134). Challenges with recruitment have been well-documented and evident from limited research in this area. In addition, compliance has been an issue in several studies, although this was not an issue in the present study.

The volume of physical activity is also an important consideration for the present and future studies involving those with dementia. The Canadian Society for Exercise Physiology (2011) recommends 150 minutes of accumulated physical activity is needed to accrue health benefits in older adults. This study prescribed 30 minutes, three times weekly, for an accumulated 90 minutes per week, and many participants fell well short of even this amount. It is important to note that guidelines such as CSEP's are developed with healthy, community-dwelling older adults in mind, and they may not be applicable to frail and cognitively-impaired older adults residing in residential care settings. These

populations may not tolerate high volumes of physical activity, and as such different levels of prescribed physical activity may be preferable due to their potentially complex clinical profile and impaired physical function. This proposition, however, will have to be tested in future research.

4.4 Methodological issues

Although the functional measures used in this study are widely used, there has been little past research into whether they are reliable for populations with dementia. No past study had evaluated the test-retest reliability of the FR and very few studies had done so for TUG and 6MW. Ries et al. (2009) found that TUG and 6MW had excellent test-retest reliability and our results also support this finding.

Finding that MMSE, TUG, and 6MW had high test-retest reliability in this population was an important observation. These measures are commonly used in clinical settings, including with people with dementia, and repeated over various periods of time. Since subjective indicators of cognitive function, physical function, and overall wellbeing can vary greatly in those with dementia over even very short time intervals, it is important for practitioners to have confidence in the interpretation of these important clinical tools. However, it is also possible that extremely high test-retest reliability values indicate tests were not sensitive enough to detect small, yet still clinically meaningful change.

Further research is required to conclude exactly what degree of change can be detected by these tests and whether or not this change is clinically meaningful. The next step would be to calculate minimal detectable change (Ries et al., 2009), but the sample

size and large variation within the sample in this study does not lend itself to this calculation.

Although this is believed to be the first study of this nature to give comparable attention to the control group, the design did not completely address the potentially separate effects of physical activity and social activity. Including a true non-treatment control group or attempting to quantify the level of social interaction taking place during the physical activity intervention may help establish the separate effect of physical activity and social activity on physical and cognitive function.

Confounding variables, such as education level and differential diagnosis of dementia in participants, may have had an impact on the overall scores on the indicators of function. However, there were no statistically significant between-groups differences at baseline so this likely did not affect the group comparison results.

There were a variety of physical limitations to the facility that presented specific logistical challenges for an intervention of this nature. First, there was no large space in which to safely perform the physical testing. Ideally a track, gymnasium, or large auditorium would be used for testing of this nature, particularly for the 6MWT. However, these areas were somewhat predictably not available in this facility. 6MWT performance may have been affected by the small walking space.

Given that older adults with dementia are more likely to fall, safety is an important concern when planning any physical activity intervention with this population. No falls or injuries occurred during any of the testing or intervention sessions, and no adverse incidents, including violence or aggression toward volunteers, were reported throughout the 12-week intervention period. Two participants did experience falls

causing fractures that took place overnight and did not occur as a direct result of taking part in the study. These participants were thus excluded from the last three weeks of the study, including follow-up testing.

While the intervention did prove to be safe, the higher potential for injury or serious changes to health status among those with dementia can lead to increased rates of participant mortality. In addition to the two participants who suffered injurious falls, one participant was withdrawn prior to midpoint testing because she began palliative care treatment. This dropout level is consistent with other studies in the literature, where participant mortality rates have been as high as 18% (Rolland et al., 2007).

4.5 Future Directions

Future research should focus on large, multicentre interventions to ensure that the adequate sample size will be obtained with respect to participant mortality. Future interventions should likely also be longer in length to help determine if there is a minimum amount of time before changes are seen in cognitive and functional measures. Focussing on individuals in with less advanced forms of dementia may help to isolate the true protective effect of being physically active.

The aspect of this study that was most unique was the attempt to account for the impact of social activity; that is, the interaction with other residents and/or program leaders that is inherent to nearly any physical activity program conducted in a clinical setting. Future research should also attempt to control for this potential effect, perhaps through the use of a true non-treatment control group in addition to physical and social activity groups.

As dementia diagnostics move forward, future research should also focus on the rehabilitative potential of those with different forms of dementia, including Alzheimer disease, vascular dementia, frontotemporal dementia, and Lewy body dementia. As we learn more about these different forms of dementia, we may learn more about the true potential of different types of physical activity to impact physical and cognitive function.

4.6 Summary

Although the small sample size makes it difficult to draw definitive conclusions from this study, the hypothesis that taking part in physical activity would result in improved physical and cognitive function as compared to taking part in social activity was not supported. No statistically significant differences were found between the two groups in MMSE, TUG, 6MW, or FR at baseline, six, or twelve weeks. However, small effect sizes were found for TUG from baseline to midpoint and FR from baseline to midpoint and from midpoint to post-test, indicating that there was some more than negligible effect of physical activity. Looking at the individual percent change scores, it was found that TUG and 6MW scores increased in the physical activity group while they either decreased (in the case of TUG) or stayed relatively stable (in the case of 6MW) in the social activity group. The study provided valuable insights into test-retest reliability of commonly used clinical tools in the dementia population and highlighted some of the inherent measurement issues of these tools. Also, the study raised several methodological considerations that can be addressed in future research.

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Appendix A

Most commonly used instruments to measure physical function in the included systematic review (Harris & Johnson, 2010)

Instrument	Author(s)	Measures	How often used?
Timed up and go (TUG)	Podsiadlo & Richardson (1991)	Basic functional mobility; ability to independently and efficiently transfer from seated to standing to walking	7/17 studies reviewed
Katz Activities of Daily Living scale (KADL)	Katz et al. (1963)	Independence in basic activities of daily living, including bathing, dressing, toileting, transferring, continence, and feeding; measure of overall functional independence	4/17 studies reviewed
Tinetti Balance Scale	Tinetti (1986)	Assessment of clinical balance and fall risk; functional balance and balance required for mobility	3/17 studies reviewed
6-minute walk	Guyatt et al. (1985)	Functional aerobic capacity/fitness; greater distance walked indicates greater aerobic fitness	3/17 studies reviewed
Functional reach	Duncan et al (1990)	Clinical balance; functional flexibility and tactile ability	4/17 studies reviewed

Appendix B

Included studies from systematic review (Harris & Johnson, 2010) and characteristics of each.

Author (Year)	Setting	Sample Size	Length of Intervention	Intervention Type	Functional Outcomes	Results
Christofolletti et al. (2008)	Long term care	54	6 months	Individualized PT and OT sessions	TUG; Berg balance scale	Statistically significant group X time interactions in Berg balance scale
Santana-Sosa et al. (2008)	Long term care	16	12 weeks	Walking, core training, joint mobility, resistance, coordination, resistance training, stretching	Senior Fitness Test, Katz & Barthel ADL scores, Tinetti balance scale	Significant improvements in upper/lower body strength and flexibility, agility, dynamic balance, gait, Tinetti balance, and ADL ability
Netz et al. (2007)	Adult day program	29	Phase 1: 10 wks Phase 2: 12 wks Phase 3: 12 wks	Upper extremity strength & ROM; coordination and fine motor skills; lower extremity strength & ROM	Performance rate (Likert scale); TUG; sit-to-stand; functional reach	No significant changes after phase 1-2; after phase 3 TUG time decreased by 3.2 seconds
Rolland et al. (2007)	Long term care	134	12 months	Circuit of walking; squats, repeated standups, lateral leg elevation, toe rises, flexibility, balance: small step trials, one/two leg balance	KADL; 6 m walk speed, TUG, one-leg balance Secondary: falls	ADL mean change, slower decline in exercisers; no difference in falls

Kuiack et al. (2004)	Adult day program	8	12 weeks	Resistance exercise; leg extension/curl, shoulder press/lat pulldown, hip abductor/adductor, chest/back, abs/back	Chair stand; stair climb; 6 m gait speed; jug lift (up to 8 lbs); balance	Significant increase in strength and power (in Watts); no increase in physical functional abilities
Arkin (2003)	Community	24	10 weeks	Stretching, balance, aerobics (treadmill/stationary bike); conversation and cognitive activity	6 minute walk, upper/lower body strength (avg lifted or estimated 1RM), chair rise, agility, arm/leg flexibility, one leg balance, coordination	Significant gains in 6 minute walk, upper and lower body strength, and duration of aerobic exercise
Salazar Thomas & Hageman (2003)	Adult day program	28	6 weeks	Training of hip extensors, abductors, knee extensors/flexors & dorsiflexors using theraband	Max strength of knee extensor, hip flexors, dorsiflexors; grip strength; TUG, walking speed, sit-to-stand	Significant increases in grip strength and sit to stand; non-significant increases in muscular strength
Toulotte et al. (2003)	Long term care	20	16 weeks	Strength, proprioception: walking on a variety of surfaces; balance: one foot stand, obstacle avoid/step over; flexibility: ankle ROM; sit and reach	TUG, chair sit and reach, 10 m walk speed, platform QFP (for balance + postural sway)	Walking, mobility, balance all improved significantly in training group; no change in control

Hageman & Salazar-Thomas (2002)	Adult day program	26	6 weeks	hip extensors, abductors, knee extensors/flexors & dorsiflexors using theraband	Max strength of knee extensor, hip flexors, dorsiflexors; grip strength; TUG, walking speed, sit-to-stand, Tinetti Performance Mobility Scale and Gait Assessment Rating Scale	Statistically significant increase in fast-speed gait; non-significant increases in all gait measures
Rolland et al (2000)	Acute care	23	5-12 weeks, mean 7	Individual; mainly endurance activities such as walking/stationary bike	Katz ADL; instrumental ADL; Tinetti static, dynamic, global balance tests	No significant change in KADL/IADL or balance
Tappen et al. (2000)	Long term care	65	16 weeks	Walking or walking combined with conversation therapy	Modified 6 minute walk	Combined walking/conversation declined only 2.2% in functional mobility
Arkin (1999)	Adult day program	14	12 months	Stretching; aerobic training on treadmill, stationary bike; weight training	6 minute walk, upper and lower body strength (chest and leg press)	Significant gain aerobic duration & 6 min walking dist; Significant increases chest/leg press

Pomeroy et al (1999)	Acute care	81	2 weeks	Individualized physiotherapy	Southampton Mobility Assessment; Two-minute walking test	"Non-significant trend toward" lower reduction in SMA/distance walked in 2 mins
Teri et al (1998)	Community	30	12 weeks	Strength training progressing to use of weights, transfer/base of support exercises, 30 mins walking	8 ft. walking speed, functional reach, one leg/tandem balance; self report health status	Improved functional reach, gait speed, one leg balance
Francese et al. (1997)	Long term care	11	7 weeks	Mainly play/fun based for non-ambulatory residents only	Lower/upper extremity strength, Tinetti balance scale	Statistically significant difference in exercise group in strength & Tinetti balance
Binder (1995)	Long term care	25	8 weeks	Strength of hip, knee, ankle movers, flexibility of all upper/lower extremity joints, increase movement speed; chair, ball, theraband, ankle weights, parallel bars	Standups X1, X5; knee extensor torque (0 + 60 degrees/sec), hip extension 1RM; time/# steps to walk 24 ft, # steps to turn, # of Romberg posits	Balance improved; knee extensor torque declined; 1RM for hip extension increased

Brill et al. (1995)	Long term care	10	11 weeks	Stretching warmup and cool-down to improve flexibility; strength exercises using therabands	Timed chair stand; hand grip strength; Cybex chest press; sit and reach; standing reach; habitual gait	Qualitative “improvements” in strength and balance; no statistics reported
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Appendix C

University of Regina Certificate of Ethics Approval

OFFICE OF RESEARCH SERVICES
M E M O R A N D U M

DATE: June 24, 2010

TO: Jonathan Harris
SPHERU

FROM: Dr. Bruce Plouffe
Chair, Research Ethics Board

Re: Physical Activity and Physical Function in Older Adults with Dementia in Long-Term Care (File # 81S0910)

Please be advised that the University of Regina Research Ethics Board has reviewed your proposal and found it to be:

- ☒ 1. APPROVED AS SUBMITTED. Only applicants with this designation have ethical approval to proceed with their research as described in their applications. For research lasting more than one year (Section 1F). **ETHICAL APPROVAL MUST BE RENEWED BY SUBMITTING A BRIEF STATUS REPORT EVERY TWELVE MONTHS.** Approval will be revoked unless a satisfactory status report is received. Any substantive changes in methodology or instrumentation must also be approved prior to their implementation.
- ☐ 2. ACCEPTABLE SUBJECT TO MINOR CHANGES AND PRECAUTIONS (SEE ATTACHED). Changes must be submitted to the REB and approved prior to beginning research. Please submit a supplementary memo addressing the concerns to the Chair of the REB. **** Do not submit a new application.** Once changes are deemed acceptable, ethical approval will be granted.
- ☐ 3. ACCEPTABLE SUBJECT TO CHANGES AND PRECAUTIONS (SEE ATTACHED). Changes must be submitted to the REB and approved prior to beginning research. Please submit a supplementary memo addressing the concerns to the Chair of the REB. **** Do not submit a new application.** Once changes are deemed acceptable, ethical approval will be granted.
- ☐ 4. UNACCEPTABLE AS SUBMITTED. The proposal requires substantial additions or redesign. Please contact the Chair of the REB for advice on how the project proposal might be revised.

Dr. Bruce Plouffe

cc: Dr. Shanthi Johnson - Kinesiology and Health Studies

** supplementary memo should be forwarded to the Chair of the Research Ethics Board at the Office of Research Services (Research and Innovation Centre, Room 109) or by e-mail to research.ethics@uregina.ca

Phone: (306) 585-4775
Fax: (306) 585-4893
www.uregina.ca/research

Appendix D.

Regina Qu'Appelle Health Region Certificate of Ethics Approval

Certificate of Approval
Research Ethics Board

PRINCIPAL INVESTIGATOR	Mr. Jonathan Harris	Faculty of Kinesiology & Health Studies, Gerontology Program University of Regina Regina SK
APPROVAL DATE	June 24, 2010	
RQHR PROJECT #	REB-10-30	
TITLE	Physical activity and physical function in older adults with dementia in long-term care.	
APPROVED		

CERTIFICATION

The protocol and consent form for the above named project have been reviewed by the Regina Qu'Appelle Health Region Research Ethics Board and the experimental procedures were found to be acceptable on ethical grounds for research involving human subjects.

The Regina Qu'Appelle Health Region Research Ethics Board meets the standards outlined by Canada's Tri-Council Policy Statement for Ethical Conduct for Research Involving Humans.

The Regina Qu'Appelle Health Region Research Ethics Board has met the criteria for purposes of Section 29 of the *Health Information Protection Act*.

Please note that all future correspondence regarding this project must include the RQHR project number.

Best wishes in your continuing research endeavours.

 Dr. Elean Paluck, Chair
 Regina Qu'Appelle Health Region
 Research Ethics Board

/lh

cc. Ms. C. Klassen, Knowledge Management & Strategic Development, WRC

This Certificate of Approval is valid provided there is no change in the experimental procedures. Any significant changes to the protocol must be reported to the Chair for the Board's consideration, in advance of implementation of such changes. You are required to provide a status report on an annual basis.

Appendix E

Letter of invitation (Proxy decision-maker)

**Faculty of Kinesiology and Health Studies
Centre for Kinesiology, Health & Sport**

University of Regina, Regina, SK S4S 0A2

Date

Address

Dear Mr./Mrs./Ms.:

Your family member/loved one _____ has been invited to take part in a research study that will be taking place at Regina Pioneer Village. As his/her guardian, you are being contacted to provide consent for him/her to do so. This study has received approval from Regina Pioneer Village, the Regina Qu'Appelle Health Region, and the University of Regina Research Ethics Boards.

Please take the time to review the attached information letter and consent form. If you are satisfied with this information, please feel free to sign the attached consent form and return it in the provided pre-addressed stamped envelope. If you have any questions or concerns prior to signing this form, please feel free to contact either Jonathan Harris or Dr. Shanthi Johnson at the telephone numbers/email addresses supplied below. We would be happy to discuss any aspect of this study with you in more detail.

Thank you in advance for your time and consideration,

Jonathan B. Harris, BScHKin (Hons.)
MSc. in Gerontology Candidate
University of Regina
(306) 737-6399 (c)
(306) 337-2439 (w)
harris7j@uregina.ca

Shanthi Johnson, PhD, RD, FDC, FACSM
Professor & Associate Dean (Grad Studies)
Faculty of Kinesiology & Health Studies
University of Regina
(306) 337-3180 or (306) 585-4854
shanthi.johnson@uregina.ca

Information Letter and Consent Form

Study Title: Physical activity and physical function in older adults with dementia in long-term care

Researchers:

Jonathan Harris, Master of Science candidate, Gerontology Program, University of Regina

Dr. Shanthi Johnson, PhD, RD, Faculty of Kinesiology & Health Studies, Saskatchewan Population Health & Evaluation Research Unit, University of Regina

Introduction:

Your family member/loved one/friend has been invited to participate in a study on the effects of a walking or social activity program to improve physical health and mental functioning. Before, during, after a 16-week program led by a group of trained volunteers from the University of Regina, Faculty of Kinesiology and Health Studies program, he or she will be tested on his or her ability to perform simple physical tasks independently and on memory and thinking ability. Before agreeing for your loved one to participate in this study, it is important that you understand its purpose, how it may affect him/her, the risks and benefits of being involved, and what they are being asked to do.

Purpose of the Study:

The purpose of this study is to investigate the effects of a walking or social activity program on the ability to think and perform physical tasks independently in older adults with dementia living in a nursing home.

Study Design:

Participants who agree to participate will be randomly assigned to either a walking group or a social activity group.

Walking Group: Half of the residents will be assigned to a walking group. This activity will last for 16 weeks. In this walking group, which will be led by a student volunteer, participants will be asked to walk for up to 30 minutes three times a week. Before and after the walking program as well as at a time point in the middle, they will be asked to take part in some simple physical tests supervised by a trained research assistant and answer a questionnaire that assesses their ability to think (i.e., the Mini Mental State Exam). For this questionnaire, they will be asked a series of simple questions by a trained individual. *It is expected that this testing will take approximately one hour every 6 weeks.*

Social Activity Group: Residents who are assigned to this group will receive a social visit from a student volunteer for one hour once a week for 16 weeks. Before and after the walking program as well as at a time point in the middle, they will be asked to take part in some simple physical tests supervised by a trained research assistant and answer a questionnaire that assesses their ability to think (i.e., the Mini Mental State Exam). For

this questionnaire, they will be asked a series of simple questions by a trained individual. *It is expected that this testing will take approximately one hour every 6 weeks.* They will not be asked to participate in the walking program, but they will continue taking part in any recreation or rehabilitative activities they currently participate in.

Possible Harm:

When your family member first starts the walking program, it is possible that he or she will experience mild muscle soreness. This mild muscle soreness is expected when beginning any new physical activity program. However, it is very important that he/she informs someone (e.g. volunteer, nurse, or another staff member) if he/she feels excessively tired, dizzy, or short of breath before, during, or after their walk.

Possible Benefits:

It is possible that your loved one will see an overall improvement in his or her health as a result of the walking program.

Confidentiality:

Confidentiality will be respected at all times. A code number will be used to identify the data collected. Only my supervisor and I will have access to test results and other sensitive information. Names will not be used in reports, presentations, or publications.

What if I don't want my loved one to be a part of the study anymore?

You have the right to decide that your loved one stop taking part in this study at any time, for any reason, without penalty. If you choose to withdraw, you can tell me or my supervisor in person, by telephone, or email. If you choose to stop taking part in this study, any data collected from your loved one will be destroyed.

Data:

Data collected in this study will be destroyed five years after the completion of the study.

Questions:

You have the right to ask questions about this study at any time before, during and after the study. If you have any questions or require more information, please contact:

Jonathan Harris, BSCHKin (Hons.) Principal Investigator
Masters of Science in Gerontology Candidate
University of Regina
Harris7j@uregina.ca
(306) 737-6399
(306) 337-2439

OR

Dr. Shanthi Johnson, PhD, RD
Professor and Associate Dean, Faculty of Kinesiology & Health Studies
University of Regina
Shanthi.Johnson@uregina.ca
(306) 337-3180

Appendix F**Consent form**

Guardian Consent: Physical activity and physical function in older adults with dementia in long-term care

I have read the information letter and consent form and have had the chance to ask questions which have been answered to my satisfaction before signing my name. I understand the purpose of the study. I understand that my family member/loved one/friend has the right to stop taking part in this study at any time, for any reason, without penalty.

I give permission for the release of information collected in this study for reports and presentations (i.e. public domain) within the confidentiality guidelines outlined earlier.

I have received a copy of the information letter and consent form.

The signature below indicates my consent to my family member/loved one/friend taking part in this research.

Name of participant (please print): _____

Signature of participant: _____

Name of researcher: _____

Signature of researcher: _____

Date: _____

Appendix G

Script for verbal assent

Hello Mr./Mrs. _____,

My name is Jonathan Harris. I am a student at the University of Regina and I am going to be working a project here for the next few months. I am testing whether walking or socializing regularly will help with memory and thinking skills and ability to perform simple movements like getting out of a chair. If you choose to participate, myself or a volunteer will either come to take you to go for a short (~30 minute) walk three times a week for the next 3 months, or myself or a volunteer will come visit you for an hour once a week for the next 3 months to work on some activities together. Also every six weeks, you will be asked to do a quick memory/thinking test and perform some simple movement tests (walking for six minutes, standing from a chair, reaching forward) that will take about one hour. If you don't feel like going for a walk or having visitors on any particular day, you do not have to participate that day. Also, if you decide at any time that you don't want to participate anymore, you can let me or one of the other volunteers know and we will respect your decision.

Do you understand what I have just told you? *(Ask participant to repeat one aspect of the study...i.e. what will you be asked to do if you agree to participate?)*

Would you be willing to participate in this project? *(Allow extra time to decide if participant is unsure or requests it)*

Appendix H

Mini-Mental State Exam form

Mini-Mental State Examination (MMSE)

Patient's Name: _____

Date: _____

Instructions: Ask the questions in the order listed. Score one point for each correct response within each question or activity.

Maximum Score	Patient's Score	Questions
5		"What is the year? Season? Date? Day of the week? Month?"
5		"Where are we now: State? County? Town/city? Hospital?"
3		The examiner names three unrelated objects clearly and slowly, then asks the patient to name all three of them. The patient's response is used for scoring. The examiner repeats them until patient learns all of them, if possible. Number of trials: _____
5		"I would like you to count backward from 100 by sevens." (93, 86, 79, 72, 65, ...) Stop after five answers. Alternative: "Spell WORLD backwards." (D-L-R-O-W)
3		"Earlier I told you the names of three things. Can you tell me what those were?"
2		Show the patient two simple objects, such as a wristwatch and a pencil, and ask the patient to name them.
1		"Repeat the phrase: 'No ifs, ands, or buts.'"
3		"Take the paper in your right hand, fold it in half, and put it on the floor." (The examiner gives the patient a piece of blank paper.)
1		"Please read this and do what it says." (Written instruction is "Close your eyes.")
1		"Make up and write a sentence about anything." (This sentence must contain a noun and a verb.)

1		<p>"Please copy this picture." (The examiner gives the patient a blank piece of paper and asks him/her to draw the symbol below. All 10 angles must be present and two must intersect.)</p>
30		TOTAL

(Adapted from Rovner & Folstein, 1987)

Instructions for administration and scoring of the MMSE

Orientation (10 points):

- Ask for the date. Then specifically ask for parts omitted (e.g., "Can you also tell me what season it is?"). One point for each correct answer.
- Ask in turn, "Can you tell me the name of this hospital (town, county, etc.)?" One point for each correct answer.

Registration (3 points):

- Say the names of three unrelated objects clearly and slowly, allowing approximately one second for each. After you have said all three, ask the patient to repeat them. The number of objects the patient names correctly upon the first repetition determines the score (0-3). If the patient does not repeat all three objects the first time, continue saying the names until the patient is able to repeat all three items, up to six trials. Record the number of trials it takes for the patient to learn the words. If the patient does not eventually learn all three, recall cannot be meaningfully tested.
- After completing this task, tell the patient, "Try to remember the words, as I will ask for them in a little while."

Attention and Calculation (5 points):

- Ask the patient to begin with 100 and count backward by sevens. Stop after five subtractions (93, 86, 79, 72, 65). Score the total number of correct answers.
- If the patient cannot or will not perform the subtraction task, ask the patient to spell the word "world" backwards. The score is the number of letters in correct order (e.g., dlrow=5, dlrow=3).

Recall (3 points):

- Ask the patient if he or she can recall the three words you previously asked him or her to remember. Score the total number of correct answers (0-3).

Language and Praxis (9 points):

- Naming: Show the patient a wrist watch and ask the patient what it is. Repeat with a pencil. Score one point for each correct naming (0-2).
- Repetition: Ask the patient to repeat the sentence after you ("No ifs, ands, or buts."). Allow only one trial. Score 0 or 1.
- 3-Stage Command: Give the patient a piece of blank paper and say, "Take this paper in your right hand, fold it in half, and put it on the floor." Score one point for each part of the command correctly executed.
- Reading: On a blank piece of paper print the sentence, "Close your eyes," in letters large enough for the patient to see clearly. Ask the patient to read the sentence and do what it says. Score one point only if the patient actually closes his or her eyes. This is not a test of memory, so you may prompt the patient to "do what it says" after the patient reads the sentence.

- **Writing:** Give the patient a blank piece of paper and ask him or her to write a sentence for you. Do not dictate a sentence; it should be written spontaneously. The sentence must contain a subject and a verb and make sense. Correct grammar and punctuation are not necessary.
- **Copying:** Show the patient the picture of two intersecting pentagons and ask the patient to copy the figure exactly as it is. All ten angles must be present and two must intersect to score one point. Ignore tremor and rotation.

(Folstein, Folstein & McHugh, 1975)

Interpretation of the MMSE

Method	Score	Interpretation
Single Cutoff	<24	Abnormal
Range	<21	Increased odds of dementia
	>25	Decreased odds of dementia
Education	21	Abnormal for 8 th grade education
	<23	Abnormal for high school education
	<24	Abnormal for college education
Severity	24-30	No cognitive impairment
	18-23	Mild cognitive impairment
	0-17	Severe cognitive impairment

Sources:

- Crum RM, Anthony JC, Bassett SS, Folstein MF. Population-based norms for the mini-mental state examination by age and educational level. *JAMA*. 1993;269(18):2386-2391.
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- Rovner BW, Folstein MF. Mini-mental state exam in clinical practice. *Hosp Pract*. 1987;22(1A):99, 103, 106, 110.
- Tombaugh TN, McIntyre NJ. The mini-mental state examination: a comprehensive review. *J Am Geriatr Soc*. 1992;40(9):922-935.

Appendix I

Timed Up and Go guidelines

Timed Up and Go (TUG) Test

1. Equipment: arm chair, tape measure, tape, stop watch.
2. Begin the test with the subject sitting correctly in a chair with arms, the subject's back should resting on the back of the chair. The chair should be stable and positioned such that it will not move when the subject moves from sitting to standing.
3. Place a piece of tape or other marker on the floor 3 meters away from the chair so that it is easily seen by the subject.
4. Instructions : "On the word *GO* you will stand up, walk to the line on the floor, turn around and walk back to the chair and sit down. Walk at your regular pace.
5. Start timing on the word "*GO*" and stop timing when the subject is seated again correctly in the chair with their back resting on the back of the chair.
6. The subject wears their regular footwear, may use any gait aid that they normally use during ambulation, but may not be assisted by another person. There is no time limit. They may stop and rest (but not sit down) if they need to.
7. Normal healthy elderly usually complete the task in ten seconds or less. Very frail or weak elderly with poor mobility may take 2 minutes or more.
8. The subject should be given a practice trial that is not timed before testing.
9. Results correlate with gait speed, balance, functional level, the ability to go out, and can follow change over time.
10. Interpretation

—	< 10 seconds = normal
—	< 20 seconds = good mobility, can go out alone, mobile without a gait aid.
	< 30 seconds = problems, cannot go outside alone, requires a gait aid.

A score of more than or equal to fourteen seconds has been shown to indicate high risk of falls.

1. Podsiadlo D, Richardson S. *The Timed "Up & Go": A Test of Basic Functional Mobility for Frail Elderly Persons*. Journal of the American Geriatrics Society 1991; 39(2): 142-148
2. Shumway - Cook A, Brauer S, Woollacott M. *Predicting the Probability for Falls in Community-Dwelling Older Adults Using the Timed Up & Go Test*. Physical Therapy 2000 Vol 80(9): 896-903.
Saskatoon Falls Prevention Consortium, Falls Screening and Referral Algorithm, TUG, Saskatoon Falls Prevention consortium, June, 2005

Appendix J.

Six Minute Walk Test guidelines

6 Minute Walk Test Instructions (www.rehabmeasures.org)

General Information:

individual walks without physical assistance for 6 minutes and the distance is measured

start timing when the individual is instructed to "Go"

stop timing at 6 minutes

assistive devices can be used but should be kept consistent and documented from test to test

if physical assistance is required to walk, this should not be performed a measuring wheel is helpful to determine distance walked

should be performed at the fastest speed possible

Set-up and equipment:

ensure the hallway free of obstacles stopwatch

measuring wheel recommended to calculate distance

Patient Instructions (derived from references below):

"Cover as much ground as possible over 6 minutes. Walk continuously if possible, but do not be concerned if you need to slow down or stop to rest.

The goal is to feel at the

end of the test that more ground could not have been covered in the 6 minutes.

"

6 Minute Walk Test

Name: _____

Assistive Device and/or Bracing Used: _____

Date: _____

Distance ambulated in 6 minutes: _____

Date: _____

Distance ambulated in 6 minutes: _____

Date: _____

Distance ambulated in 6 minutes: _____

Date: _____

Distance ambulated in 6 minutes: _____

Appendix K

Functional Reach guidelines

Name of Instrument: Functional Reach Test

Author: Pamela W. Duncan, Debra K. Weiner, Julie Chandler and Stephanie Studenski

Contact Info:

Name: Pamela W. Duncan
Address: Graduate Program in Physical Therapy
 P.O. Box 3965, Duke University Medical Center
 Durham, NC 27710

Phone:

Fax:

E-mail:

Privacy Use Cost: \$

Public Use Cost: \$

Year Developed: 1990

Where to obtain Instrument:

- ☒ Contact author
- ☒ Other: www.arom.com

Description of the Instrument

- ☒ Functional Reach test is a measure of balance and is the difference, in inches, between arm's length and maximal forward reach, using a fixed base of support.
- ☒ This test can be used to detect balance impairment, change in balance performance over time, and in the design of modified environments for impaired older persons.
- ☒ The test utilizes a force platform, an electronic system for measuring functional reach or a 48-inch measuring device or "yardstick".
- ☒ A reach of less than or equal to 6 inches predicted fall

Form of instrument:

- ☒ Risk/Hazard Assessment Tool

Method of delivery:

- ☒ In-person interview/assessment

Relevance to injury/ Percentage of the instrument specific to injury

- ☒ To assess balance that may contribute to risk of falling among the elderly.

Time to administer or complete the instrument

- ☒ 1-2 minutes

Methods of data analyses:

- ☒ Quantitative

Setting/sample instrument used in:

- ☒ Volunteers, age 21-87 years, were recruited from 3 resources: a) employees at the Duke University Medical Center and the Durham Veterans Administration Hospital; b) students of the Duke University Physical Therapy Program; and c) the Duke Aging Center registry of community-dwelling elderly.

Was it pilot tested? No

Reliability**Measures**

- ☒ Test-retest reliability $r = .89$
- ☒ Interrater agreement on reach measurement = .98

Validity Measures

Functional Reach Test was strongly associated with measurements of centre of pressure excursion $r = .71$ and the R^2 using linear regression was .51.

Additional testing completed by Eagle et al. (1999) on a sample of elderly inpatients indicated the following:

- ☒ Sensitivity (ability to detect falls when they are present) = 76%
- ☒ Specificity (ability to identify correctly the absence of falls) = 34%
- ☒ Positive Predictive Value (how well test predicted compared to actual number of falls) = 33%
- ☒ Negative Predictive Value (how well negative test correctly predicts absence of falls) = 77%
- ☒ Accuracy (overall rate of agreement between the test and the actual number of falls) = 46%
- ☒ Prevalence (ratio of the number of people who have fallen divided by the total

number of people at risk for falling) = 30%

Reference

Duncan, P.W., Weiner, D.K., Chandler, J. & Studenski, S. (1990). Functional reach: a new clinical measure of balance. Journal of Gerontology: MEDICAL SCIENCES, 45(6), M192-M197.

Other References

Eagle, J., Salamara, S., Whitman, D., Evans, L.A., Ho, E., & Olde, J. (1999). Comparison of Three Instruments in Predicting Accidental Falls in Selected Inpatients in a General Teaching Hospital. Journal of Gerontological Nursing, 25(7), 40-45.

Whitney, S.L., Poole, J.L., & Cass, S.P. (1999). A Review of Balance Instruments for Older Adults. The American Journal of Occupational Therapy, 52(8), 666-671.

Appendix L**Chart audit checklist****Date of Birth:** _____**Clinical Diagnosis:** _____**Years Since Clinical Diagnosis:** _____**Co-morbidities:** _____**Prescribed Medications:** _____**Education Level:** _____**Unit/Room Number:** _____

Appendix M

Daily record form for volunteer activity leaders

[illegible]