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Effectiveness of Chiropractic Care in Improving Sensorimotor Function Associated with Falls Risk in Older People

Kelly R. Holt

Abstract

This thesis assessed whether chiropractic care was effective in improving sensorimotor function that is related to fall risk in community-dwelling older adults over a 12 week period. A pragmatic randomised controlled trial was conducted that compared the effect of chiropractic care to a ‘usual care’ control on proprioception (joint position sense), postural stability (static posturography), a broad measure of sensorimotor function (choice stepping reaction time), multisensory integration (the sound-induced flash illusion), and health-related quality of life (SF-36). Outcomes were assessed at four weeks and 12 weeks after a baseline assessment. Participants in the trial included 60 community dwelling older adults from the Auckland region. Of potential participants screened for eligibility, 92% were eligible. Chiropractic care was provided by 12 chiropractic practices from across Auckland in their usual practice setting, following an approach tailored to the participants’ individual clinical needs.

The key findings from the study were that the chiropractic group improved compared to the usual care control group in ankle joint position sense (p=0.045, mean difference across four and 12 week assessments 0.20˚, 95% CI 0.01-0.39˚), and choice stepping reaction time (p=0.01, mean difference at 12 week assessment 118ms, 95% CI 24 to 212ms), and they were also less susceptible to the sound-induced flash illusion (p=0.01, mean difference at 12 week assessment 13.5%, 95% CI 2.9 to 24.0%). Between group differences were also observed in the physical component of health-related quality of life with the chiropractic group improving compared to the control group between the four and 12 week assessments (p=0.047, mean difference 2.4, 95% CI 0.04 to 4.8).

Further research is now required to understand the potential mechanisms of action associated with the improvements that were observed in sensorimotor function, multisensory integration, and the physical component of quality of life in the chiropractic group. Future studies are also required to investigate whether chiropractic care may play a role in preventing falls in older people.
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guided me towards the area of falls prevention as a focus for my thesis. In particular I would also like to thank my first research mentor, and thesis advisor, Professor Bernadette Murphy. Bernie inspired me as a student, lit a fire in me that drove me to become involved in research, then helped me to plan my thesis and put the results into some context. I thank you all for your guidance and inspiration.

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CHAPTER 3. SYSTEMATIC REVIEW OF THE EFFECTS OF MANUAL THERAPY ON BALANCE AND FALLS


Nature of contribution by PhD candidate | Study design, literature search, selection of studies for inclusion, study assessment, data extraction, manuscript preparation, manuscript editing, manuscript submission.

Extent of contribution by PhD candidate (%) | 85%

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CHAPTER 1. INTRODUCTION

1.1. Rationale for the thesis

This thesis reports the results of a randomised controlled trial that investigated whether 12 weeks of chiropractic care had a positive effect on measures of sensorimotor function that relate to falls risk. Falls are a major health concern for older adults and this thesis sought to examine what potential role chiropractors may play in helping to prevent falls in their older adult patients.

Falls are a significant cause of death, injury, and loss of quality of life in older adults (American Geriatrics Society 2001, Taylor and Stretton 2004). Falls account for over 80% of injury related hospital admissions in people over the age of 65, and they are the leading cause of injury-related death in older adults (Stephenson, Langley et al. 2005, Kannus, Khan et al. 2006). Approximately 30-40% of community dwelling older adults suffer from at least one fall per year (Tinetti, Speechley et al. 1988, Dyson 2005, Gill, Taylor et al. 2005). This incidence rate rises dramatically with increasing age or when a variety of risk factors are present (Tinetti, Speechley et al. 1988). Compared with healthy community dwelling older adults, the risk of falling increases in those experiencing lower limb muscle weakness (odds ratio (OR) = 4.4), gait deficits (OR = 2.9), balance deficits (OR = 2.9), or with a recent history of falling (OR = 3.0), and in individuals over 80 years of age, compared with those under 80 (OR = 1.7) (Rubenstein and Josephson 2002). Falls are often multifactorial in their origin, with no specific single cause being identified (Rubenstein and Josephson 2002). This can make it difficult to understand the reasons why many falls occur. However, the most common causes of falls reported in the literature are accident and environment-related causes (31%), followed by gait and balance disorders (17%), and dizziness and vertigo (13%) (Rubenstein and Josephson 2002).

It is estimated that half of falls leads to an injury and 5 to 10% of falls result in a fracture (Tinetti, Speechley et al. 1988, Nevitt, Cummings et al. 1991). In New Zealand approximately 230 deaths occur each year that are due to falls (Dyson 2005). This is
second only to motor vehicle accidents with respect to injury related deaths (Stephenson, Langley et al. 2005). In people 65 or over, falls account for 54% of injury related deaths, which is by far the most common cause of injury related death in this age group (Stephenson, Langley et al. 2005). Besides the loss to society that results from falls related deaths, there are significant economic, health, and social impacts on the community due to the physical, mental and emotional trauma associated with falls (Taylor and Stretton 2004, Stephenson, Langley et al. 2005).

In New Zealand the cost of hospital care alone for falls related injuries was over $386 million (NZD) between 2000 and 2003, accounting for over half of all injury related hospital costs across the entire population (Stephenson, Langley et al. 2005). For people 65 years of age and over falls account for 83% of injury related hospital costs (Stephenson, Langley et al. 2005).

Besides the economic costs associated with falls, there are also significant health and social costs. Falls frequently result in a loss of independence as functional ability decreases following a falls related injury. This decline in function can continue for 12 months or more in older adults who have fallen and sustained a fracture (Russell, Hill et al. 2006). Even if physical injury is avoided, falls are a significant source of psychosocial distress. A fall can lead to a sense of powerlessness and a fear of falling in the future (Kong, Lee et al. 2002). This can then result in a less active lifestyle, leading to reduced strength, flexibility, and mobility (Kong, Lee et al. 2002). The overall result of this may be a decreased ability to complete activities of daily living and an increased likelihood of being placed in residential care, or increased reliance on family or community for support (Taylor and Stretton 2004). This loss of independence may be of greater concern to an older individual than the fear of pain and suffering itself (Kong, Lee et al. 2002). Not surprisingly, a history of falling has been found to contribute to depression and an overall loss in quality of life (Walsh, Polus et al. 2004, Michalowska, Fiszer et al. 2005).

With the significant burden to society associated with falls, governments around the world have invested in falls prevention strategies (Costello 2004, Dyson 2005). The New Zealand Government launched a 10 year National Falls Prevention Strategy in 2005 that aimed to reduce the incidence and severity of injury from falls, and to reduce the social,
psychological, and economic impact of falls on individuals and society in general (Dyson 2005). Part of this Strategy involved working with researchers to identify and prioritise research needs that may assist in achieving the Strategy’s goals. The New Zealand Government, largely through its ‘Accident Compensation Corporation’, has supported a number of initiatives that have aimed to prevent falls in older adults, such as the Otago Exercise Programme (OEP), tai chi classes, and vitamin D supplementation (Accident Compensation Corporation 2003, Accident Compensation Corporation 2006, Accident Compensation Corporation 2008). The research supporting the effectiveness of these falls prevention strategies, particularly the OEP (Thomas, Mackintosh et al. 2010), is encouraging, but mixed results in some trials mean there is still a lack of clarity regarding which approaches are most suitable for which population groups (Gillespie, Robertson et al. 2012).

Many falls prevention programmes are now being developed and implemented that incorporate a multifactorial approach (Close, Ellis et al. 1999, Elley, Robertson et al. 2008, Gillespie, Robertson et al. 2012). These intervention programmes involve a thorough assessment of known falls risk factors followed by appropriate referral when risk factors are identified (Elley, Robertson et al. 2008). Although some multiple intervention programmes have been shown to be effective, others have not been effective in reducing falls in older people (Close, Ellis et al. 1999, Elley, Robertson et al. 2008, Gillespie, Robertson et al. 2012). Multifactorial intervention approaches have also been criticised for being less cost effective than single intervention approaches (Davis, Robertson et al. 2010).

The role that chiropractors and other manual therapists may play in preventing falls in their patients is currently unclear. To date, few controlled trials have investigated how chiropractors and other manual therapists may influence falls risk (Hawk, Pfefer et al. 2007, Dougherty, Hawk et al. 2012). There is however a growing body of basic science evidence that suggests that chiropractic care may influence sensory and motor systems that potentially have an impact on some of the neuromuscular risk factors associated with falling (Haavik and Murphy 2012). The extent of this potential impact, if any, is currently unknown. The primary aim of this thesis was to investigate this potential
relationship by conducting a randomised controlled trial that investigated the effect of chiropractic care on sensorimotor function associated with risk of falling in older adults.

Besides the potential for a positive treatment effect of chiropractic care on fall risk, there is also a general public health role that chiropractors may play in this area. All health care providers are encouraged to support patients to make positive behavioural changes where appropriate (Hawk, Rupert et al. 2005). This is particularly true in the area of fall prevention where a number of fall risk factors are modifiable (Nachreiner, Findorff et al. 2007). This may be important for chiropractors to consider because the nature of complaints that lead older adults to seek chiropractic care may place them at an even greater risk of falling compared with the general older population. Little is known about the demographics and fall risk status of older patients attending chiropractic care. Therefore, this thesis also includes a cross-sectional study to investigate the proportion of older patients in a convenience sample of chiropractic practices who had experienced a previous fall to explore this issue.

1.2. Objectives of the thesis

In light of these considerations, a literature review of the topic and systematic review of manual therapy interventions to prevent falls were conducted. An exploratory study was also undertaken to investigate the likely prevalence of falls risk factors in older adults attending chiropractic care. Informed by the results of these, a randomised controlled trial was designed to assess the effectiveness of chiropractic care in improving sensorimotor function associated with risk of falling amongst older adults. Prior to the conduct of the main trial, the reliability and validity of the proposed outcome measures were tested.

Therefore, the specific thesis objectives were:

1. To conduct a literature review of falls risk factors.
2. To conduct a systematic review of the effects of manual therapy on balance and falls.
3. To estimate the proportion of older adults who attend chiropractic care who are at risk of falling.
4. To determine whether 12 weeks of chiropractic care was effective in improving sensorimotor function that is related to fall risk in community-dwelling older adults.

1.3. Structure of the thesis

The thesis is divided into seven chapters, including the introduction, literature review, systematic review, cross-sectional study, reliability/validity study, main trial, and thesis conclusions. The introduction has briefly presented the rationale for the thesis and its objectives. Chapter two is a literature review that provides background information that is relevant to the prevalence and burden of falls on society, and known fall risk factors. Current intervention strategies are reviewed. Chapter two also reviews the current understanding of the neurological mechanisms associated with chiropractic care, and how these mechanisms may provide a link between chiropractic care and improved sensorimotor function that may be important with respect to falls risk. Attention is also given to outcome measures used to assess falls risk that may be relevant to an experimental study that involves chiropractic care. Chapter three is a systematic review that assesses the existing research concerning the effects of manual therapies on balance and falls.

Chapter four is the cross-sectional study that sought to investigate the proportion of older chiropractic patients who had fallen in the past and estimate the proportion of older chiropractic patients who are at risk of falling. Chapter five is a reliability and validity study that investigated the outcome measures used in the main trial. Chapter six is the main trial of the thesis, the randomised controlled trial that assessed the effectiveness of chiropractic care in improving sensorimotor function associated with falls risk in older people. Finally, Chapter seven summarises the results of the thesis, its implications, and suggestions for future research that stem from it.
CHAPTER 2. LITERATURE REVIEW

2.1. Introduction

This literature review provides the context for the thesis. Section 2.2 expands on the background information presented in the introduction relating to the prevalence and burden of falls. Section 2.3 reviews the literature relating to risk factors associated with falling. Section 2.4 reviews intervention strategies that focus on individual risk factors as well as general intervention strategies. An introduction to chiropractic care and a brief review of the literature relating to chiropractic care and sensorimotor function is presented in Section 2.5. This section also includes a discussion of postulated mechanisms for how chiropractic care may reduce falls risk. This chapter concludes with a review of outcomes measures that may be useful when assessing the potential effects of chiropractic care on sensorimotor function that is associated with falls risk.

2.2. Background

Falls are generally defined as ‘an unexpected event in which the participant comes to rest on the ground, floor, or lower level’ (Lamb, Jorstad-Stein et al. 2005, Hauer, Lamb et al. 2006). In New Zealand and Australia approximately 30% of community dwelling older adults suffer from at least one fall per year, which is consistent with other international estimates (Tinetti, Speechley et al. 1988, Dyson 2005, Gill, Taylor et al. 2005). As mentioned in the introduction, this rate increases dramatically when a variety of risk factors are present (Tinetti, Speechley et al. 1988).

Falls cause more injury related deaths and hospital admissions in older adults than all other factors combined (Stephenson, Langley et al. 2005, Kannus, Khan et al. 2006). Significant injuries associated with falls include fractures, in particular hip fractures, and head trauma (Tinetti, Speechley et al. 1988, Grisso, Kelsey et al. 1991, Nevitt, Cummings et al. 1991). Of particular concern is that as the population ages the number of falls related injuries is rising sharply (Chang, Morton et al. 2004, Russell, Hill et al. 2006). From 1989 to 1998 the crude rate of falls-induced traumatic brain injury deaths in the United States of America increased by 60% in people over 80 years of age (Stevens and
Adekoya 2001). This has resulted in spiralling health care costs associated with treating falls related injuries.

In New Zealand the Accident Compensation Corporation estimates that they spent $272 million dollars in 2010 on injury costs associated with falls in the home alone (Accident Compensation Corporation 2011). When the social and economic direct and indirect costs of falls are combined it has been estimated that falls in New Zealand cost the country $1.8 billion per year, which is a considerable burden for a country of only 4.5 million people (Collins 2012, Statistics New Zealand 2013). In Australia the estimate of healthcare costs associated with falls is as high as four and a half billion Australian dollars per year (Hendrie, Hall et al. 2004, Walsh, Polus et al. 2004). With a population of a little over 23 million people this amounts to a contribution of close to $200 (AUD) per year for every man, woman, and child in Australia towards falls-related health care costs (Australian Bureau of Statistics 2013). In the US it is estimated that falls-related health-care costs exceeded $20 billion (USD) per annum by 1994 and they are predicted to reach over $32 billion (in 1994 US dollars) by 2020 (American Academy of Orthopedic Surgeons 1997, Chang, Morton et al. 2004). These financial costs are projected to increase exponentially over the next 50 years as the proportion of the population over the age of 65 in these countries rapidly increases (Hendrie, Hall et al. 2004, Moller 2005).

2.3. Falls risk factors

2.3.1. Background

As the social and economic impact of falls has been realised over recent years, significant government funds have been invested into learning more about falls risk factors and studying and implementing falls prevention programmes (Costello 2004, Dyson 2005).

Most falls occur due to an interplay of a number of risk factors (Tinetti 2003, Rao 2005). Risk factors are characteristics that are more commonly found in individuals who experience an adverse event compared to those that do not experience the event (Rubenstein and Josephson 2006). Risk factors for falls are best evaluated using a prospective study design as it ensures that the exposure occurred before the fall, so reduces the problem of reverse causality due to recall bias (Deandrea, Lucenteforte et al. 2010). Meaningful direct comparisons of the results of some prospective studies may not
be possible due to heterogeneity of studies with respect to follow-up times. The most common follow-up time for prospective falls studies appears to be 12 months (Nevitt, Cummings et al. 1991, Hill, Schwarz et al. 1999, Bergland and Wyller 2004, Muir, Berg et al. 2010). However, the follow-up time can range from six months to three years (Graafmans, Ooms et al. 1996, Brauer, Burns et al. 2000, Pluijm, Smit et al. 2006). Over 130 different risk factors have been identified for falls (Kwan, Close et al. 2011), with the risk of falling increasing when a combination of these risk factors are present (Tinetti, Speechley et al. 1988, Robbins, Rubenstein et al. 1989).

A variety of fall risk factors have consistently been reported in reviews. These include:

- **Female gender** (Deandrea, Lucenteforte et al. 2010, Tinetti and Kumar 2010, Kwan, Close et al. 2011),
- **Living alone or being unmarried** (Bloch, Thibaud et al. 2010, Deandrea, Lucenteforte et al. 2010, Kwan, Close et al. 2011),
- **Fear of falling** (Deandrea, Lucenteforte et al. 2010, Kwan, Close et al. 2011),
- **Gait abnormalities**, impaired mobility, or use of a walking aid (American Geriatrics Society 2001, Rao 2005, Rubenstein and Josephson 2006, Ganz,

- **Vertigo or dizziness** (Rubenstein and Josephson 2006, Deandra, Lucenteforte et al. 2010, Tinetti and Kumar 2010, Vieira, Freund-Heritage et al. 2011),


- **Hearing problems** (Soriano, DeCherrie et al. 2007, Deandra, Lucenteforte et al. 2010, Tinetti and Kumar 2010),

- **Proprioceptive loss** (Kannus, Sievanen et al. 2005, Soriano, DeCherrie et al. 2007),

- **Presence of pain** (Deandra, Lucenteforte et al. 2010, Tinetti and Kumar 2010),


Many of these risk factors are modifiable and can be addressed using appropriate intervention strategies that aim to reduce falls risk (American Geriatrics Society 2001, Gillespie, Robertson et al. 2009). A number of the risk factors, such as a history of falling, advancing age, and a decrease in activities of daily living, may not directly cause falls, but are markers of underlying causes (Rubenstein and Josephson 2006). They may
simply be associated with increased frailty, which is an indicator of multisystem impairment and vulnerability, including increased vulnerability to falling (Ensrud, Ewing et al. 2009).

This section discusses these commonly reported fall risk factors. Section 2.4 then reviews intervention strategies that relate to specific risk factors as well as general intervention strategies and multifactorial interventions that aim to reduce the risk of falling.

2.3.2. History of falling

A previous fall is one of the strongest and most consistently reported fall risk factors (American Geriatrics Society 2001, Rubenstein and Josephson 2006, Tinetti and Kumar 2010). In prospective studies a previous fall generally refers to a fall in the 12 months before the participant is enrolled in the study (Close, Ellis et al. 1999, Covinsky, Kahana et al. 2001). However, some studies use different timeframes, which may lead to variations in predicted odds ratios (ORs) between studies due to heterogeneity of risk criteria (Bergland and Wyller 2004).

A number of systematic reviews have reported ORs for a history of falling as a fall risk factor of between 1.5 to 7.0 (Rubenstein and Josephson 2002, Deandrea, Lucenteforte et al. 2010, Tinetti and Kumar 2010). Deandrea et al (2010) performed a meta-analysis of 18 prospective studies and reported an odds ratio of 2.77 for those with a history of falling compared with those who had not fallen previously (95% Confidence Interval (CI) 2.37 to 3.25). However, there was evidence of heterogeneity between the studies associated with different approaches for establishing a history of falling, the duration of follow-up, and the frequency of falls assessments. Heterogeneity was an issue for most fall risk factors investigated in this meta-analysis.

2.3.3. Increasing age

Increasing age is universally accepted as being associated with an increased falls risk (Rubenstein and Josephson 2006, Deandrea, Lucenteforte et al. 2010, Tinetti and Kumar 2010). Falls are reported to occur in approximately one third of community dwelling older adults in developed countries (Deandrea, Lucenteforte et al. 2010, Tinetti and Kumar 2010, Gillespie, Robertson et al. 2012). The incidence of falls continues to increase with advancing age, with people over the age of 80 reported to be almost twice
as likely (Mean OR 1.7) to suffer from a fall compared to older adults under the age of 80 years (Rubenstein and Josephson 2002). In their meta-analysis Deandrea et al (2010) calculated that a 5 year increase in age resulted in a small, but significant increase in fall risk (OR 1.12, 95% CI 1.07 to 1.17).

In New Zealand the rate of unintentional fall-related hospitalisations is over 20 times greater in individuals over the age of 80 years compared to those between 25-39, and over 10 times greater than those aged 60-64 (Figure 2:1) (Dyson 2005). For unintentional fall-related deaths the rate in New Zealand increases to 100 times greater in those over 80 compared to 25-39 year olds, and almost 50 times greater when compared to those aged 60-64 (Figure 2:2) (Dyson 2005).

Figure 2:1 - Unintentional Fall-Related Hospitalisations in New Zealand Between 1993-2002 (Dyson, 2005)
Like a history of falling, increasing age is not a direct cause of falling, but a marker of underlying causes (Rubenstein and Josephson 2006). With increasing age generally comes a decline in function of sensorimotor systems and the cardiopulmonary system, which are essential for the ability to transfer and walk safely (Bugnariu and Fung 2007, Diz, Varagic et al. 2008, Aagaard, Suetta et al. 2010, Hotta and Uchida 2010, Tinetti and Kumar 2010, Pannese 2011). With this decline in function comes reduced muscle strength (Sturnieks, St George et al. 2008, Beenakker, Ling et al. 2010), reduced reaction time (Sturnieks, St George et al. 2008), impaired sensorimotor integration (Bugnariu and Fung 2007), increased risk of syncope (Rubenstein and Josephson 2002), and other changes that result in an increased risk of falling (Rubenstein and Josephson 2002, Lord, Menz et al. 2003, Sturnieks, St George et al. 2008, Pijnappels, Delbaere et al. 2010).
2.3.4. Female gender

In their analysis of socio-demographic fall risk factors, Deandrea et al (2010) reported an OR of 1.30 (95% CI 1.18-1.42) for female gender compared with male gender for fall risk. Besides an overall increased risk of falling, women also tend to suffer from fall related injuries at a higher rate than men (Stevens and Sogolow 2005, Nachreiner, Findorff et al. 2007). Stephens and Sogolow (2005) analysed nationally representative data in the US from over 22,500 cases of fall related emergency department visits and reported that 70.5% of visits were made by women. Women were also 2.2 times as likely to suffer a fracture from a fall and 1.8 times more likely to be hospitalised due to a fall than men.

Campbell, Spears and Borrie (1990) used logistic modelling to investigate physical and sociological variables related to sex differences in fall rate and reported a decrease in relative risk (RR) of women falling compared to men from 2.02 (95% CI 1.40 to 2.92) to 1.55 (95% CI 1.04 to 2.31) when they controlled for age, use of psychotropic drugs, inability to rise from a chair without using arms, going outdoors less than daily, and living alone. The latter two of these variables may be associated with gender differences in levels of physical activity, as older men have been reported to be more physically active than women (Davis, Neuhaus et al. 1994). Physical activity influences muscle strength, which is greater in older men than women, and is associated with fall risk (Oman, Reed et al. 1999, Rubenstein and Josephson 2002). Physical activity status has also been shown to play a key role in balance performance so provides another potential explanation for gender differences in falling in older adults (Bulbulian and Hargan 2000).

2.3.5. Living alone or being unmarried

Living alone has been associated with an increased fall risk (OR 1.33, 95% CI 1.21 to 1.45) (Deandrea, Lucenteforte et al. 2010). It is not clear what exactly causes the increased risk of falling in those who are living alone, but it is most likely due to a combination of factors. Possible factors that have been suggested in the literature include (Campbell, Spears et al. 1990):

- Women carrying out high risk tasks that are usually performed by men.
- An increase in tiredness and clumsiness due to an inability to share the workload in household activities.
• Reluctance to heat the house adequately for one person resulting in hypothermia.
• Lack of a partner reducing the desire to go for walks or other physical activity leading to physical deconditioning.
• Lack of someone to offer support if an older person stumbles while walking.

It is likely that some confounding may take place due to age and gender as women are at an increased risk of falling and they are more likely to be living alone due to their greater life expectancy (Mota-Pinto, Rodrigues et al. 2011). Bloch, Thibauld et al. (2010) provided some support for this assumption when they performed a subgroup analysis that suggested living alone was a marginally significant fall risk factor for those over 80 years of age (OR 1.25, 95% CI 1.01 to 1.54), but not for older people under the age of 80 (OR 1.12, 95% CI 0.93 to 1.34).

There is likely to be a link between the increased risk of falling associated with living alone and the protective effect of being married that has been reported for falling, particularly in those over the age of 80 years (OR 0.68, 95% CI 0.53 to 0.87) (Bloch, Thibaud et al. 2010). Being married will result in a reduction in the proposed factors associated with living alone and increased fall risk, and may also be important from a psychosocial perspective, with older adults who are married being less likely to be depressed, which is also a fall risk (Rubenstein and Josephson 2002, Mechakra-Tahiri, Zunzunegui et al. 2010).

### 2.3.6. Presence of home hazards

Most falls occur in and around the home, with home hazards often considered to be the most important environmental risk factor for falling (Rao 2005, Letts, Moreland et al. 2010). Key environmental hazards include poor lighting, loose carpet or rugs, clutter, unstable furniture, obstructed walkways, and wet surfaces (Lord, Menz et al. 2006, Letts, Moreland et al. 2010, Vieira, Freund-Heritage et al. 2011). However, the results of studies that have examined the association between home hazards and falls have been mixed (Lord, Menz et al. 2006). Letts et al. (2010) performed a meta-analysis of studies that investigated the physical environment as a fall risk factor in older adults and reported that the presence of home hazards resulted in a non-significant increase in fall risk (OR 1.15, 95% CI 0.97 to 1.36), but when only high quality studies were considered the risk
became significant (OR 1.38, 95% CI 1.03 to 1.87). The authors of this meta-analysis also suggested that repeat fallers are at a greater risk of falling due to home hazards.

Although environmental hazards are claimed to be the leading cause of falls (Rao 2005), in actuality falls are not generally caused by the environmental hazard. Instead they are the result of an interaction between intrinsic factors associated with age and disease, such as changes in postural control, muscle strength, and step height, combined with the presence of external hazards or hazardous activity (Lord, Menz et al. 2006, Rubenstein and Josephson 2006, Vieira, Freund-Heritage et al. 2011). Evidence to support this assertion can be found in the secondary analyses of two studies that found that environmental hazards play a greater role in causing falls in vigorous people compared to frail people (Speechley and Tinetti 1991, Northridge, Nevitt et al. 1995). This is thought to be related to the interaction between the person and environment, in particular the person’s competence compared to the demands of the environment, and also the person’s level of risk-taking behaviour (Lord, Menz et al. 2006).

2.3.7. Fear of falling

Most definitions of fear of falling include some aspect of being afraid or worried about falling, but others include ‘falls efficacy’, which refers to an individual’s perceived ability to undertake activities of daily living without falling (Legters 2002, Hadjistavropoulos, Delbaere et al. 2011). Fear of falling may be assessed using simple yes/no responses to questions that ask ‘are you afraid of falling’, or by asking individuals to indicate their degree of fear (Legters 2002). It may also be assessed using well validated scales such as the Activities Specific Balance Confidence Scale, and the Falls Efficacy Scale, which aim to measure falls efficacy (Tinetti, Richman et al. 1990, Powell and Myers 1995).

Fear of falling is a well-recognised fall risk factor (Friedman, Munoz et al. 2002, Deandrea, Lucenteforte et al. 2010, Kwan, Close et al. 2011). The odds ratio rises from 1.55 (95% CI 1.14 to 2.09) when all fallers are considered, to 2.51 (95% CI 1.78 to 3.54) for recurrent fallers (Deandrea, Lucenteforte et al. 2010).

Fear of falling is very common in older people, with a prevalence rate of 50% or more frequently reported in community dwelling older adults (Kressig, Wolf et al. 2001, Zijlstra, van Haastregt et al. 2007). An increased fear of falling has been reported in
women, in those of an advanced age, in people who have suffered from a previous fall, and those with perceived poor health (Zijlstra, van Haastregt et al. 2007, Kempen, van Haastregt et al. 2009).

Fear of falling may develop following a fall, as well as being a predictor of a future fall in individuals who have not previously fallen (Friedman, Munoz et al. 2002). Other factors that may lead to a fear of falling are balance or gait problems, knowledge of others that have fallen, and depression (Hadjistavropoulos, Delbaere et al. 2011). It is unclear if fear of falling is an independent fall risk factor, or if it simply reflects a balance or gait problem that is the true risk factor (Hadjistavropoulos, Delbaere et al. 2011). It has been hypothesised however, that fear of falling may result in anxiety, which has a direct negative effect on balance (Hadjistavropoulos, Carleton et al. 2011).

Fear of falling often leads to avoidance of activities, which causes a variety of potentially negative consequences (Zijlstra, van Haastregt et al. 2007). These include functional decline, restriction of social participation, decreased quality of life, and institutionalisation (Zijlstra, van Haastregt et al. 2007, Kempen, van Haastregt et al. 2009). Avoidance of activity can then, in turn, cause deconditioning and poor balance performance, which increases fall risk (Hadjistavropoulos, Delbaere et al. 2011).

2.3.8. Decrease in activities of daily living

Activities of daily living (ADLs) refers to the basic tasks of everyday life such as eating, bathing, and dressing (Wiener, Hanley et al. 1990). They can be divided into basic ADLs, which include bathing, dressing, eating, grooming, transferring, and walking across the room; and instrumental ADLs, which include taking medications, using the telephone, handling finances, housekeeping, cooking, shopping, and using transportation (Tinetti and Kumar 2010). A decrease in ADLs has consistently been reported to be associated with an increased falls risk (American Geriatrics Society 2001, Deandrea, Lucenteforte et al. 2010, Tinetti and Kumar 2010, Kwan, Close et al. 2011). A number of studies have reported ORs in the range of 1.5 to 6.2 for a decline in ADLs as a fall risk factor (American Geriatrics Society 2001, Tinetti and Kumar 2010, Kwan, Close et al. 2011). In their meta-analysis Deandrea et al (2010) reported an OR for a decline in instrumental ADLs of 1.46 (95% CI 1.20 to 1.77).
A decrease in ADLs has a complex and multifaceted relationship with increased fall risk (Grue, Ranhoff et al. 2009). It is a consequence of falling, a cause of falling, and most likely an indirect marker of increased fall risk due to its association with frailty and other direct fall risk factors (Nourhashemi, Andrieu et al. 2001, Grue, Ranhoff et al. 2009, de Albuquerque Sousa, Dias et al. 2011, Dias, Freire et al. 2011, Hadjistavropoulos, Delbaere et al. 2011). As previously mentioned, avoidance of activity due to fear of falling can result in deconditioning and an increased fall risk (Hadjistavropoulos, Delbaere et al. 2011). A decrease in ADLs is also associated with frailty, which is itself an independent fall risk factor (Nourhashemi, Andrieu et al. 2001, Ensrud, Ewing et al. 2009, de Albuquerque Sousa, Dias et al. 2011).

2.3.9. Medication use

The role that medication use plays in increasing the risk of falling has been assessed by numerous systematic reviews and meta-analyses (Leipzig, Cumming et al. 1999, Leipzig, Cumming et al. 1999, Hartikainen, Lonnroos et al. 2007, Soriano, DeCherrie et al. 2007, Hegeman, van den Bemt et al. 2009, Woolcott, Richardson et al. 2009, Deandrea, Lucenteforte et al. 2010, Kwan, Close et al. 2011, Vieira, Freund-Heritage et al. 2011). Although there is some disagreement between the reviews about the effects of some medications on falls risk, consistent findings suggest the use of many centrally acting medications increase the risk of falling (Hartikainen, Lonnroos et al. 2007). These medications include sedatives, hypnotics, antidepressants, antipsychotics, and neuroleptics (Leipzig, Cumming et al. 1999, Hartikainen, Lonnroos et al. 2007, Woolcott, Richardson et al. 2009, Vieira, Freund-Heritage et al. 2011). Estimating the true effect that medication classes have on fall risk is difficult due to confounding variables such as indication (Woolcott, Richardson et al. 2009, Tinetti and Kumar 2010). This occurs when the condition a medication is prescribed to treat is a fall risk factor in its own right.

Recently, Woolcott et al (2009) updated previous meta-analyses and used Bayesian methodology to calculate pooled estimates of the ORs for a variety of drug classes. In their unadjusted analysis, antihypertensive agents (OR 1.24, 95% CI, 1.01 to 1.50); diuretics (OR 1.07, 95% CI, 1.01 to 1.14); sedatives and hypnotics (OR 1.47, 95% CI, 1.35 to 1.62); neuroleptics and antipsychotics (OR 1.59, 95% CI, 1.37 to 1.83); antidepressants (OR 1.68, 95% CI, 1.47 to 1.91); benzodiazepines (OR 1.57, 95% CI, 1.43 to 1.72); and nonsteroidal anti-inflammatory drugs (OR 1.21, 95% CI, 1.01 to 1.44)
were associated with an increased risk of falling. However, the ORs for diuretics (OR 0.99, 95% CI, 0.78 to 1.25) and neuroleptics/antipsychotics (OR 1.39, 95% CI, 0.94 to 2.00) were no longer statistically significant after adjustment for other confounding variables.

Polypharmacy, irrespective of drug classes, is often reported to be a risk factor for falling (American Geriatrics Society 2001, Hartikainen, Lonnroos et al. 2007, Soriano, DeCherrie et al. 2007, Deandrea, Lucenteforte et al. 2010, Tinetti and Kumar 2010, Kwan, Close et al. 2011). Deandrea et al (2010) reported a small, but significant, increase in OR (1.06, 95% CI, 1.04 to 1.08) for fall risk with each 1-drug increase in prescribed medications. Other reviews have reported ORs of between 1.3 to 2.7 for the risk of taking four or more medications on fall risk (Hartikainen, Lonnroos et al. 2007, Tinetti and Kumar 2010). However, in their large cross-sectional study that investigated the association between falls, chronic disease, and polypharmacy in older women, Lawlor, Patel et al. (2003) reported that when they adjusted for the presence of chronic disease and other confounding variables, polypharmacy became an insignificant risk factor for falling. This supports the proposition that indication is a confounding variable that may be more important than polypharmacy itself as a fall risk factor (Lawlor, Patel et al. 2003, Woolcott, Richardson et al. 2009, Tinetti and Kumar 2010).

It has been hypothesised that adverse medication effects, such as unsteadiness, impaired alertness and cognition, impaired balance, and dizziness are the reasons behind the increased risk of falling associated with medication use (Hartikainen, Lonnroos et al. 2007, Tinetti and Kumar 2010).

2.3.10. Gait abnormalities, impaired mobility and use of a walking aid

Gait impairments or walking difficulties are associated with a strong increase in fall risk (OR 2.06, 95% CI 1.82 to 2.33) (Deandrea, Lucenteforte et al. 2010). Use of a walking aid, such as a walking stick or walker, is associated with a similar increase in fall risk (OR 2.18, 95% CI 1.79 to 2.65) (Deandrea, Lucenteforte et al. 2010). This may be due to the walking aid simply being a marker for gait related problems that are the true cause of falling (Ganz, Bao et al. 2007).

The prevalence of gait disorders increases rapidly with age from 15% at age 60 to 82% at age 85 (Axer, Axer et al. 2010). Gait disorders can be caused by a large variety of
problems such as peripheral neuropathies, vestibular dysfunction, myopathies, Parkinson’s disease, cerebellar dysfunction, and problems with planning and executive function caused by dementia or cognitive impairment (Axer, Axer et al. 2010).

2.3.11. Vertigo or dizziness

The risk of falling associated with vertigo or dizziness in older adults is OR 1.80 (95% CI 1.39 to 2.33) for all fallers and OR 2.28 (95% CI 1.90 to 2.75) for recurrent fallers (Deandrea, Lucenteforte et al. 2010). It is thought to cause approximately 13% of all falls in older adults and is associated with a considerable emotional and functional burden (Rubenstein and Josephson 2002, Gopinath, McMahon et al. 2009).

Dizziness is a common complaint associated with ageing and is reported by about one third or more of older adults (Gopinath, McMahon et al. 2009, Walther, Rogowski et al. 2010). In older adults with vestibular disorders the most common diagnoses are benign paroxysmal positional vertigo (BPPV) (43.8%), and metabolic inner ear disease (42.2%) (Gazzola, Gananca et al. 2006). There are many other recognised causes of dizziness in older adults including orthostatic hypotension, adverse medication effects, migraine, multiple sclerosis, and anxiety (Gopinath, McMahon et al. 2009, Tinetti and Kumar 2010).

2.3.12. Balance impairments

Balance impairment is a moderate fall risk factor in community dwelling older adults (OR 1.98, 95% CI 1.60 to 2.56, RR 1.42, 95% CI 1.08 to 1.85) (Muir, Berg et al. 2010). A number of reviewers have indicated that it is difficult to calculate a single summary measure for balance impairment as a fall risk factor due to non-equivalence associated with the variety of measures that are used to assess postural stability and balance (Deandrea, Lucenteforte et al. 2010, Muir, Berg et al. 2010).

Postural stability refers to an individual’s ability to maintain the centre of mass of their body within the boundary in which they can sustain their position without changing their base of support (Lord, Sherrington et al. 2007). Maintaining postural stability requires a complex interplay between sensory and motor systems in the body. Sensory contributions from vision, vestibular sense, and proprioception are processed and integrated in the brain, and an appropriate motor response is generated in order to maintain balance.
(Sturnieks, St George et al. 2008). This process of maintaining postural stability is susceptible to damage or impairment at any stage of the sensorimotor pathway (Horlings, van Engelen et al. 2008, Sturnieks, St George et al. 2008, Orr 2010). Balance impairment may therefore be caused by general functional decline in postural regulating systems associated with ageing, or a variety of conditions that have an impact on the function of the sensory, motor and integrative systems (Bugnariu and Fung 2007, Sturnieks, St George et al. 2008).

Although balance and postural stability are widely acknowledged to be important fall risk factors, falls do not generally occur because an individual is simply unstable on their feet (Lord, Ward et al. 1994, Lord, Rogers et al. 1999, Woollacott and Shumway-Cook 2002, Deandrea, Lucenteforte et al. 2010, Muir, Berg et al. 2010). Falls are more likely to occur because an individual is unable to rapidly recover when their balance becomes compromised during every day activities (Woollacott and Shumway-Cook 2002, Tucker, Kavanagh et al. 2010). This may explain why tasks that assess an individual’s ability to react and respond quickly with their body have greater predictive value on fall risk than measures of postural stability alone (Brauer, Burns et al. 2000, Lord and Fitzpatrick 2001, Buatois, Gueguen et al. 2006, Pirtola and Pertti 2006, Pijnappels, Delbaere et al. 2010).

2.3.13. Muscle weakness

Muscle weakness, in particular lower limb weakness, is one of the most consistently reported falls risk factors (American Geriatrics Society 2001, Rubenstein and Josephson 2002, Moreland, Richardson et al. 2004, Horlings, van Engelen et al. 2008, Tinetti and Kumar 2010). Muscle weakness is associated with an overall increase in the number of falls, the likelihood of recurrent falls, and the risk of injurious falls (Moreland, Richardson et al. 2004, Horlings, van Engelen et al. 2008). A meta-analysis by Moreland et al (2004) reported an OR for muscle weakness of 1.76 (95% CI 1.31 to 2.37) for any fall and 3.06 (95% CI 1.86 to 5.04) for recurrent falls.

A variety of neuromuscular diseases that cause muscle weakness have been linked to an increased fall risk (Pieterse, Luttikhold et al. 2006). Examples of these diseases include muscular dystrophies, myopathies, Parkinson’s disease, amyotrophic lateral sclerosis, myasthenia gravis, and multiple sclerosis (Pieterse, Luttikhold et al. 2006). These diseases may impair balance by causing deficiencies in muscle tone, proximal or distal
limb strength, axial strength, or speed of muscle contraction (Michalowska, Fiszer et al. 2005, Pieterse, Luttikhold et al. 2006, Horlings, van Engelen et al. 2008, Orr 2010, Allen, Sherrington et al. 2011, Sosnoff, Socie et al. 2011). These deficiencies may result in impaired balance recovery in the face of external balance perturbations, inadequate obstacle clearance, or decreased joint stabilisation, which may all play a role in increasing fall risk (Horlings, van Engelen et al. 2008, Sturnieks, St George et al. 2008).

2.3.14. Vision problems

Vision impairment is a well-recognised fall risk factor (Lord 2006, Dhital, Pey et al. 2010). A number of reviews have reported an OR of between 1.3 to 3.5 for vision impairments as a risk factor for falling (Rubenstein and Josephson 2002, Deandrea, Lucenteforte et al. 2010, Tinetti and Kumar 2010, Kwan, Close et al. 2011). The strength of the association is increased in recurrent fallers (OR 1.60, 95% CI 1.28 to 2.00) compared to all fallers (OR 1.35, 95% CI 1.18 to 1.54) (Deandrea, Lucenteforte et al. 2010).

The relationship between vision impairment and fall risk is complex, due to the multitude of vision problems that exist and the multifactorial nature of falls (Dhital, Pey et al. 2010). One reason for this complexity is likely due to the variety of compensatory mechanisms that human beings employ when they are suffering from a sensory impairment (Kulmala, Viljanen et al. 2009). In their twin study, Kulmata et al (2009) reported that decreased visual acuity on its own resulted in a small, non-significant increased rate of falling (Incidence rate ratio (IRR) 1.5, 95% CI 0.6 to 4.2). The rate however almost doubled when vision impairment was combined with impaired balance (IRR 2.7, 95% CI 0.9 to 8.0), more than tripled if combined with a hearing impairment, and became highly significant if all three sensory modalities were impaired (IRR 29.4, 95% CI 5.8 to 148.3). Kulmata et al (2009) concluded that when combined with other sensory impairments, vision impairment has an increased impact on fall risk, as the combined impairment results in a lack of compensatory information on which to base corrective fall prevention responses.

A variety of visual impairments that have been associated with increased fall risk include poor visual acuity (Lord, Ward et al. 1994, Ivers, Cumming et al. 1998, Klein, Moss et al. 2003), poor contrast sensitivity (Lord, Ward et al. 1994, Ivers, Cumming et al. 1998, Lord
and Dayhew 2001), reduced depth perception (Ivers, Cumming et al. 1998, Lord and Dayhew 2001), visual field loss (Ivers, Cumming et al. 1998, Klein, Moss et al. 2003, Patino, McKean-Cowdin et al. 2010, Black, Wood et al. 2011), age-related macular degeneration (Szabo, Janssen et al. 2008), glaucoma (Ivers, Cumming et al. 1998), and the presence of cataracts (McCarty, Fu et al. 2002). Lord (2006) reported that over many years of study his group found that reduced contrast sensitivity and depth perception are two of the strongest risk factors for falling amongst nine measures of vision.

Contrast sensitivity is the ability to detect edges under low contrast conditions, such as during sub-optimal illumination, and is thought to be more important for detecting ground level hazards (Harwood 2001, Lord 2006). Lord (2006) suggests that poor edge contrast sensitivity may predispose older people to trips over hazards such as kerbs, steps and home obstacles. Poor depth perception is most likely associated with falls because it affects an individual’s ability to judge distances and spatial relationships, which is important when trying to negotiate environmental hazards (Lord 2006). Both edge contrast sensitivity and depth perception may be impaired by the use of multifocal glasses due to the lower lenses causing blurriness in the lower visual field, which results in a decreased ability to detect and navigate around objects when walking (Lord, Dayhew et al. 2002). This impairment results in a greater risk of falling in wearers of multifocal glasses compared to wearers of non-multifocal glasses (OR 2.27, 95% CI 1.04 to 4.97) (Lord, Dayhew et al. 2002).

### 2.3.15. Hearing problems

Deandrea et al (2010) reported that hearing impairments are a small, but significant, falls risk factor (OR 1.21, 95% CI 1.05 to 1.39). One of the proposed mechanisms to explain this relationship is that hearing impairments affect an individual’s ability to detect and interpret auditory stimuli that help them to orient in space, or notice and avoid environmental hazards that could lead to a fall (Soriano, DeCherrie et al. 2007, Viljanen, Kaprio et al. 2009). It has also been postulated that hearing and balance impairments are related due to the close anatomical relationship between the cochlear and vestibular apparatus (Viljanen, Kaprio et al. 2009). Another potential mechanism relates to a breakdown in multisensory integration that involves hearing. Setti, Burke and Kenny (2011) demonstrated that older adults who have fallen had greater difficulty in integrating audio-visual information compared with older people who had not fallen or younger
people. They argued that falling may be related to impairment in multisensory integration as opposed to poor sensory acuity. It is also possible that hearing loss is just a manifestation of frailty and therefore not an independent falls risk factor (Lang, Michel et al. 2009). Grue et al (2009) reported that falling was associated with hearing loss in their sample of acute hospitalised older persons, but when logistic regression analysis was performed that included co-variables such as age over 85 and cognitive impairment, falls were not independently related to hearing loss.

Studies of the association between hearing and balance are scarce, but a small amount of evidence exists that suggests that individuals with poor hearing have greater postural sway, more difficulty walking, and a loss of the ability to perform instrumental activities of daily living (Grue, Ranhoff et al. 2009, Viljanen, Kaprio et al. 2009, Viljanen, Kaprio et al. 2009).

2.3.16. Proprioceptive loss

Proprioception is the ability to sense the position, location, orientation and movement of the body and its parts (Westlake and Culham 2006). In the literature there is some disagreement in the definition of proprioception, with some authors arguing that it should only relate to the unconscious processing of information that is necessary for reflexive and postural motor control (Konczak, Corcos et al. 2009). Others embrace a broader definition that encompasses the overall perception of joint position and movement in space, that is based on sensory information other than visual, vestibular, and auditory sensation (Lord, Menz et al. 2003, Soriano, DeCherrie et al. 2007, Goble, Mousigian et al. 2011). Despite the lack of agreement on a definition of proprioception, there is support for the important role that proprioception plays in maintaining postural stability and preventing falls (Lord, Menz et al. 2003, Westlake and Culham 2006, Horlings, van Engelen et al. 2008, Konczak, Corcos et al. 2009).

It is difficult to estimate the association between proprioceptive loss and fall risk due to the insensitivity of the assessments that are often used to detect sensation loss, and the tendency for investigators to take a disease oriented approach to fall risk as opposed to a physiological approach (Lord, Menz et al. 2003, Sturnieks, St George et al. 2008). Proprioception is essential for maintaining balance and gait control, so it’s association with fall risk may best be estimated by referring to risks associated with balance and gait.
impairments (Westlake and Culham 2006). Proprioceptive ability declines with ageing, or may become compromised by diseases such as Parkinson’s disease, diabetes mellitus, or other conditions that cause nervous system damage (DeMott, Richardson et al. 2007, Sturnieks, St George et al. 2008, Konczak, Corcos et al. 2009, Tinetti and Kumar 2010, Goble, Mousigian et al. 2011).

Poor proprioceptive ability has been linked to impairments in the control of voluntary movements. These include difficulties in calibrating hand position in space, sustaining constant muscle force levels and movement amplitudes, discriminating object weights, performing targeted movements, producing coordinated gait patterns, and controlling the timing of muscle contractions (Goble, Coxon et al. 2009). This, in turn, is thought to negatively impact balance and locomotor control in older adults, leading to an increased risk of falling (Lord, Ward et al. 1994, Hurley, Rees et al. 1998, La Grow, Robertson et al. 2006, Westlake and Culham 2007).

The sensory modalities that are considered to be most important for postural stability are vision, vestibular function, and proprioception (Lord and Ward 1994). Of these modalities, proprioceptive input from the lower limb is thought to be the most important sensory contributor to standing balance (Lord and Ward 1994, Sturnieks, St George et al. 2008). This is likely due to the lower proprioceptive threshold in the perception of postural sway compared with the visual or vestibular thresholds (Fitzpatrick and McCloskey 1994). The importance of proprioception to postural stability and balance, walking stability, sit to stand performance, stair walking ability, and risk of falling, has previously been established in older adults (Lord, Rogers et al. 1999, Westlake and Culham 2006).

There is however some conflicting evidence regarding the strength of the relationship between poor proprioceptive function and falls risk (You 2005, Sturnieks, St George et al. 2008). Surprisingly, relatively little research has been performed that helps to gain a greater understanding of the nature of this relationship (Sturnieks, St George et al. 2008). Sturnieks, St George et al. (2008) believe that conflicting results in this area may be due to the insensitivity of some of the wide array of assessments that are used to detect proprioceptive impairment. They argue that reduced proprioception is a risk factor for falls in older people, but the association does not emerge unless the measures of proprioception are appropriately ascertained.
2.3.17. Presence of pain

Musculoskeletal pain is associated with an increased fall risk (OR 1.39, 95% CI 1.19 to 1.62) (Deandrea, Lucenteforte et al. 2010). This association gets stronger the more pain causes interference to activities of daily living (OR 1.53, 95% CI 1.15 to 2.05) (Leveille, Bean et al. 2002, Blyth, Cumming et al. 2007, Leveille, Jones et al. 2009). Widespread pain has the strongest association with falling (OR 1.66, 95% CI 1.25 to 2.21), and the foot is the single site of pain most closely linked to increased fall risk (OR 1.35, 95% CI 1.10 to 1.66) (Leveille, Bean et al. 2002, Leveille, Jones et al. 2009). Those suffering from the most severe pain are also at more risk of falling compared to those suffering from minimal amounts of pain (OR 1.53, 95% CI 1.12 to 2.05) (Leveille, Bean et al. 2002, Leveille, Jones et al. 2009).

A number of mechanisms have been proposed to explain the link between pain and falling. These include; reflex muscle inhibition, deconditioning causing muscle weakness, joint instability, gait alterations, slowed reaction time, and changes to attentional demands or cognitive function (Leveille, Bean et al. 2002, Leveille, Jones et al. 2009, Tinetti and Kumar 2010). Neck pain may also influence afferent input from the cervical spine to the central nervous system, which may contribute to poor sensorimotor control, impaired proprioception, and reduced postural stability (Treleaven 2008, Uthaikhup, Jull et al. 2012).

2.3.18. Depression or cognitive impairment

Depression and cognitive impairment are among the most common mental health problems in older adults (Rubenstein and Josephson 2006, Huang, Wang et al. 2011). They are also important falls risk factors, with depression having a slightly stronger association with falls (OR 1.63, 95% CI 1.36 to 1.94) than cognitive impairment (OR 1.36, 95% CI 1.12 to 1.65) (Deandrea, Lucenteforte et al. 2010).

Cognitive impairment has a strong relationship with impairment of gait and balance, and may be associated with underlying disease processes that increase falls risk (Shaw 2002, Rubenstein and Josephson 2006, Axer, Axer et al. 2010). Impaired cognition results in higher level gait disorders that are characterised by a breakdown in planning, intention, and executive function (Axer, Axer et al. 2010). The link between depression and falls is not well understood, but may be due to an increase in risk taking behaviour, a lack of
attention to environmental hazards, increased general frailty that is associated with depression, increased use of psychoactive medication use, or it may simply be due to a previous fall and therefore not a causative risk factor (Rubenstein and Josephson 2006, Kvelde, Pijnappels et al. 2010).

2.3.19. Other medical conditions

A variety of medical conditions that have not been directly addressed in previous sections are associated with an increased falls risk. The most notable of these conditions are:

- Parkinson’s disease (OR 2.71, 95% CI 1.08 to 6.84) (Deandrea, Lucenteforte et al. 2010),
- Diabetes (OR 1.19, 95% CI 1.08 to 1.31) (Deandrea, Lucenteforte et al. 2010),
- Rheumatic joint diseases (OR 1.47, 95% CI 1.28 to 1.70) (Deandrea, Lucenteforte et al. 2010), and
- Urinary incontinence (OR 1.40, 95% CI 1.26 to 1.57) (Deandrea, Lucenteforte et al. 2010).

Most of these conditions are thought to indirectly increase fall risk because of the impact they have on many of the risk factors for falling that have previously been discussed. For example, Parkinson’s disease results in balance impairments, poor motor control, and proprioceptive deficits (Konczak, Corcos et al. 2009, Allen, Sherrington et al. 2011). Diabetes often causes sensorimotor neuropathy, which may cause balance impairments and gait deficits (Lin, Chen et al. 2010, Morrison, Colberg et al. 2010); and arthritis may cause gait impairment, muscle weakness and pain (Rubenstein and Josephson 2006, Levinger, Menz et al. 2011).

2.4. Falls intervention strategies

2.4.1. Background

The identification of falls risks is particularly important when the risk factors are modifiable (Nachreiner, Findorff et al. 2007). By identifying falls risk factors, appropriate
intervention strategies can be implemented in an attempt to reduce the chance of an individual suffering from a fall. The following section reviews general intervention strategies as well as approaches that are recommended when individual risk factors are identified.

2.4.2. Exercise interventions and tai chi

Exercise interventions are amongst the most beneficial and cost effective interventions that are employed to reduce falls risk (Davis, Robertson et al. 2010, Gillespie, Robertson et al. 2012). Exercise interventions that have proven to be effective in preventing falls include multiple-component group exercise (RR 0.85, 95% CI 0.76 to 0.96) and multiple-component home-based exercise (RR 0.78, 95% CI 0.64 to 0.94) (Gillespie, Robertson et al. 2012). Although exercise interventions on the whole have been shown to be effective in reducing falls risk, many individual programmes have failed to have a significant impact (Gillespie, Robertson et al. 2012). This may be due to a lack of specificity of the exercise intervention for the individuals involved, as exercise programmes are often not individualised, and group exercise programmes may not be suitable or effective for all members of the group (Lord, Sherrington et al. 2007).

One of the most cost effective falls prevention interventions was developed in New Zealand and is called the Otago Exercise Programme (OEP) (Davis, Robertson et al. 2010). The OEP is a community-based strength and balance retraining programme that is commonly delivered by physiotherapists and nurses (Taylor and Stretton 2004, Thomas, Mackintosh et al. 2010). The OEP significantly reduces the risk of death (RR 0.45, 95% CI 0.25 to 0.80) and the rate of falling (incidence rate ratio (IRR) 0.68, 95% CI 0.56 to 0.79) in community dwelling older adults (Thomas, Mackintosh et al. 2010), and has the greatest impact in those aged over 80 years of age (Robertson, Campbell et al. 2002). It has been described as one of the best value for money programmes for preventing falls in older adults living in the community (Davis, Robertson et al. 2010).

Tai chi may help improve balance and has also been reported to reduce the risk of falling (RR 0.71, 95% CI 0.57 to 0.87) (Gillespie, Robertson et al. 2012). However, meta-analyses have revealed that the effect of tai chi on the rate of falls is less conclusive (Logghe, Verhagen et al. 2010, Gillespie, Robertson et al. 2012). A recent large scale New Zealand based trial compared the effectiveness of the Accident Compensation
Corporation funded modified tai chi programme to a low level exercise active control (Taylor, Hale et al. 2012). The rate of falls fell by 58% over the course of the study for all groups combined, but no differences were reported in falls rates between groups.

2.4.3. History of falling

Guidelines developed jointly by a panel from the American Geriatrics Society, the American Academy of Orthopedic Surgeons, and the British Geriatrics Society, recommended that older persons under routine care of a health professional should be asked at least once a year if they have experienced a fall, and if a fall is reported a screening “Get Up and Go Test” should be performed (American Geriatrics Society 2001). This test involves observing while the person stands up from a chair, without using their arms, and walks several paces and returns. The panel recommended that if the patient has difficulty completing this test, or they exhibit unsteadiness while performing the test, further evaluation is warranted. If an older person reports for medical care following a fall, or they are identified as being in another high risk group, a more detailed evaluation is appropriate (American Geriatrics Society 2001, Ganz, Bao et al. 2007). Other high risk groups include patients that have experienced multiple falls in a 12 month period or demonstrate abnormalities of balance or gait (American Geriatrics Society 2001, Ganz, Bao et al. 2007).

2.4.4. Gender

Although gender is obviously not a modifiable risk factor, Campbell et al (1990) hypothesised that if gender related modifiable risk factors were tackled this may reduce the gender gap that exists in falls in older adults. Gender related modifiable risk factors that may be addressed include decreasing the use of psychotropic medication by women, providing increased help with household tasks, and increasing their physical activity with daily walks and training programmes (Campbell, Spears et al. 1990). To date the effectiveness of this approach has not been investigated in the literature.

2.4.5. Living alone or being married

Although intervention programmes are unlikely to address living arrangements or marital status, it has been proposed that increased help with certain household tasks, or
encouragement to perform physical activity in those who live alone may have a beneficial effect in preventing falls (Campbell, Spears et al. 1990).

2.4.6. Presence of home hazards

Occupational therapists often assess the homes of older people who have fallen for hazards in an attempt to reduce fall risk (Letts, Moreland et al. 2010). Interventions utilised generally include education concerning home hazards, the installation of home safety devices, and recommendations to rectify or move hazardous rugs, power cords, or furniture (Lord, Menz et al. 2006). The complex nature of the role environmental hazards play in causing falls means that reducing the risk of falls by household modification is not straightforward. Combined with this complex relationship, the confounding caused by varying levels of compliance, and the effect of awareness associated with the interventions, limit the ability of investigators to prove efficacy in home hazard reduction studies (Lord, Menz et al. 2006). This may be the reason behind the inconsistent results of randomised controlled trials that have investigated the impact of home assessment and modification on falls (Lord, Menz et al. 2006, Turner, Arthur et al. 2011, Gillespie, Robertson et al. 2012). A number of meta-analyses have pooled the results of these home hazard studies and generally reported a modest reduction in falls in the general population (RR 0.79 to 0.89), and a larger reduction (RR 0.61 to 0.62) in those with a greater risk of falling (Clemson, Mackenzie et al. 2008, Gillespie, Robertson et al. 2012).

2.4.7. Fear of Falling

Interventions that have been shown to be positive, in at least some studies, for reducing an individual’s fear of falling, are multifactorial programmes, tai chi, other exercise programmes, the use of a hip protector, and cognitive behavioural interventions (Zijlstra, van Haastregt et al. 2007, Zijlstra, van Haastregt et al. 2009). Many of these interventions were not primarily aimed at reducing fear of falling, but a relationship was observed when studying their effect on overall fall risk.

2.4.8. Decrease in activities of daily living

When considering interventions associated with decreased ADLs it should be noted that ADLs may actually cause falls (Kwan, Close et al. 2011). Tinetti et al (2010) suggested that there is a trade-off between safety and functional independence, so to reduce their
fall risk an older person may require help with some ADLs, which can then lead to a loss of independence, and with it an increased risk of falling. For those at risk of falling who have a reduction in ADLs there is some evidence to suggest that occupational therapy may assist in maintaining functional ability and decreasing fall risk (Steultjens, Dekker et al. 2004).

2.4.9. Medication use

Despite the general acceptance that at least some medications are associated with increased fall risk, there is relatively little evidence that suggests medication reduction alone results in a reduced risk of falling (Soriano, DeCherrie et al. 2007, Gillespie, Robertson et al. 2012). However, withdrawal of antipsychotic medication has been shown to reduce the rate of falls (Rate ratio (RaR) 0.34, (95% CI, 0.16 to 0.74) (Campbell, Robertson et al. 1999), and a medication review and education programme for general practitioners resulted in fewer falls in older adults (Adjusted OR 0.61, 95% CI 0.41 to 0.91) (Pit, Byles et al. 2007). These findings, combined with the accepted risk that medications play in causing falls, have prompted researchers and experts in the field to suggest that patients who have fallen should have their medications reviewed and modified when appropriate (American Geriatrics Society 2001, Rao 2005, Tinetti and Kumar 2010).

2.4.10. Gait abnormalities and impaired mobility

Gait and mobility assessment usually includes simple functional tests, such as the timed up and go test, or the one-leg standing balance test, or a more comprehensive assessment that involves a combination of functional tests, such as the Performance-Oriented Mobility Assessment (Rubenstein and Josephson 2006, Tinetti and Kumar 2010). If these tests suggest mobility is impaired, possible interventions include recommending the use of an assistive device, exercise training aimed at improving gait, or referral for assessment of possible neurological or musculoskeletal disorders (American Geriatrics Society 2001, Tinetti and Kumar 2010). Many exercise programmes that incorporate a gait training aspect have proven to be successful in decreasing fall risk, either when used alone, or as a part of a multicomponent intervention programme (Chang, Morton et al. 2004, Rubenstein and Josephson 2006).
2.4.11. Vertigo or dizziness

The treatment approach to dizziness or vertigo depends largely on the cause of the dysfunction (Salles, Kressig et al. 2003, Walther, Rogowski et al. 2010). Thankfully the most common cause of vertigo in older adults, BPPV, is also one of the most readily treatable (Walther, Rogowski et al. 2010). Particle repositioning manoeuvres such as the Epley and Semont manoeuvres are effective treatments for BPPV and have been shown to reduce falls risk in older adults (Gananca, Gazzola et al. 2010). If dizziness is present upon standing, postural blood pressure should be taken, and if orthostatic hypotension is confirmed, precipitating factors such as polypharmacy should be addressed if possible (Tinetti and Kumar 2010). Other treatment recommendations include balance and exercise interventions, appropriate pharmacological treatment, counselling, and vestibular rehabilitation (Salles, Kressig et al. 2003, Walther, Rogowski et al. 2010).

2.4.12. Balance impairments

If balance impairments are identified, the most beneficial interventions for preventing falls are exercise interventions and tai chi (Chang, Morton et al. 2004, Leung, Chan et al. 2011, Rand, Miller et al. 2011, Sherrington, Tiedemann et al. 2011, Gillespie, Robertson et al. 2012).

Other interventions for impaired balance that may be beneficial, but do not yet have adequate support in the literature, include treatment of predisposing conditions such as Parkinson’s disease (Nutt, Horak et al. 2011), or provision of an assistive device when appropriate (Tinetti and Kumar 2010).

2.4.13. Vision problems

Due to the link between impaired vision and falls, evidence based guidelines recommend that a falls assessment should include a vision assessment, with a full eye examination for individuals with impaired vision (American Geriatrics Society 2001). However, a number of falls prevention trials that have investigated vision assessments, with appropriate interventions such as vision correction, occupational therapy, replacement of multifocal lens glasses with single focus lenses, and cataract surgery, have had mixed results (Day, Fildes et al. 2002, Campbell, Robertson et al. 2005, Cumming, Ivers et al. 2007, Desapriya, Subzwari et al. 2010, Haran, Cameron et al. 2010). Although some trials
reported at least some benefit, others have reported an increased risk of falling in frail older people following vision assessment and intervention (Campbell, Robertson et al. 2005, Cumming, Ivers et al. 2007, Haran, Cameron et al. 2010). It is thought that since vision assessment and intervention generally results in the prescription of new corrective lenses, frail older people may be at a greater risk of falling during the considerable period of time they require to become accustomed to their new glasses (Cumming, Ivers et al. 2007).

2.4.14. Hearing problems

Despite uncertainty regarding the potential mechanisms involved in the link between hearing and falls, hearing assessment and use of hearing aids has been included in at least one successful falls prevention programme (von Renteln-Kruse and Krause 2007). The use of cochlear implants has also been shown to improve balance in children (Cushing, Chia et al. 2008), but to date no intervention studies have investigated whether addressing hearing impairments alone is effective in preventing falls in older adults.

2.4.15. Proprioceptive loss

A variety of interventions have been investigated that aim to improve proprioception. Exercise programmes and tai chi have been shown to improve proprioceptive ability in older adults (Westlake and Culham 2007, Li, Xu et al. 2008, Morrison, Colberg et al. 2010, Teixeira, Silva et al. 2010). As previously discussed, similar interventions have also been shown to reduce the rate of falls and risk of falling in older adults (Gillespie, Robertson et al. 2012). Other interventions that have shown positive results in improving proprioception include ankle taping, foot and ankle compression, and proprioceptive feedback training (Vuillerme, Chenu et al. 2006, Hijmans, Zijlstra et al. 2009, You, Saliba et al. 2009).

2.4.16. Presence of pain

Relatively few interventions have been investigated that specifically aimed to reduce pain in an attempt to prevent falls (Kita, Hujino et al. 2007, Spink, Menz et al. 2011). Spink et al (2011) reported a decreased rate of falls, but not a decrease in the proportion of fallers, in a group of patients with disabling foot pain undergoing a multifaceted podiatry intervention; and Kita et al (2007) reported a decrease in fall rate following an exercise
intervention in older patients suffering from musculoskeletal disease. The role analgesics may play in treating pain, and therefore potentially reducing fall risk, remains unclear due to the confounding effects of indication (American Geriatrics Society 2009, Tinetti and Kumar 2010). It is however possible that there is a positive link between the use of daily analgesics and fall risk, but the relationship requires further investigation (Leveille, Bean et al. 2002).

2.4.17. Depression or cognitive impairment

Multicomponent intervention strategies have proven to be less effective in individuals with lower levels of cognition (Jensen, Nyberg et al. 2003, Shaw, Bond et al. 2003), and evidence is lacking to support the use of other interventions in individuals who are cognitively impaired (Oliver, Connelly et al. 2007). The OEP has been associated with an improvement in executive function, which may be one of the reasons that exercise programmes help to prevent falls (Liu-Ambrose, Donaldson et al. 2008). This finding opens up an avenue of research that requires further investigation for the prevention of falls in individuals with cognitive impairment.

2.4.18. Other falls intervention strategies

In their Cochrane reviews, Gillespie, Robertson et al. (2012) reviewed interventions for preventing falls in older people living in the community, and Cameron, Gillespie et al. (2012) reviewed interventions for older people residing in nursing care facilities and hospitals. Key findings from these Cochrane reviews that have not previously been discussed are:

- **Multifactorial interventions in community dwelling older adults** reduce rate of falls (RaR 0.76, 95% CI 0.67 to 0.86) but not fall risk (RR 0.93, 95% CI 0.86 to 1.02) (Gillespie, Robertson et al. 2012).

- **Multifactorial interventions in ‘care facilities’** failed to reach significance in reducing the rate of falls (RaR 0.78, 95% CI 0.59 to 1.04) or fall risk (RR 0.89, 95% CI 0.77 to 1.02). In hospital settings they were effective in reducing the rate of falls (RaR 0.69, 95% CI 0.49 to 0.96), but studies assessing risk of falling were inconclusive (RR 0.71, 95% CI 0.46 to 1.09) (Cameron, Gillespie et al. 2012).
• Exercise interventions in care facilities and hospitals showed inconsistent evidence of effectiveness, with no overall difference between intervention and control groups for rate of falls (RaR 1.03, 95% CI 0.81 to 1.31) or risk of falling (RR 1.07, 95% CI 0.94 to 1.23) (Cameron, Gillespie et al. 2012).

• Vitamin D supplementation may reduce falls in people with low levels of vitamin D but not in all community dwelling older people (RaR 1.00, 95% CI 0.90 to 1.11; RR 0.96, 95% CI 0.89 to 1.03) (Gillespie, Robertson et al. 2012).

• Vitamin D supplementation in older adults in nursing care facilities or hospitals reduced the rate of falls (RaR 0.63, 95% CI 0.46 to 0.86) but not risk of falling (RR 0.99, 95% CI 0.90 to 1.08) (Cameron, Gillespie et al. 2012).

• An anti-slip shoe device reduces the rate of falls in icy conditions (RaR 0.42, 95% CI 0.22 to 0.78) (Gillespie, Robertson et al. 2012).

• Cognitive behavioural therapy was not effective as a preventative measure for reducing the rate of falls or risk of falling (RaR 1.00, 95% CI 0.37 to 2.72; RR 1.11, 95% CI 0.80 to 1.54) (Gillespie, Robertson et al. 2012).

• Knowledge or educational interventions did not show a reduction in rate of falls or risk of falling (RaR 0.33, 95% CI 0.09 to 1.20; RR 0.88, 95% CI 0.75 to 1.03) (Gillespie, Robertson et al. 2012).

Despite the mixed findings of multifactorial intervention trials (Gillespie, Robertson et al. 2009, Cameron, Murray et al. 2010), current guidelines and recommendations suggest an individualised, multifactorial intervention approach to preventing falls (American Geriatrics Society 2001, Rao 2005, Tinetti and Kumar 2010). Authors of negative multifactorial intervention trials have suggested a variety of reasons for their negative results, including poor adherence to programme protocols, referrals, or interventions; poor participation or dropout rate or low study numbers, control group contamination due to increased attention to falls prevention, or usual care including active interventions, baseline group differences, and of course the possibility that interventions or protocols that were utilised are ineffective at preventing falls (van Haastregt, Diederiks et al. 2000, Elley, Robertson et al. 2008, de Vries, Peeters et al. 2010, Russell, Hill et al. 2010).
2.5. Chiropractic care and its potential relationship with falls prevention

It is possible that chiropractic care may influence aspects of sensorimotor function that are associated with an increased risk of falling. If this is the case, the chiropractic profession may play a role, beyond a general public health role, in reducing the risk of falls in older adults.

Falls occur when an individual is unable to maintain the centre of gravity of their trunk within the base of support provided by their feet on the floor (Van Fleet 1995). As previously discussed, postural stability and maintenance of balance is dependent on the appropriate function of information from several sensory, motor, and central processing systems (Sturnieks, St George et al. 2008, Faraldo-Garcia, Santos-Perez et al. 2012, Taylor, Ketels et al. 2012). These include vision, vestibular sense, proprioception, muscle strength, and reaction time (Sturnieks, St George et al. 2008). The sensory systems send feedback to the brain regarding the position and motion of ourselves and objects around us, the brain then processes and integrates this information and formulates appropriate motor responses in order to maintain balance (Sturnieks, St George et al. 2008). This integrative processing in the central nervous system is known as sensorimotor integration (Figure 2:3), and combined with the appropriate function of the related sensory and motor systems, its precision has a profound effect on postural stability (Lord and Ward 1994, Peterka 2002, Lord, Menz et al. 2003, Sturnieks, St George et al. 2008, Taylor, Ketels et al. 2012).

This leads to an area of potential interest to the chiropractic profession as there is a growing body of evidence that demonstrates a significant effect of chiropractic adjustments on the function of many of these sensorimotor systems and processes (Haavik Taylor, Holt et al. 2010, Haavik and Murphy 2012). Chiropractic adjustment is the term used by the chiropractic profession that is analogous to the more commonly used term ‘spinal manipulation’ (Haavik and Murphy 2012). Chiropractic adjustments have been reported to improve or alter visual acuity and visual field size (Carrick 1997, Wingfield and Gorman 2000), joint position sense error (Haavik and Murphy 2011), reaction time (Kelly, Murphy et al. 2000), cortical processing (Kelly, Murphy et al. 2000, Haavik Taylor and Murphy 2007), cortical sensorimotor integration (Haavik Taylor and

When this is considered, as well as other aspects of falls risk discussed in Section 2.3, it suggests that a number of possible mechanisms of action exist that may provide a link between chiropractic care and improving falls risk. In particular, chiropractic care may influence:

1. Neuroplastic processes within the central nervous system through altered afferent input related to spinal function.

2. Pain that, in turn, affects cognition, particularly with respect to attentional focus, and physical function.

3. Muscle strength or muscle activation patterns.

These potential mechanisms are discussed in the following sections with an explanation of how they may provide a link between chiropractic care and reduced falls risk.

2.5.1. Chiropractic care may influence neuroplasticity

The clinical focus of chiropractic practice is often referred to as the vertebral subluxation, or simply ‘subluxation’ (Henderson 2012). Vertebral subluxations may be seen as being analogous to the ‘somatic dysfunction’, ‘spinal lesion’ or ‘osteopathic lesion’ often discussed in the osteopathic literature, or other terms that relate to manipulable spinal lesions in the physical medicine literature (Korr 1975, Fryer, Morris et al. 2004). In an attempt to clarify the nature of vertebral subluxations, a number of consensus statements and definitions of vertebral subluxation have been created. One of the most frequently quoted consensus definitions was adopted by the Association of Chiropractic Colleges in 1996 and states that a subluxation ‘is a complex of functional and/or structural and/or pathological articular changes that compromise neural integrity and may influence organ system function and general health’ (Owens 2002). Expressed more simply, a vertebral
subluxation is thought to be a biomechanical derangement of the spine that produces clinically significant effects on neurological function (Henderson 2012).

Amongst the chiropractic profession there is a broad range of views regarding the subluxation and its place in chiropractic practice. Some chiropractors even argue that subluxations do not exist and that they are a mythical entity that should be thrown out of the chiropractic lexicon (Simpson 2012). It is fair to say that the profession has a long way to go regarding its understanding of the nature of subluxations, assuming they do exist, before agreement is possible with respect to this entity that forms the foundation of chiropractic clinical practice.

It has been hypothesised that the articular dysfunction component of the putative vertebral subluxation results in altered afferent input to the central nervous system that modifies the way in which the central nervous system processes and integrates all subsequent sensory input (Haavik Taylor et al., 2010; Henderson, 2012). A brief review of the literature supporting this hypothesis follows.

Articular dysfunction associated with vertebral subluxations is thought to involve misalignment and/or alterations to the motion between intervertebral joints in the spine (Henderson 2012). Intervertebral articulations are complex joints that have complicated coupled motion patterns that make it challenging for researchers to characterise and study (Cholewicki, Crisco et al. 1996, Panjabi, Crisco et al. 2001). A number of animal models have been developed in order to help study the potential effects of misalignment or abnormal mobility on neurological afferent receptors in and around the spinal joints (Sato and Swenson 1984, Bolton and Holland 1998, Bolton 2000, Henderson, Cramer et al. 2007).

These models, and the research of others, supports the notion that spinal dysfunction may lead to altered afferent input to the central nervous system (Pickar and McLain 1995, Henderson 2012). This altered afferent input has been linked to synaptic changes in the spinal cord, changes in sensory thresholds, and changes in reflex excitability (Bakkum, Henderson et al. 2007, Henderson 2012). The most likely source of this altered afferent input appears to be related to the function of mechanoreceptors in the joints and muscles around the spine, in particular the muscle spindles located in the paraspinal muscles (Pickar 2002, Reed, Cao et al. 2013). It has been proposed that the deep paraspinal muscles act more as proprioceptive sensors as opposed to playing a significant role in
spinal movement (Kulkarni, Chandy et al. 2001). This is due to the mechanical
disadvantage they face due to their insertion points, and they are also known to have very
high muscle spindle densities, which make them ideal candidates to act as sensors of joint
position and movement (Kulkarni, Chandy et al. 2001, Boyd-Clark, Briggs et al. 2002).
In their animal models, Bolton et al. (1996, 1998) showed that vertebral displacement
may be signalled to the central nervous system by afferent nerves arising from deep
intervertebral muscles. They also showed that afferent nerves innervating the
zygapophyseal joints did not contribute significantly to the signalling of vertebral
displacement (Bolton and Holland 1996). This supports the theory that vertebral
subluxations lead to altered input from deep intervertebral muscle afferents to the central
nervous system.

Studies that investigate the effects of spinal adjustments on the function of the nervous
system also support this theory. Pickar and Wheeler (2001) used a cat model to show that
muscle spindles and golgi tendon organs with receptive endings in paraspinal muscles
respond to force-time profiles that are similar to the loads that are delivered during spinal
adjustments. There is evidence for the effects of spinal adjustments in several areas. The
first area is in the effect of spinal adjustments on reflex excitability (Herzog, Conway et
sensory processing and sensorimotor integration (Zhu, Haldeman et al. 1993, Suter,
McMorland et al. 1999, Suter, McMorland et al. 2000, Haavik Taylor and Murphy 2007,
Haavik Taylor and Murphy 2007, Haavik Taylor and Murphy 2008, Haavik Taylor and
Murphy 2010). Lastly spinal adjustments have been shown to lead to altered motor
control (Suter, McMorland et al. 1999, Suter, McMorland et al. 2000, Marshall and
Murphy 2006, Haavik Taylor and Murphy 2008).

Changes in somatosensory processing and sensorimotor integration following
chiropractic adjustments involve consistent central neural plastic alterations (Marshall
and Murphy 2006, Haavik Taylor and Murphy 2007, Haavik Taylor and Murphy 2007,
Haavik Taylor and Murphy 2008, Haavik Taylor and Murphy 2010, Haavik and Murphy
2011). This has led to the development of a model that attempts to explain how
chiropractic adjustments improve function and reduce symptoms through normalising
alterations to afferent feedback from the spine associated with vertebral subluxations
(Figure 2:4).
Figure 2:4 - Vertebral Subluxation Model Proposed by Haavik and Murphy (2012)

(a) Model that depicts the proposed effects of spinal dysfunction, leading to altered sensorimotor integration which over time in some susceptible individuals may lead to pain and gross dysfunction. (b) Schematic view of proposed effects of spinal manipulation leading to normalisation of afferent input and restoration of appropriate sensorimotor integration and function: From Haavik and Murphy (2012) *The role of spinal manipulation in addressing disordered sensorimotor integration and altered motor control* Journal of Electromyography and Kinesiology, Volume 22, Issue 5, page 769, Fig 1. Reprinted with kind permission from Elsevier Ltd.

Studies that have investigated sensorimotor function and neuroplasticity in subjects with neck pain syndromes provide support for this model, because they have demonstrated changes in sensorimotor function in these patient populations that have been normalised.


The link between cervical function and postural control has been well documented in cases of chronic neck pain, neck muscle fatigue, cervicobrachial pain syndrome, cervical root compression, cervical myelopathy, head injury, and whiplash injury (Karlberg, Persson et al. 1995, Rubin, Woolley et al. 1995, Persson, Karlberg et al. 1996, Branstrom, Malmgren-Olsson et al. 2001, Michaelson, Michaelson et al. 2003, Takayama, Muratsu et al. 2005, Takayama, Muratsu et al. 2005, Stapley, Beretta et al. 2006, Uthaikhup, Jull et al. 2012). Recently an association between cervical osteoarthritis and postural stability has also been reported (Boucher, Descarreaux et al. 2008). It therefore appears that there is a strong link between cervical function and accurate proprioceptive processing, and thus postural control (Treleaven 2008).

The lower back has also been implicated in poor postural control, as patients with low back pain or lumbar disc herniation exhibit increased postural sway (Sohn, Lee et al. 2013, Svoboda, Janura et al. 2013). This increased postural sway may also be due to a central processing change associated with an alteration in afferent input. The work of Zhu et al., who investigated alterations in somatosensory evoked potentials, suggests that this central processing change could be due to a decrease in the amplitude of the actual neural signal generated from areas of “muscle spasm” in patients with chronic low back pain (Zhu, Haldeman et al. 1993, Zhu, Haldeman et al. 2000). This group found decreased somatosensory evoked potential amplitudes evoked from magnetic stimulation of the “spasmed” muscle, which returned to normal following successful treatment with joint manipulation. Murphy and Dawson (1995) demonstrated improvement in intramuscular two-point sensory discrimination following local trigger point therapy to the forearm.
musculature, which suggests that local musculoskeletal treatment can improve central processing of somatosensory input.

When considering a potential link between chiropractic care and improved postural control it is also important to consider the extensive neural connections that exist between mechanoreceptors in the spine, in particular the cervical spine, and the cerebellum and vestibular nuclei of the brainstem (Bolton, Kerman et al. 1998, Brandt and Bronstein 2001, Morningstar, Pettibon et al. 2005). It has been postulated that vertebral subluxations have the potential to promote symptoms that may mimic lesions of the vestibular nuclei and cerebellum and lead to changes in postural control mechanisms that may result in a decreased ability to maintain balance (Seaman and Winterstein 1998, Walsh, Polus et al. 2004). If chiropractic care aids in the correction of vertebral subluxations, then, theoretically, it can also lead to improvement in vestibular integration within the brainstem, which may enhance postural stability and reduce an individual’s risk of falling.

2.5.2. Chiropractic care may influence pain

It has been suggested that pain operates like an additional processing burden, which may influence attentional capacity relating to other tasks (Sanchez 2011). The presence of pain may therefore also influence a person’s ability to maintain balance. Aspects of nervous system function associated with proprioception, sensorimotor function, and multisensory processing are all dependent to some degree on the attentional load or capacity and/or the working memory capacity of the person that is being assessed (Mishra, Martinez et al. 2007, Kvelde, Pijnappels et al. 2010, Goble, Mousigian et al. 2011). Pain, attention, and working memory are closely linked at both a neural and behavioural level (Sanchez 2011). Pain may interfere with the ability to recall information, which may, for example, be important when completing joint position sense tasks.

A number of studies have reported improvements in a variety of pain syndromes following chiropractic care (Wilkey, Gregory et al. 2008, Haas, Spegman et al. 2010, McMorland, Suter et al. 2010, Thorman, Dixner et al. 2010, Stockkendahl, Christensen et al. 2012). If chiropractic care alters the perception of pain, it may also lead to changes in proprioception, sensorimotor function, and multisensory integration that are important for
falls risk. It may also improve fall risk by altering afferent input to the central nervous system that is associated with pain.

2.5.3. Chiropractic care may influence muscle strength or muscle activation patterns.

As discussed in Section 2.3.13, lower limb muscle weakness is associated with an increased fall risk (Moreland, Richardson et al. 2004). Quadriceps muscle strength and activation are also important mediators of an individual’s ability to take a compensatory step, which is associated with falls risk (Lord and Fitzpatrick 2001, Kvelde, Pijnappels et al. 2010, Pijnappels, Delbaere et al. 2010). One previous controlled pilot study reported a significant (p≤0.05) increase in quadriceps muscle strength following a single chiropractic adjustment session (Hillermann, Gomes et al. 2006). However group allocation was not randomised, which resulted in baseline group differences, and post-intervention between group differences were not significant (p=0.2). Suter, McMorland et al. (1999) also reported a decrease in quadriceps muscle inhibition and increased quadriceps muscle activation following a chiropractic adjustment session. If these changes also occur over a longer time period, they may influence an individual’s ability to take appropriate compensatory steps when faced with a perturbation to postural stability. If this is the case, it provides another potential link between chiropractic care and decreased falls risk.

A similar potential link relates to the effects of chiropractic care on feed forward activation of abdominal muscles. Feed forward activation refers to very rapid activation of deep abdominal muscles in response to postural perturbations associated with limb movements (Vasseljen, Unsgaard-Tondel et al. 2012). This acts to stabilise the trunk so limb movement can safely take place without compromising postural and spinal stability (Hodges and Richardson 1996). Impaired feed forward activation has been associated with nonspecific low back pain (Hodges and Richardson 1996). Marshall and Murphy (2006) reported that a chiropractic adjustment of the sacroiliac joint improved feed forward activation times in the internal oblique and transverse abdominis muscles of a group of young athletes when they undertook rapid movements of the upper limb.

It is not yet known whether delayed feed forward activation plays an important role in compensatory stepping. However, it seems logical that if appropriate activation of
abdominal, trunk and other supportive muscles are required to help provide postural stability during a stepping task, impairment of this activation may interfere with the performance of the stepping task (Komiyama and Kasai 1997). If this is the case, and chiropractic care improves feed forward activation, it may also enhance an individual’s ability to take compensatory steps and therefore reduce their risk of falling.

Besides these potential neurological benefits associated with chiropractic care, it may also help patients with a variety of musculoskeletal disorders who are at an increased risk of falling. Chiropractors routinely provide care to patients with lower limb dysfunction, muscle weakness, neck pain, back pain and other conditions that may affect balance and lead to an increased risk of falling (American Geriatrics Society 2001, Bryant, Atkins et al. 2003, Holt and Beck 2005, Rao 2005, Rubenstein and Josephson 2006). If chiropractic care results in improvements in these conditions, this may also play a positive role in preventing falls.

Many of the potential mechanisms of action discussed in this section are based on assumptions that have been drawn from an area of research that is in its infancy. Many of the trials that are discussed are small, uncontrolled, or lack methodological rigour (Suter, McMorland et al. 1999, Hillermann, Gomes et al. 2006). A great deal of further research is required to determine whether these assumptions are correct and which potential mechanisms should be evaluated further when considering a potential role for chiropractic care in preventing falls.

2.6. Outcome measures that are relevant to falls and chiropractic care

Section 2.5 reviewed the growing body of literature that supports a link between chiropractic care and changes in sensory and/or motor function. The next section discusses the assessment of outcome measures that may be relevant when investigating whether chiropractic care plays a role in reducing falls risk in older people.

2.6.1. Sensorimotor function

A number of the falls risk factors already discussed, particularly postural stability and proprioception, are influenced by sensory and/or motor function (Lord and Ward 1994, Sturnieks, St George et al. 2008). With the general decline in sensorimotor function that occurs in ageing, comes an increased risk of falling (Lord and Ward 1994, Sturnieks, St
George et al. 2008). The following section reviews a broad measure of sensorimotor function associated with compensatory stepping called the choice stepping reaction time (Lord and Fitzpatrick 2001).

Impaired stepping is associated with falls in older people as it may reduce the ability of an individual to effectively respond to balance perturbations (Maki and McIlroy 2006). The most effective measures that can be taken when we are on the verge of losing balance is to take a step in order to change the base of support (Maki and McIlroy 1997). The ability to take compensatory steps is a vital functional response, when faced with both small and large perturbations, in order to prevent an individual from falling (Maki and McIlroy 1997, Maki and McIlroy 2006). A complex cascade of sensorimotor events must take place in order to take a compensatory step. This involves detecting instability, then rapidly planning and executing an appropriate motor response. Older adults may be less able to execute appropriate compensatory responses due to age related changes in sensorimotor function (Maki and McIlroy 1997, Lord and Fitzpatrick 2001, Maki and McIlroy 2006).

Lord and Fitzpatrick (2001) developed a device that measures voluntary stepping reaction time. This device involves an individual standing on a platform with two panels in front of them, one in front of each foot, and one panel beside each foot. These panels can be individually illuminated, and the study participant is asked to place their corresponding foot on the illuminated panel as quickly as possible (Figure 2:5). The time taken from the panel illuminating until the foot is planted on the panel is called the choice stepping reaction time.
Choice stepping reaction time has been assessed in a number of prospective and retrospective trials and has been shown to be a significant, independent predictor of falls and multiple falls (Lord and Fitzpatrick 2001, St George, Fitzpatrick et al. 2007, Pijnappels, Delbaere et al. 2010). In a large retrospective trial involving 447 older retirement-village residents, Lord and Fitzpatrick (2001) found that those who had fallen in the last 12 months had a mean choice stepping reaction time of 1322 milliseconds (ms) (SD 331ms), which was significantly greater (p<0.01) than the choice stepping reaction time of non-fallers (1168ms, SD 203ms). In this study, choice stepping reaction time was the strongest predictor of falls out of a long list of neuropsychological and sensorimotor tests. This included tests of visual contrast sensitivity, proprioception, muscle strength, simple reaction time, postural stability, and attentional flexibility. Lord and Fitzpatrick (2001) determined, through multiple regression analysis, that increased choice stepping reaction time was best predicted by a poor performance in a neuropsychological test (Part B of the Trail Making Test), impaired quadriceps strength, increased simple reaction time, increased body sway with eyes open on a compliant surface, and decreased maximal balance range.
When building a model to predict falls, Lord and Fitzpatrick (2001) found that measures of strength, central processing speed, and balance, became redundant when choice stepping reaction time was included in the model. This suggests that choice stepping reaction time provides a broad composite measure for the neuropsychological and sensorimotor factors that are important when formulating and initiating appropriate compensatory steps (Lord and Fitzpatrick 2001).

Pijnappels, Delbaere et al. (2010) performed regression and path analyses on prospective data from 294 participants involved in the retrospective trial conducted by Lord and Fitzpatrick (2001). Path analysis is used to indicate whether dependencies between variables are likely to be direct or indirect, and whether predictors are mediated by underlying variables (Pijnappels, Delbaere et al. 2010). In this study, choice stepping reaction time was able to predict multiple falls, and the path analysis model revealed that the association between choice stepping reaction time and multiple falls was entirely mediated by reaction time and balance. The authors hypothesised that poor reaction time may predispose an individual to falling, independently of postural control, as they may have an impaired response to balance threats encountered in daily life that require supraspinal processing. In turn, these physiological parameters of reaction time and balance were mediated by quadriceps strength, visual contrast sensitivity, and cognitive processing. These findings suggest that choice stepping reaction time is dependent on both physiological and cognitive mediators, and therefore if interventions are able to improve choice stepping reaction time, the improvement may be due to multiple changes in physiology and cognition (Pijnappels, Delbaere et al. 2010).

Zheng, Delbaere et al. (2012) also performed a path analysis in a study that involved testing simple choice stepping reaction time and choice stepping reaction time that involved a dual task requiring cognitive attention. Participants were also assessed for white matter hyperintensities using magnetic resonance imaging (MRI) in order to evaluate the relationship between white matter hyperintensities and choice stepping reaction time. White matter hyperintensities are signals observed on MRI that are common in older adults that are likely to have an ischemic origin (Zheng, Delbaere et al. 2012). The severity of white matter hyperintensities observed on MRI is considered to be a risk factor for falls, as well as being associated with balance and gait impairments (Baezner, Blahak et al. 2008, Srikanth, Beare et al. 2009). In their study, Zheng, Delbaere et al. (2012) found that a broad array of neuropsychological and sensorimotor tests were
associated with poor performance in both dual task and simple choice stepping reaction time. When they performed structural equation modelling to further investigate the relationship between mediating variables, they found that the impaired performance in simple choice stepping reaction time was mediated directly by sensorimotor function; such as muscle strength, vision and balance, but the neuropsychological involvement in choice stepping reaction time was indirect, and was related to the effect that slow information processing and reduced attention capacity has on postural control. The final conclusion from this study was that white matter hyperintensity volumes were only associated with poor dual task choice stepping reaction time and not simple choice stepping reaction time, which was explained primarily by impaired neurophysiological function. These results are interesting when considering the conclusions made by Lord and Fitzpatrick (2001) and Pijnappels, Delbaere et al. (2010). What is clear from this work is that choice stepping reaction time requires attention, coordination, reaction time, balance, and strength, and is a very good composite measure of sensorimotor function that is associated with falls, and it is a significant predictor of falls.

Besides the differences in choice stepping reaction time already discussed between fallers and non-fallers, choice stepping reaction time has also been shown to be worse in females, older people compared to younger people, individuals who have suffered from hip fractures, people with depression, and individuals with vitamin D deficiency (Lord and Fitzpatrick 2001, St George, Fitzpatrick et al. 2007, Kvelde, Pijnappels et al. 2010, Nightingale, Sturnieks et al. 2010, Pijnappels, Delbaere et al. 2010, Menant, Close et al. 2012).

Lord and Fitzpatrick (2001) and St George, Fitzpatrick et al. (2007) reported that younger people are approximately 400ms quicker than older people at completing a choice stepping reaction time task. This is most likely due to the general decline in sensorimotor function that occurs with ageing (Lord and Fitzpatrick 2001, St George, Fitzpatrick et al. 2007). Gender differences have been reported in choice stepping reaction time, with females being slower than males by approximately 80ms (Lord and Fitzpatrick 2001, Pijnappels, Delbaere et al. 2010). ANCOVA analysis by Pijnappels, Delbaere et al. (2010) suggested that this finding was related to quadriceps strength, but the difference remained in the study by Lord and Fitzpatrick (2001) after adjusting for quadriceps and ankle dorsiflexion strength.
The link between hip fractures and poor choice stepping reaction time relates to on-going issues with weight transfer and acceptance (Nightingale, Sturriecks et al. 2010). Vitamin D insufficiency may result in slowed choice stepping reaction time because of the impact it can have on muscle strength, coordination, and balance (Menant, Close et al. 2012).

Kvelde, Pijnappels et al. (2010) performed a path analysis on 51 participants from the trial by Lord and Fitzpatrick (2001) who showed mild to severe depression. This path analysis suggested that self-reported depressed mood was related to poor choice stepping reaction time, and the relationship was mediated by physiological and cognitive pathways. This supports the previously reported work from the same group (Pijnappels, Delbaere et al. 2010).

Due to the importance of choice stepping reaction time in predicting falls, it has been included as an outcome measure in a small number of trials that investigated falls prevention interventions (Lord, Castell et al. 2003, Rissel, Passmore et al. 2013, Schoene, Lord et al. 2013). Although poor choice stepping reaction time may not directly cause falls, it is assumed that if an intervention results in improved performance of choice stepping reaction time, it may be due to improvements in physiology and cognition that are important for the maintenance of balance and preventing falls, so it may be used as a surrogate measure of falls risk (Pijnappels, Delbaere et al. 2010).

Lord, Castell et al. (2003) conducted the most significant, methodologically sound trial to date that has investigated the effect of an intervention on choice stepping reaction time. This trial involved 551 older adults from Sydney and Wollongong, Australia, who were living in retirement villages. The trial found that the intervention group, who were doing group exercise classes for six months, showed a significant (p<0.01) reduction in choice stepping reaction time (35ms reduction) compared with the control groups (12ms increase), who were either doing flexibility and relaxation classes, or were not engaged in any group activity. This trial also reported a statistically significant (IRR 0.69, 95% CI 0.48 to 0.99) reduction in the rate of falls in the exercise group over a 12 month period. Two smaller studies, one uncontrolled, have also reported statistically significant improvements in choice stepping reaction time associated with cycle training (p<0.05), or eight weeks of home-based step training using a videogame (p<0.01) (Rissel, Passmore et al. 2013, Schoene, Lord et al. 2013). To date no studies have been published that have
investigated the effects of chiropractic care, or other manual therapeutic interventions, on choice stepping reaction time.

2.6.2. Proprioception

Some of the measures that are commonly used to evaluate proprioceptive function include assessments of threshold to perception of passive movement, threshold to velocity discrimination, and joint position sense (Vuillerme, Chenu et al. 2006, Westlake, Wu et al. 2007, Munn, Sullivan et al. 2010).

Threshold to perception of passive movement involves passive movement of a joint at a slow speed (e.g. 0.25°/s), with the threshold being the joint angle at which movement is perceived, with the direction of displacement being accurately stated (Westlake, Wu et al. 2007). Threshold to velocity discrimination requires participants to choose the faster of two randomised passive joint movements. The threshold value is the smallest difference between the two velocities of movement that can correctly be identified in a repeated fashion (Westlake, Wu et al. 2007).

Assessments of joint position sense generally involve one of the following three methods. The slope box method, which involves participants having to place a foot on a sloped surface and estimate the steepness of the slope (Hijmans, Zijlstra et al. 2009). Joint matching, which involves matching a joint angle from one limb to the opposite limb (Lord and Ward 1994, Vuillerme, Chenu et al. 2006). Finally, joint angle reproduction, which involves a participant actively or passively moving a joint to a target angle, returning it to the resting position, and then moving the joint, either actively or passively, back towards the target angle and stopping when the target angle has been achieved (Westlake, Wu et al. 2007, You, Saliba et al. 2009). When assessed in this manner the joint position sense error is the difference between the target and actual angle. A number of different methods are used to assess joint position sense in this way. These include different combinations of active and passive joint repositioning (e.g. passive target positioning followed by active repositioning). Assessments also vary in the postural position that participants are placed in, such as standing or reclined in a chair, when performing the repositioning tasks. There is currently little agreement between investigators regarding the best approach to take for the assessment of joint position sense.
Impaired ankle and knee proprioception has been demonstrated in older populations compared with younger groups (Hurley, Rees et al. 1998, You 2005, Goble, Mousigian et al. 2011, Baert, Mahmoudian et al. 2013). Estimates of impairment in joint position sense that relate to ageing generally range from 0.5° to 1.5°, with differences in magnitude being dependent on the testing method and position used (Hurley, Rees et al. 1998, Batavia, Gianutsos et al. 1999, You 2005, Westlake and Culham 2006, Goble, Coxon et al. 2009). Other assessments of proprioceptive function, such as movement detection thresholds and movement velocity sense, are also impaired with ageing (Westlake, Wu et al. 2007). This impairment may be related to changes in muscle spindle morphology and function, central integrative ability, or structural degeneration of receptors in conditions such as osteoarthritis (Hurley, Rees et al. 1998, Baert, Mahmoudian et al. 2013).

Proprioception involves sensory feedback from muscles, tendons, and joints (Westlake and Culham 2006, Sturnieks, St George et al. 2008). The main source of proprioceptive afferent input arises from muscle spindles, but it is also dependent on feedback from mechanoreceptors in joint capsules and cutaneous tactile receptors (Gilman 2002, Sturnieks, St George et al. 2008). These receptors provide afferent information to the central nervous system, which then integrates this information with other relevant sources of sensory input to determine distal body segmental position, and to formulate appropriate motor responses to postural challenges, or to coordinate voluntary movement (Goble, Coxon et al. 2012, Kalisch, Kattenstroth et al. 2012). Proprioceptive accuracy relies on both accurate sensory input and appropriate central integration (Hurley, Rees et al. 1998). Impairment to both peripheral and central neurophysiological factors is thought to be responsible for the decline in proprioceptive ability that is seen with ageing (Goble, Coxon et al. 2009, Kalisch, Kattenstroth et al. 2012).

Muscle spindles, which are the most important peripheral proprioceptive receptors, undergo a variety of changes with ageing (Goble, Coxon et al. 2009). These include capsular thickening, a decrease in diameter size, and a decrease in intrafusal fibre density (Shaffer and Harrison 2007, Goble, Coxon et al. 2009). Together, these morphological changes result in functional impairments, such as reduced static and dynamic muscle spindle sensitivity (Shaffer and Harrison 2007). With ageing, there is also a decrease in
the number of cutaneous receptors, such as Meissner and Pacinian corpuscles, and a
decrease in joint mechanoreceptors, such as Ruffini, Pacinian, and Golgi tendon type
receptors (Shaffer and Harrison 2007, Goble, Coxon et al. 2009, Kalisch, Kattenstroth et
al. 2012).

It has recently been established that central nervous system function and processing
abilities also play a significant role in proprioceptive acuity in older adults (Goble,
Mousigian et al. 2011, Goble, Coxon et al. 2012). This may involve cognitive function,
with working memory and attentional load playing a significant role in proprioceptive
based tasks (Goble, Mousigian et al. 2011). Structural differences associated with ageing,
particularly in the right putamen, are also associated with poor proprioceptive ability
(Goble, Coxon et al. 2012). It is also possible that neural plastic changes within the vast
neural networks that are involved in processing and integrating proprioceptive
information are also involved in the proprioceptive decline seen in ageing (Goble, Coxon
et al. 2009). These neural areas include the primary somatosensory and motor cortices,
the premotor cortex, the secondary association areas, and subcortical areas such as the
basal ganglia, (Goble, Coxon et al. 2009, Goble, Coxon et al. 2011, Goble, Coxon et al.
2012).

Goble, Mousigian et al. (2011) investigated the relationship between working memory
and attentional load on proprioception in older adults. They did this by comparing the
performance of young adults to older adults, with high or low working memory ability,
on a proprioceptive matching paradigm task. They tested the participants in a ‘low
attentional load’ condition and a ‘high attentional load’ condition that involved a non-
sequential counting task. They found that older adults with poor working memory had
larger proprioceptive matching errors compared to younger adults. They also made
significantly larger errors during the ‘high attentional load’ condition compared to
younger adults or older adults with high working memory ability. The authors concluded
that cognitive factors play a significant role in proprioceptive acuity, with older adults
with low working memory appearing prone to compromised proprioceptive encoding,
especially when placed under a high attentional load condition. This supports previous
research that has demonstrated compromised sensorimotor function when older adults are
asked to perform dual tasks (Woollacott and Shumway-Cook 2002, Goble, Mousigian et
al. 2011). It has been hypothesised that this compromised sensorimotor performance is
due to a limitation of attentional resources in older adults to cope with both tasks (Woollacott and Shumway-Cook 2002).

Structural brain changes associated with age have been reported in numerous studies (Raz and Rodrigue 2006). These structural changes may influence the function of the brain networks that are associated with proprioception (Goble, Coxon et al. 2009). Goble, Coxon et al. (2012) recently reported that structural differences and reduced activation in the right putamen are associated with poor proprioceptive ability in older adults. They suggested that this may reflect a general decline in dopamine regulation that is associated with the ageing brain, and that, perhaps, the ageing brain lies on a preclinical continuum of Parkinson’s disease. This is further supported by the substantial body of literature that has reported proprioceptive impairment in individuals suffering from Parkinson’s disease (Konczak, Corcos et al. 2009).

Older adults with proprioceptive deficits have been reported to respond to training tasks that focus on proprioceptive ability, suggesting that training induced neuroplastic changes in proprioception do occur in older adults (Tsang and Hui-Chan 2004, Westlake, Wu et al. 2007, Goble, Coxon et al. 2009). However, there is evidence to suggest that when proprioceptive feedback to older adults is impaired, they may undergo neuroplastic changes that are not reversed at the same rate as younger adults when the feedback is restored (Teasdale and Simoneau 2001). This may be due to a diminished capacity to centrally integrate and reweight proprioceptive information (Goble, Coxon et al. 2009).

Besides ageing, proprioception may also be compromised in diseases such as Parkinson’s disease, diabetes mellitus, or other conditions that cause nervous system damage (DeMott, Richardson et al. 2007, Sturnieks, St George et al. 2008, Konczak, Corcos et al. 2009, Tinetti and Kumar 2010).

As well as being an important mediator of postural stability, proprioception also assists in joint stability and protects joints against excessive movement and joint damage (Baert, Mahmoudian et al. 2013). Not surprisingly, poor proprioception has been associated with ankle instability and sprains (Willems, Witvrouw et al. 2005, Munn, Sullivan et al. 2010). Munn, Sullivan et al. (2010) recently published a systematic review and meta-analysis that investigated differences in joint position sense in individuals with functional ankle instability compared to healthy controls. They concluded that in studies that used active positioning movements, there was a mean difference of 0.6˚ (95% CI: 0.2 to 1.0˚,
p=0.002) between subjects with functional ankle instability compared to healthy controls. However, the conclusions from this meta-analysis were limited due to poor overall methodology of included studies. It may also be appropriate to ask the question of whether changes in proprioception in this clinical population are a cause of functional ankle instability, or are caused by it, due to structural damage to receptors in the ankle associated with the mechanical instability and laxity of the joint. Structural peripheral receptor damage may also play a role in the reduced joint position sense that is seen in osteoarthritis. Baert, Mahmoudian et al. (2013) reported that greater impairments, in the range of one to two degrees, on a joint repositioning task, existed when comparing women with established osteoarthritis to those with early osteoarthritis. There was little to no difference between those with early osteoarthritis and a healthy control group. The authors concluded that the impaired proprioception in the established osteoarthritis group was more likely due to structural degeneration than a cause of osteoarthritis in the knee.

Compared with limb proprioception, much less research has focused on spinal proprioception, or the effect of the spine on limb proprioception (Swinkels and Dolan 1998, Allison and Fukushima 2003, Knox and Hodges 2005, Knox, Cordo et al. 2006, Knox, Beilstein et al. 2006, Strimpakos, Sakellari et al. 2006, Jull, Falla et al. 2007). There is however a growing body of evidence that suggests the function of the spine may play an important role in accurate proprioception. Over recent years it has been demonstrated that neck pain and previous whiplash injury are associated with reduced joint position sense (Knox, Beilstein et al. 2006, Haavik and Murphy 2011, Uthaikhup, Jull et al. 2012).

Uthaikhup, Jull et al. (2012) evaluated differences in sensorimotor function, including cervical joint position sense, in a group of older adults with chronic neck pain, and compared them to a similar group without neck pain. Cervical joint position sense was measured using an active / active head repositioning task that involved matching a neutral target angle following various head movements. They reported that the neck pain group performed more poorly across a range of sensorimotor tasks, including the joint position sense task. The neck pain group exhibited errors in head repositioning of up to 2.3° compared to the pain free group, depending on which head movement was involved. The authors of this quasi-experimental trial suggested that their findings support the conclusion that altered afferent input from the cervical spine contributes to poor sensorimotor function. The authors acknowledged that their study had a small sample size.
(n=40) and that comorbidities may have been a confounding variable. However, they failed to acknowledge a number of other limitations of the study. These included the inherent limitations of the non-randomised control used in the quasi-experimental design and that pain may have resulted in changes to antalgic neutral neck positions following a repositioning task. Pain may also have influenced the attentional load that participants directed at the repositioning task, which has been shown to affect joint position sense accuracy (Knox, Beilstein et al. 2006, Goble, Mousigian et al. 2011).

Previous research has suggested that pain may influence the sensitivity of muscle spindles through alterations to fusimotor drive (Thunberg, Ljubisavljevic et al. 2002). It may also interfere with other aspects of sensorimotor function that may influence afferent feedback to the central nervous system (Sterling, Jull et al. 2003). These factors provide mechanisms that support the conclusions made by Uthaikhup, Jull et al. (2012).

Haavik and Murphy (2011) are the only authors to date to investigate the effects of chiropractic care on joint position sense. In their study they reported a significant improvement in elbow joint position sense (p<0.01) following a single chiropractic adjustment session in a group of patients with a history of subclinical neck pain.

2.6.3. Balance

A number of different types of balance assessments exist. These include static posturographic assessments that involve standing on a stable firm or foam surface, dynamic posturography, which involves assessing balance on a moving surface; dual task assessments that combine a balance assessment with a secondary task, and functional balance tests that assess functional movements related to balance.

Various parameters of static posturographic assessment, such as amplitude and speed of mediolateral movement of the centre of pressure of the body, have been shown to have significant associations with future falls, but the small number of prospective trials that have been conducted make it difficult to draw definitive conclusions (Pirtola and Pertti 2006). This may be partly due to the substantial inter-subject and intra-subject variability, and the large number of false positive results that are obtained from posturographic measures (Visser, Carpenter et al. 2008). A number of studies have used static posturography to investigate the effects of various treatments on balance (Visser, Carpenter et al. 2008). At times, results have been inconsistent, with some authors
suggesting that the jury is still out regarding the clinical usefulness of static posturographic assessment (Maurer, Mergner et al. 2003, Colnat-Coulbois, Gauchard et al. 2005, Visser, Carpenter et al. 2008).

In an attempt to overcome the limitations of static posturographic tests, researchers have turned to dynamic posturography. This involves assessing balance on a platform that accelerates and decelerates beneath an individual’s feet, to recreate the type of conditions that may be experienced on a bus or a train for example (Visser, Carpenter et al. 2008). Early dynamic posturographic measures showed little predictive value with respect to future falls (Pirtola and Perti 2006). This was thought to be due to the short distance of travel that was capable before the platform had to decelerate in these early devices (Visser, Carpenter et al. 2008). More recently, moving platforms that are capable of delivering perturbations with delayed deceleration, or manipulating different sensory conditions or input, have been developed, which show more promise than measures of static posturography for discriminating fallers from non-fallers (Buatois, Gueguen et al. 2006, Visser, Carpenter et al. 2008, Johnson, James et al. 2013).

Recently, supportive evidence has been accumulating for the predictive ability of balance assessments that test an individual’s ability to dual task (Hsu, Nagamatsu et al. 2012). Dual tasking refers to the ability to perform two tasks at once, such as walking and talking. Dual task balance assessments combine a cognitive task, such as counting backwards from a randomly selected three digit number, with a physical task such as maintaining balance on a tilting platform (Condron and Hill 2002). Postural control requires significant attentional requirements, particularly in older adults. However, older adults appear less able than younger adults to devote appropriate attention to postural control when they are confronted with a challenging cognitive task (Woollacott and Shumway-Cook 2002, Zijlstra, Ufkes et al. 2008). This is an issue when it comes to fall risk because falls in older adults appear to occur more often when they are walking and performing a secondary task, such as talking, as opposed to simply walking on its own (Woollacott and Shumway-Cook 2002). Woollacott and Shumway-Cook (2002) hypothesised that many falls are not due to balance deficits in isolation, but an inability to allocate adequate attentional demand when confronted by multi-task conditions. Recent evidence has supported this view by reporting that balance assessments that involve dual tasks may have added predictive value of fall risk than single task balance assessments (Zijlstra, Ufkes et al. 2008, Hsu, Nagamatsu et al. 2012, Kotecha, Chopra et al. 2013).
An alternative to posturographic assessment of postural stability is the use of clinical balance tests. A number of functional tests that involve a balance component have been developed that are valid indicators of fall risk in older adults. These include tests such as the Berg Balance Scale, the Timed Up and Go test, and the step test (Brauer, Burns et al. 2000, Pollock, Eng et al. 2011). Although these tests are reliable and relate to a past history of falls, they are limited in their ability to detect subtle changes in postural stability (Berg, Wood-Dauphinée et al. 1992, Berg, Wood-Dauphinée et al. 1995, Brauer, Burns et al. 2000, Beauchet, Fantino et al. 2011, Pollock, Eng et al. 2011). Their sensitivity to change and responsiveness is also questionable (Knorr, Brouwer et al. 2010, Pollock, Eng et al. 2011), and they are susceptible to floor and/or ceiling effects (Knorr, Brouwer et al. 2010, Pollock, Eng et al. 2011). The weight of more recent evidence suggests that the discriminative and predictive validity of these tests is fairly poor for single fallers and older adults who are relatively healthy and high functioning, but they appear to have reasonable predictive ability in multiple fallers, or less healthy older adults (Muir, Berg et al. 2008, Schoene, Wu et al. 2013). Their usefulness in studies that aim to test the effects of an intervention on balance in relatively healthy older adults has therefore been questioned (Brauer, Burns et al. 2000, Knorr, Brouwer et al. 2010, Schoene, Wu et al. 2013).

A small number of studies have been conducted that have investigated the effects of chiropractic care on balance. Chapter 3 is a systematic review that was conducted as a part of this thesis that assessed the evidence for the effects of manual therapy interventions on balance and falls.

2.6.4. Multisensory integration

Historically it was thought that human perception involves distinct sensory modalities operating in a modular fashion independently of each other (Shimojo and Shams 2001). More recently it has become evident that this historical view is incorrect, and that perception involves multiple senses interacting and working together synergistically to accurately and efficiently process information from the environment (Shimojo and Shams 2001, Lovelace, Stein et al. 2003, Bolognini, Rossetti et al. 2011, Stevenson, Zemtsov et al. 2012). Various experiments have shown that integrating information from multiple senses enhances our ability to interact with the environment (Lovelace, Stein et al. 2003, Diederich and Colonius 2004, Mahoney, Li et al. 2011, Parise, Spence et al. 2012,
Stevenson, Zemtsov et al. 2012). It has been found that the accuracy and robustness of a percept is increased when the brain is able to combine and integrate sensory information from a number of sensory modalities (Ernst and Bulthoff 2004). When information from more than one sensory modality is utilised it enhances detection and localisation of stimuli, and speeds up reaction times (Lovelace, Stein et al. 2003, Diederich and Colonius 2004, Mahoney, Li et al. 2011, Parise, Spence et al. 2012). Accurate multimodal sensory processing relies on appropriate function of both peripheral sensory organs and central cortical and subcortical structures (Mozolic, Hugenschmidt et al. 2012). As has been previously discussed, many of these structures and organs become less efficient as we age, which results in changes to multisensory processing and integration (Setti, Burke et al. 2011, Mozolic, Hugenschmidt et al. 2012).

This thesis focusses on sensorimotor function, so it should be acknowledged that multisensory integration does not always involve a motor component. It is logical however, that multisensory integration and sensorimotor integration are inextricably linked. For example, when crossing the road the percept of a car horn, which is combined with an image of an oncoming car in the peripheral vision, is very likely to result in a ‘foveation’ of the peripheral image through motor responses that produce eye and head movements. This audio and visual input is then combined with a somatosensory perception of body position so an appropriate motor response can be undertaken in order to avoid a potentially hazardous situation. There is evidence to support this fundamental interconnectedness that involves parallel sensorimotor and multisensory circuitry, and models of postural control that involve multisensory integration (van der Kooij, Jacobs et al. 1999, Cappe, Rouiller et al. 2012, Kipping, Grodd et al. 2013).

Somewhat paradoxically, certain aspects of multisensory integration have been reported to be ‘enhanced’ in older adults. This tends to involve older adults making greater gains in response time compared to younger adults when they are presented with congruent multisensory targets as opposed to unisensory targets (Laurienti, Burdette et al. 2006, Peiffer, Mozolic et al. 2007, Diederich, Colonius et al. 2008, Diaconescu, Hasher et al. 2013). To discuss these changes in multisensory integration as enhancements may not, however, be totally accurate. The changes in multisensory processing that do take place in older adults should perhaps be considered as enhancements in the context of certain laboratory based paradigms that measure response times, but in the real world they may be beneficial or detrimental to the individual depending on the environmental context and
task demands (Mozolic, Hugenschmidt et al. 2012). For example, when stimuli from different modalities are incongruent, or become a distraction, older adults become less efficient at processing the relevant sensory stimuli, which may lead to inappropriate motor responses (Polakoff, Ashworth et al. 2006).

A number of mechanisms have been proposed that may contribute to the changes in multisensory integration that occur with ageing. They relate to general cognitive slowing, inverse effectiveness associated with sensory deficits, alterations in the time window of integration of multisensory information, inefficient top-down modulation of sensory information, and increased background sensory noise (Mozolic, Hugenschmidt et al. 2012).

Ageing is associated with a general slowing of sensorimotor and cognitive processing that is exacerbated when tasks are difficult and require more cognitive processing (Salthouse 2000, Verhaeghen and Cerella 2002). In multisensory assessment paradigms, multisensory tasks contain redundant information that can facilitate responses, but unisensory conditions do not. This means that the unisensory condition may be more difficult to respond to and may require a greater cognitive load. If this is the case, then it may appear that older adults show a greater ability to integrate multisensory information, when in fact this is just an artefact of different processing speeds between younger and older adults caused by the difference in difficulty of the cognitive load (Salthouse 2000, Verhaeghen and Cerella 2002). Laurienti, Burdette et al. (2006) suggested this premise was incorrect when they investigated multisensory integration in young versus older adults. Log transformations of response time data were performed to correct for differences related to general cognitive slowing. After log transformation, older adults still exhibited greater gains in multisensory integration compared to younger adults. This suggests that general cognitive slowing does not account for the greater gains seen in the study by Laurienti, Burdette et al. (2006) and other similar studies (Peiffer, Mozolic et al. 2007).

An alternative explanation for the change in multisensory integration seen in ageing is that older adults may use multisensory perception strategies to compensate for unisensory deficits in sensitivity or acuity that occur with ageing (Laurienti, Burdette et al. 2006). If a multimodal stimulus is presented instead of a unisensory stimulus, the extra sensory cues will significantly enhance the perception of the stimulus. This is known as the
inverse effectiveness principle (Mozolic, Hugenschmidt et al. 2012). This model makes sense intuitively, but evidence supporting this model is not clear, as older adults have been reported to show larger multisensory gains than younger adults, even when they had similar response times when presented with a unisensory stimulus (Peiffer, Mozolic et al. 2007).

Another potential mechanism that is relevant to multisensory integration and ageing relates to the size of the temporal binding window. The temporal binding window is hypothesised to represent the time frame in which stimuli from different sensory modalities must be perceived in order for them to be perceptually bound together so they are perceived as a coherent, unified, external event (Stevenson, Zemtsov et al. 2012). Older adults have a temporal binding window that is roughly twice as wide as the temporal binding window observed in younger adults (Laurienti, Burdette et al. 2006, Diederich, Colonius et al. 2008). Diederich, Colonius et al. (2008) argued that the larger width of the temporal binding window in older adults is an adaptive response to slowing of peripheral sensory processing. They provided convincing evidence for their argument, but they did however point out that the larger temporal binding window in older adults cannot fully compensate for the peripheral slowing. Therefore this mechanism does not fully explain why multisensory integration in older adults may be enhanced, if it occurs.

The fourth potential mechanism relates to attentional control. Selective attention allows us to focus on particular stimuli while ignoring others. Young adults are better able to divide attention across multiple sensory modalities and are better able to restrict attention to a single sensory modality than older adults (Poliakoff, Ashworth et al. 2006). It is therefore possible that enhanced multisensory integration in older adults may result from deficits in attentional control that allows more cross-modal information to be processed (Poliakoff, Ashworth et al. 2006, Mozolic, Hugenschmidt et al. 2012). There is conflicting evidence in this area however, as it appears that older adults display an increase in baseline cross-modal interactions that are not modulated by attentional control (Hugenschmidt, Mozolic et al. 2009).

This final point above leads to an interesting alternative explanation for the enhanced multisensory integration seen in ageing. Older adults appear to filter less background sensory information, meaning they experience more baseline ‘noise’ than younger adults (Mozolic, Hugenschmidt et al. 2012). This results in greater integration of sensory
information in older adults, even when they are selectively attending to a sensory stimulus (Hugenschmidt, Mozolic et al. 2009, Mozolic, Hugenschmidt et al. 2012). This suggests that ‘enhancements’ in multisensory integration in ageing are at least partly due to older adults processing more sensory information than younger adults, regardless of the relevance of sensory stimuli or their attentional state (Hugenschmidt, Mozolic et al. 2009).

Evidence to support the view that the changes in multisensory integration in ageing are not always beneficial comes from a recent study that suggested that altered multisensory processing may be associated with an increased risk of falling in older adults (Setti, Burke et al. 2011). This experiment investigated the susceptibility of older adults with a history of falling to a visual illusion that is induced by sound. Their susceptibility to the illusion was compared to older adults with no history of falling, as well as healthy younger adults (Setti, Burke et al. 2011). This visual illusion was first described by Shams, Kamitani et al. (2000) who called it the sound-induced flash illusion. The first description of this illusion involved flashing a uniform white disc on a black background, a variable number of times, approximately 50 milliseconds apart, and accompanying the flashes with one or more beeps, each spaced 57 milliseconds apart. When a single flash was presented with two or more beeps, observers consistently incorrectly reported seeing multiple flashes. When flashes were presented with no beeps, or an equivalent number of beeps to the number of flashes, the observers correctly reported the number of flashes that had been presented. This indicated that the illusion is one of perception and is not due to the difficulty of the task or other factors. Surprisingly, when subjects were informed of the nature of the illusion, the illusion persisted. The illusion was found to decline when flashes were presented more than 70 milliseconds apart (Shams, Kamitani et al. 2000, Shams, Kamitani et al. 2002).

The sound-induced flash illusion has received a considerable amount of attention from the scientific community over the past ten years (Bhattacharya, Shams et al. 2002, Shams, Iwaki et al. 2005, Mishra, Martinez et al. 2007, Mishra, Martínez et al. 2009, Bolognini, Rossetti et al. 2011, Setti, Burke et al. 2011, de Haas, Kanai et al. 2012, Kamke, Vieth et al. 2012, Shams 2012, Stevenson, Zemtsov et al. 2012, Apthorp, Alais et al. 2013, Keil, Muller et al. in press). This research suggests that the sound-induced flash illusion is caused by a rapid dynamic interplay between the visual and auditory cortical areas that occurs early in the perceptual process and is triggered by the second sound (Shams, Iwaki
et al. 2005, Mishra, Martínez et al. 2007, Mishra, Martínez et al. 2009). It has been suggested that the extra-striate visual cortex plays an important role in the illusion (Mishra, Martínez et al. 2009). It also appears that a fairly direct feed forward, or lateral circuitry pathway, is involved as opposed to feedback modulation from higher cortical areas (Shams, Iwaki et al. 2005). The illusion is resilient to change and is resistant to feedback training (Rosenthal, Shimojo et al. 2009).

Mishra, Martínez et al. (2007) recorded event related potentials in the primary visual cortex, extra-striate visual cortex, and the auditory cortex, which suggest these regions are associated with the illusion. In their trial that utilised whole head event related potentials recordings, Mishra, Martínez et al. (2007) reported that event related potentials were recorded as early as 20-40ms after the second auditory stimulus in the auditory cortex, and they were associated with event related potentials in the visual cortex with an onset of 30-60ms after the second auditory stimulus. These findings were also associated with changes in gamma band electroencephalogram activity in the visual cortex and increased negativity in the superior temporal polymodal cortex. The authors concluded that the sound-induced flash illusion is generated by complex cross-modal interactions between auditory, visual, and polymodal cortical areas.

It has been proposed that an individual’s susceptibility to the sound-induced flash illusion relates to the width of the temporal window in which they will combine multisensory input into a single percept (Stevenson, Zemtsov et al. 2012). Of clinical interest is that some populations exhibit both an increased temporal binding window as well as an increased susceptibility to multisensory illusions. These populations include people with autism, dyslexia, and schizophrenia (Hairston, Burdette et al. 2005, Foucher, Lacambre et al. 2007, Pearl, Yodashkin-Porat et al. 2009, Foss-Feig, Kwakye et al. 2010, Kwakye, Foss-Feig et al. 2011, Martin, Giersch et al. 2013).

Susceptibility to the sound-induced flash illusion has also been linked to grey matter volume in areas of the visual cortex, and can be modulated by attention, or an individual’s pre-stimulus brain state (Mishra, Martínez et al. 2009, Bolognini, Rossetti et al. 2011, de Haas, Kanai et al. 2012, Keil, Muller et al. in press). These findings reinforce the important role that brain connectivity and its functional state play in multisensory integration.
In their experiment that investigated the susceptibility of older people who had fallen to the sound-induced flash illusion, Setti, Burke et al. (2011) recruited three groups of participants. Sixteen younger adults (mean age 24.4, SD 4.0) were recruited from the student population at Trinity College in Dublin, Ireland, and 32 community dwelling older adults were recruited through a research centre in Dublin. The older adults were separated into a fall-prone group (n=16, mean age 72.4, SD 7.2), and a group characterised as healthy older adults with no history of falling (n=16, mean 68.7, SD 5.4). The fall prone group in this trial were identified by asking whether they had fallen within the past five years. Healthy older adults had no history of falling within the past five years.

The investigators presented audio and visual stimuli in combination with varying time intervals between the first and second presentation. They called this lag between presentations the stimulus onset asymmetry. The stimulus onset asymmetries that they used extended beyond the 70ms cut-off that Shams, Kamitani et al. (2002) identified as the point at which the illusion begins to lose its effect in young, healthy participants. The stimulus onset asymmetries included were 30ms, 70ms, 110ms, 150ms, 190ms, 230ms, and 270ms (Setti, Burke et al. 2011). The authors used both positive and negative stimulus onset asymmetries, meaning that the single flash was either presented with the first beep or with the second beep. The outcomes were consistent with both positive and negative stimulus onset asymmetries. The authors found that the younger group was most susceptible to the illusion with stimulus onset asymmetries of 70ms. Their percentage of correct responses then increased when the stimulus onset asymmetry was increased to 110ms, and then further increases were reported with each subsequent increase in stimulus onset asymmetry. With a stimulus onset asymmetry of 190ms the proportion of correct responses in the younger group was approximately 0.85.

The healthy older group were roughly equally susceptible to the illusion at the 70ms stimulus onset asymmetry as the younger group (proportion of correct responses = 0.5-0.55). This proportion decreased slightly to under 0.5 at 110ms stimulus onset asymmetry, before remaining steady at approximately 0.6 as the stimulus onset asymmetry increased to 270ms. The older adults with a history of falling became more susceptible to the illusion as the stimulus onset asymmetry increased. The difference between the older adult groups was not statistically significant with a 70ms stimulus onset asymmetry, but the difference between groups became significant with all magnitudes of stimulus onset asymmetry above 70ms. For all larger stimulus onset
asymmetries that were assessed, the proportion of correct responses in the older group with a history of falling settled between 0.2 and 0.3 (Figure 2:6).

It should be noted that unisensory perception was equal across the groups, which suggests the differences reported are a function of faulty processing and integration in the central nervous system. Although the extended timeframe used to identify fall-prone individuals may have introduced recall bias, and only small participant numbers were used, the results throughout the trial remained consistent with variable trial conditions. This is likely to reflect the robust nature of the illusion and its resilience to change (Rosenthal, Shimojo et al. 2009).

![Figure 2:6 - Sound-Induced Flash Illusion Susceptibility Reported by (Setti, Burke et al. 2011)](image)

**Figure 2:6 - Sound-Induced Flash Illusion Susceptibility Reported by (Setti, Burke et al. 2011)**

Proportion of correct responses across the different stimulus onset asymmetries for each of the three participant groups: younger, older non-fall-prone and older fall-prone, when presented with an illusory condition. From (Setti, Burke et al. 2011) *Is inefficient multisensory processing associated with falls in older people?* Experimental Brain Research, Volume 209, Issue 3, page 380, Fig 1. Reprinted with kind permission from Springer Science and Business Media. SOA = stimulus onset asymmetry.
Setti, Burke et al. (2011) explained their findings by suggesting that older adults may rely more heavily on multisensory information in everyday life as unisensory information becomes degraded and less reliable. If this is the case, the temporal binding window of integration in older adults may become less fixed, resulting in irrelevant information becoming integrated at times, which may lead to inefficient multimodal perception from discrete sources in the environment. Another possible explanation for the findings reported by Setti, Burke et al. (2011) is that older adults, and particularly those with a history of falling, may filter less baseline sensory information, resulting in incoming streams that contain irrelevant or conflicting information or noise (Mozolic, Hugenschmidt et al. 2012). This potentially results in an individual becoming more distractible and less efficient at processing relevant stimuli. If this is the case, it may result in an impaired response when confronted by a hazardous postural situation that requires a rapid compensatory step for example. This potential link may explain why Setti, Burke et al. (2011) observed differences in susceptibility to the sound-induced flash illusion that were linked to an individual’s falls history.

Setti, Burke et al. (2011) concluded that if the differences between groups observed in their study do in fact relate to multisensory processing in the central nervous system, then impaired multisensory integration in older adults may be amenable to rehabilitative training due to the neuroplasticity that remains in the older brain.

However, the sound-induced flash illusion is considered to be resistant to change, with only one study published that has reported an improvement in illusion performance following an intervention (Rosenthal, Shimojo et al. 2009). In this study, that involved three different experiments, Rosenthal, Shimojo et al. (2009) demonstrated that susceptibility to the illusion persisted even when participants were provided with feedback training to help them identify when an illusory stimulus was presented. The only condition that resulted in improvement in illusion performance was when participants were provided with feedback training and were given a monetary reward based on their performance. Under these conditions an improvement was observed. However, following the experiment, participants reported that they continued to perceive the illusion, but they felt there was a phenomenological difference between the illusory and non-illusory conditions that helped them to discriminate between the two conditions. The authors suggested that if the illusion was resistant to feedback training, it would support the hypothesis that the illusion involves modification of visual processing by
higher cortical decision-related levels. They therefore concluded that the resistance to feedback training they observed suggests that the illusion is more dependent on modification in perceptual processes as opposed to decision factors.

To date no studies have been published that have investigated the effects of chiropractic care or spinal manipulation on multisensory processing or integration. However, a small amount of evidence exists that link chiropractic interventions, such as spinal manipulation, to changes in vision and audition (Gorman 1993, Stephens and Gorman 1996, Carrick 1997, Wingfield and Gorman 2000, Leboeuf-Yde, Pedersen et al. 2005, Di Duro 2006, Hawk, Khorsan et al. 2007). Of some historical note is that chiropractic was founded in 1895 by D.D. Palmer after he reportedly ‘racked’ a misaligned vertebra back into place in his deaf janitor’s spine. This apparently resulted in restoration of his hearing after 17 years of considerable hearing loss (Leach 2004). A number of theories have been proposed that may explain a possible link between changes in audition and vision following chiropractic care that involve alterations to brain function (Carrick 1997, Terrett 2002).

Given that there is a growing body of evidence that supports an effect of chiropractic care on somatosensory processing and integration (Haavik Taylor, Holt et al. 2010, Haavik and Murphy 2012), and that somatosensory function can have an impact on other sensory modalities (King and Walker 2012, Hoefer, Tyll et al. 2013, Lenggenhager, Scivoletto et al. 2013), it appears worth investigating the possible effects chiropractic care may have on multisensory processing and integration.

### 2.6.5. Health-related quality of life

Health-related quality of life relates to how an individual’s health impacts on their ability to function, and their perceived well-being in physical, mental and social domains of life (Stenhagen, Ekstrom et al. in press). Health-related quality of life is not usually discussed as a distinct falls risk factor, but many of its mediators, such as bodily pain, mental health, functional independence, and general frailty, are known to be associated with an increased risk of falling (Ware 2000, Deandrea, Lucenteforte et al. 2010, Kanwar, Singh et al. 2013). Suffering from a fall may also have a significant long term impact on health-related quality of life due to the physical and mental consequences of falling (Michalowska, Fiszer et al. 2005, Stenhagen, Ekstrom et al. in press). Besides its
relationship with falls, health-related quality of life is also a good generic measure of health status, and it is routinely used in clinical trials to assess changes in physical and mental health associated with health interventions (Stephens, Alpass et al. 2010).

Many different instruments are commonly used to assess health-related quality of life (Haywood, Garratt et al. 2005). The SF-36 (QualityMetric Inc, Lincoln, Rhode Island) is the most widely used of these survey instruments and has been extensively used in general population surveys and clinical trials (Ware 2000, Ferguson, Robinson et al. 2002, Haywood, Garratt et al. 2005, Farivar, Cunningham et al. 2007). The SF-36 has been shown to be a reliable and valid questionnaire for use in older populations and it also correlates with performance based measures in community dwelling older adults (Lyons, Perry et al. 1994, Sherman and Reuben 1998).

The SF-36 has been translated into many languages around the world, and hundreds, if not thousands, of studies have been performed in order to demonstrate cross-cultural validity of the instrument (Ware 2000, Hawthorne, Osborne et al. 2007). It has been demonstrated to be a valid and reliable measure of health-related quality of life for the New Zealand population (Scott, Tobias et al. 1999). However, cross-cultural validity of the SF-36 has been questioned with respect to measuring Maori and Pacific health (Scott, Sarfati et al. 2000). The mental and physical health summary scores that are generated by the SF-36 are seen as being distinct, yet Maori and Pacific models of health generally see physical and mental health as being inseparable (Scott, Sarfati et al. 2000). Scott et al (2000) suggested that the summary scores are therefore invalid for use among Maori and Pacific people, which may be important when considering the use of summary scores when making multinational comparisons.

Besides different international comparisons, the SF-36 has also been used to investigate health status amongst different clinical populations and groups (Ware 2000). Due to its responsiveness, reliability, and validity, the SF-36 has been recommended as the most appropriate instrument to use when a broad ranging assessment of health-related quality of life is required in older populations with low morbidity (Haywood, Garratt et al. 2005).

A small number of controlled trials have reported improvements in health-related quality of life associated with chiropractic care in a variety of study populations (Gudavalli, Cambron et al. 2006, Bishop, Quon et al. 2010, Bronfort, Evans et al. 2012). The evidence from these trials is inadequate to make any firm conclusions about the effects of
chiropractic care on quality of life and general well-being of most clinical populations (Hawk, Khorsan et al. 2007, Parkinson, Sibbritt et al. 2013).

2.7. Conclusions of the literature review

This chapter reviewed the most important fall risk factors and fall prevention strategies. It was evident from this review that the interaction and synergism between multiple risk factors makes it difficult to determine risk factors that truly predispose an individual to falling, and those that are simply an indirect marker of increased fall risk. The modifiable risk factors with the strongest association with falling, and that appear to have a direct causal relationship with falling, are muscle weakness, balance impairment, gait deficits, and medication use.

Where appropriate, the effectiveness of interventions that may be appropriate for modifiable risk factors has been discussed. One major challenge in assessing fall prevention programmes is they have often been studied as a part of multifactorial intervention programmes, or in generalised community settings, as opposed to studies that are limited to at risk individuals, or those with a specific risk factor or disease. The most effective fall prevention strategies for community dwelling older adults appear to be exercise interventions and tai chi, and for subgroups with specific risk factors, interventions such as vitamin D supplementation, medication review and modification, or cataract surgery are effective. Multifactorial intervention approaches are recommended by advisory groups, but mixed study results, caused by limitations in trial design or implementation, cast some doubt on the conclusions that can be drawn regarding their effectiveness.

The review of chiropractic care and its potential relationship with falls prevention discussed a number of mechanisms that may provide a link between chiropractic care and a decrease in falls risk. This section revealed that most of these potential mechanisms have not been adequately investigated in longer term studies or in studies that include older adult participants. Chapter three is a systematic review that investigates this potential relationship further by assessing the evidence for the effects of manual therapy interventions on falls and balance.

The section about possible outcome measures that could be used in trials to assess the effects of chiropractic care on falls risk factors found that measures of sensorimotor
function and multisensory integration are available that may be appropriate for use in a randomised controlled trial. These include assessments of sensorimotor function that are associated with falls risk such as choice stepping reaction time, joint position sense, and postural stability. The sound-induced flash illusion is a measure of multisensory integration and may also be a useful outcome measure to consider when investigating the effects of chiropractic care on aspects of sensory function that are related to fall risk. A review of the SF-36 was also included which found that the SF-36 is a suitable instrument to use when a broad ranging assessment of health-related quality of life is required in older populations.
CHAPTER 3. SYSTEMATIC REVIEW OF THE EFFECTS OF MANUAL THERAPY ON BALANCE AND FALLS

3.1. Introduction

Chiropractors and other manual therapists may be in a position to assist older patients to prevent falls due to the therapeutic interventions that they employ. Manual therapy may include a variety of hands on techniques used by practitioners such as chiropractors, osteopaths and physiotherapists (Hondras, Linde et al. 2005). Manual therapists routinely treat patients with lower limb dysfunction, muscle weakness, neck pain, back pain, and other conditions that may affect balance and lead to an increased risk of falling (American Geriatrics Society 2001, Bryant, Atkins et al. 2003, Holt and Beck 2005, Rao 2005, Rubenstein and Josephson 2006). If manual therapy results in successful treatment of conditions that increase fall risk, then it may be possible that manual therapists can play a positive role in fall prevention programmes.

Manual therapy may also have a positive influence on fall risk if it results in an improvement in one or more of the various components of the nervous system that are important for the maintenance of balance (Della Volpe, Popa et al. 2005). These components include the cerebellum, the vestibular system and the somatosensory system amongst others. This has led to an area of interest to manual therapists, as a number of studies have demonstrated that manual therapy interventions influence the function of the central nervous system (Haavik Taylor and Murphy 2007, Haavik Taylor and Murphy 2007, Haavik Taylor, Holt et al. 2010, Haavik Taylor and Murphy 2010, Haavik and Murphy 2011).

This link may be due to important connections between receptors in the cervical spine in particular, as well as other joints, with the vestibular system, visual system, and other neural systems that are important for maintaining postural stability (Treleaven 2008). If articular or other lesions interfere with mechanoreceptors within the joints or associated muscle spindles, they may result in reduced postural control and balance (Walsh, Polus et al. 2004). If manual therapy results in correction or improvement of these lesions, it may lead to improved integration of neurological information in the central nervous
system that is important for the maintenance of balance and therefore the prevention of falls (Walsh, Polus et al. 2004, Haavik Taylor, Holt et al. 2010).

The objective of this systematic literature review was to assess the evidence for the effects of manual therapy interventions on falls and balance.

3.2. Methods

3.2.1. Study inclusion criteria

3.2.1.1. Types of studies

All published randomised and quasi-randomised controlled trials were eligible for inclusion, including trials in which treatment allocation was not concealed. Trials in any language and unpublished trials were also eligible for inclusion.

3.2.1.2. Types of participants

Trials that investigated the effects of manual therapy interventions on falls or balance were included in this review. Although falls are a problem primarily associated with older adults, in order to increase the reach of this review, no age restrictions were placed on the trials that were included. No restrictions were made based on participants’ fall risk or status at enrolment, or known medical conditions that may increase fall risk.

3.2.1.3. Types of interventions

Trials that involved at least one type of manual therapy, including manipulation, mobilisation, massage, or other treatments that involve touch, were included in this review. Comparison groups included sham therapies, usual care, placebo controls, or other interventions that did not include manual therapy. No exclusions were made based on frequency, intensity, or duration of manual therapy interventions, or types of therapeutic techniques used.

3.2.1.4. Types of outcome measures

The main outcomes of interest were the rate of falls and the number of fallers reported. Secondary outcomes were measures of balance, including computerised balance platform assessment and functional balance tests.
3.2.2. Electronic searches

The following databases were searched through to June 2011: The Cochrane Central Register of Controlled Trials (CENTRAL - The Cochrane Library current issue), The Cochrane Database of Systematic Reviews (OVID), MEDLINE (OVID), EMBASE, CINAHL, PsycINFO, AMED (Allied and Complementary Medicine), Current Controlled Trials (www.controlled-trials.com), MANTIS (Manual Alternative and Natural Therapy Index System), ICL (Index to Chiropractic Literature), National Institutes of Health (USA) and Google Scholar.

Search terms included; manual therapy OR chiropractic OR osteopathic OR physiotherapy OR physical therapy OR manipulation OR massage OR mobilization OR mobilisation, combined with; accidental falls OR falls OR balance OR postural stability.

3.2.3. Data collection and analysis

3.2.3.1. Selection of studies

Abstracts of identified trials were screened against the eligibility criteria. Full text copies of any studies that were potentially relevant were assessed for inclusion.

3.2.3.2. Data extraction and management

The articles were evaluated and key data were extracted and summarised in data extraction forms, including methods, participants (age, gender, diagnosis and settings), interventions, outcome measures, and results.

3.2.3.3. Quality assessment

Methodological assessment was conducted independently by two authors (KH and CRE) using the Cochrane Bone, Joint & Muscle Trauma Group Quality Assessment Tool. Disagreements were resolved by discussion and consensus. This assessment tool allows raters to assign a score from zero to two on 12 quality assessment items (total score out of 24). The items that are assessed are; allocation concealment; analysis of participants that withdrew; assessor, treatment provider and participant blinding; comparability of treatment and control groups and care programmes; clear definitions of inclusion and exclusion criteria, interventions and outcome measures; the clinical
usefulness of outcome measures, and duration of follow up (Poolman, Struijs et al. 2006).

3.3. Results

3.3.1. Selection of studies

The literature search identified 1,271 potentially relevant trials. Titles and abstracts were screened for inclusion criteria, resulting in 78 trials that were reviewed in greater detail. Eleven trials met the inclusion criteria for detailed data extraction. Nine trials that met the inclusion criteria were identified using MEDLINE (Karlberg, Magnusson et al. 1996, Bennell, Hinman et al. 2005, Giemza, Ostrowska et al. 2007, Reid, Rivett et al. 2008, Alburquerque-Sendin, Fernandez-de-las-Penas et al. 2009, Hawk, Cambron et al. 2009, Palmgren, Lindeberg et al. 2009, Vaillant, Rouland et al. 2009, Hoch and McKeon 2011). The search of ICL identified one additional trial (Hawk, Pfefer et al. 2007). The search of Google Scholar identified one further trial that met the inclusion criteria of the review (Jones, Fryer et al. 2004). Searches of The Cochrane Central Register of Controlled Trials (CENTRAL - The Cochrane Library current issue), The Cochrane Database of Systematic Reviews (OVID), EMBASE, CINAHL, PsycINFO, AMED (Allied and Complementary Medicine), Current Controlled Trials www.controlled-trials.com), MANTIS (Manual Alternative and Natural Therapy Index System), and National Institutes of Health (USA), did not identify any additional trials that met the inclusion criteria of the review.

3.3.2. Methodological quality

The summary scores for methodological quality are included in Table 3:1. Most of the 11 trials included in the review were rated as having poor to fair methodological quality. Out of the eleven trials, five scored 15/24 or higher (Bennell, Hinman et al. 2005, Reid, Rivett et al. 2008, Alburquerque-Sendin, Fernandez-de-las-Penas et al. 2009, Vaillant, Rouland et al. 2009, Hoch and McKeon 2011). Many of the trials lacked sufficient detail to gauge adequacy of allocation concealment prior to group allocation and a number did not use comparable treatment and control groups. Due to the nature of the interventions being studied, it was not possible for most trials to blind participants or treatment providers to group allocation. Many of the care programmes or interventions
varied considerably between groups, and some studies only monitored outcomes immediately post a single intervention. Only four of the trials included follow-up of longer than eight weeks from baseline measures. Most trials adequately described inclusion and exclusion criteria, and used appropriate, clinically useful, and clearly defined, outcome measures.

Table 3:1 - Cochrane Bone, Joint & Muscle Trauma Group Quality Assessment Tool Score

<table>
<thead>
<tr>
<th>Study</th>
<th>Total Score (Maximum 24)</th>
<th>Allocation Concealment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Alburquerque-Sendin, Fernandez-de-las-Penas et al. (2009)</td>
<td>15</td>
<td>Unclear</td>
</tr>
<tr>
<td>Bennell, Hinman et al. (2005)</td>
<td>20</td>
<td>Adequate</td>
</tr>
<tr>
<td>Giemza, Ostrowska et al. (2007)</td>
<td>10</td>
<td>Inadequate</td>
</tr>
<tr>
<td>Hawk, Cambron et al. (2009)</td>
<td>10</td>
<td>Inadequate</td>
</tr>
<tr>
<td>Hawk, Pfefer et al. (2007)</td>
<td>14</td>
<td>Adequate</td>
</tr>
<tr>
<td>Hoch and McKeon (2011)</td>
<td>17</td>
<td>Adequate</td>
</tr>
<tr>
<td>Jones, Fryer et al. (2004)</td>
<td>9</td>
<td>Unclear</td>
</tr>
<tr>
<td>Karlberg, Magnusson et al. (1996)</td>
<td>13</td>
<td>Unclear</td>
</tr>
<tr>
<td>Palmgren, Lindeberg et al. (2009)</td>
<td>12</td>
<td>Adequate</td>
</tr>
<tr>
<td>Reid, Rivett et al. (2008)</td>
<td>20</td>
<td>Adequate</td>
</tr>
<tr>
<td>Vaillant, Rouland et al. (2009)</td>
<td>16</td>
<td>Unclear</td>
</tr>
</tbody>
</table>

3.3.3. Study characteristics

The characteristics of the included studies are summarised in Table 3:2. Only two small trials included falls as an outcome measure, but as a feasibility study and a pilot study they were not powered to provide meaningful conclusions about the effects of the intervention on falls (Hawk, Pfefer et al. 2007, Hawk, Cambron et al. 2009). All included trials reported outcomes of functional balance tests, or tests that utilised a computerised balance platform.
The ability to draw conclusions from a number of the studies was limited by poor study design or very low participant numbers (Karlberg, Magnusson et al. 1996, Jones, Fryer et al. 2004, Giemza, Ostrowska et al. 2007, Hawk, Pfefer et al. 2007, Palmgren, Lindeberg et al. 2009). Two studies were limited by low participant numbers (n≤30) (Vaillant, Rouland et al. 2009, Hoch and McKeon 2011). Although these trials only included 24 and 20 participants respectively, they were cross-over trials and they did report a number of benefits in sensorimotor function, including improvements in balance measures, following a single ankle joint mobilisation, with or without massage, compared with no treatment, or sham magnetic therapy (Vaillant, Rouland et al. 2009, Hoch and McKeon 2011).

Of the three studies that did not include the limitations mentioned above, one reported that bilateral talocrural joint manipulation did not improve standing stability, but only asymptomatic volunteers that appeared to have no standing stability problems were enrolled in the study (Alburquerque-Sendin, Fernandez-de-las-Penas et al. 2009). Another study reported only one balance measure and included a variety of physiotherapy treatments as well as massage and mobilisation (Bennell, Hinman et al. 2005). The final study was somewhat limited by sample size (n=34), but reported an immediate, sustained, significant improvement, in a variety of outcomes associated with dizziness in patients with cervicogenic dizziness, following sustained natural apophyseal glides (Reid, Rivett et al. 2008). This final study also reported some improvements in computerised balance assessments at 12 weeks post intervention.

Roulard et al. 2009). Three of the trials that reported some improvement in outcomes included a variety of other physiotherapeutic interventions besides manual therapy, so results of these trials should be considered with this in mind (Karlberg, Magnusson et al. 1996, Bennell, Hinman et al. 2005, Giemza, Ostrowska et al. 2007). Although Bennell, Hinman et al (2005) reported some improvement in a functional balance test, the improvement observed was similar to that seen in the placebo group so is unlikely to be as a result of the manual therapy intervention. A meta-analysis of included studies was not performed due to heterogeneity of interventions and outcomes.

Table 3:2 - Characteristics of Included Studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Alburquerque-Sendin, Fernandez-de-las-Penas et al. (2009)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&quot;Immediate effects of bilateral manipulation of talocrural joints on standing stability in healthy subjects.&quot;</td>
</tr>
<tr>
<td>Methods</td>
<td>Randomised controlled trial</td>
</tr>
<tr>
<td></td>
<td>Single blind (assessor was blinded)</td>
</tr>
<tr>
<td></td>
<td>Method of randomisation not described</td>
</tr>
<tr>
<td></td>
<td>Purpose: To investigate the immediate effects of bilateral talocrural joint manipulation on standing stability in healthy subjects</td>
</tr>
<tr>
<td></td>
<td>Losses: No losses reported</td>
</tr>
<tr>
<td>Participants</td>
<td>Setting: Not adequately described, but appears to be a University based laboratory or osteopathy clinic in Salamanca, Spain</td>
</tr>
<tr>
<td></td>
<td>N=62 (74% female)</td>
</tr>
<tr>
<td></td>
<td>Sample: Healthy young volunteers recruited through an announcement at Universidad de Salamanca, Spain</td>
</tr>
<tr>
<td></td>
<td>Age: 18 to 22 or 32 (authors use both values in paper - mean 21 years)</td>
</tr>
<tr>
<td></td>
<td>Exclusion Criteria: Alterations of stability, presence of deformities or orthopedic lesions in the lower extremity or lumbar spine, history of trauma to lower extremities or lumbar spine, contraindications to manipulative procedure, treatment to the lower extremity in the previous year, engaged in strenuous activity before the study period. Number of exclusions is not reported.</td>
</tr>
<tr>
<td>Interventions</td>
<td>Experimental: Bilateral talocrural joint manipulation (n=32)</td>
</tr>
<tr>
<td></td>
<td>Control: No intervention (n=30)</td>
</tr>
<tr>
<td>Outcome Measures</td>
<td>Stabilometric analysis using a Diagnostic Support Platform Pre and five minutes post intervention or control</td>
</tr>
<tr>
<td>Results</td>
<td>Changes on the X coordinate range, length of motion, and mean speed approximated to statistical significance (P = 0.06), and changes on the Y coordinate range reached statistical significance (P = 0.02). Average X</td>
</tr>
</tbody>
</table>
and Y motions, and anterior-posterior or lateral velocities did not show significant differences.

Concluded that bilateral manipulation of the talocrural joint did not modify standing stability but future studies with greater sample size and symptomatic patients are needed.

**Notes**

Possible Type II error occurred.

**Study**

Bennell, Hinman et al. (2005)

"Efficacy of physiotherapy management of knee joint osteoarthritis: a randomized, double blind, placebo controlled trial."

**Methods**

Randomised controlled trial

Double blind

Randomised to two groups using a random number generator

Objective: To determine whether a multimodal physiotherapy programme including taping, exercises, and massage is effective for knee osteoarthritis, and if benefits can be maintained with self-management.

Losses: 21 of 140 (15%) (13 from intervention group, 2 from control group)

Intention to treat analysis

**Participants**

Setting: Community based physiotherapy clinics in Melbourne, Australia

N= 140 (650 volunteers screened)

Sample: Community sample with knee osteoarthritis 50 years and over

Age: Mean 67 years for physiotherapy group and mean 70 years for placebo group

Inclusion Criteria: Presence of knee osteoarthritis based on American College of Rheumatology criteria

Exclusion Criteria: Physiotherapy or knee surgery in the previous 12 months, lower limb arthroplasty, Synvisc or intra-articular steroid injections in the previous six months, systemic arthritic condition, known allergic reaction to tape, body mass index over 36 kg/m²

**Interventions**

Physiotherapy treatment including knee taping; exercises for quadriceps, hip and back muscles; balance exercises; thoracic spine mobilisation; soft tissue massage

Placebo treatment consisting of sham ultrasound and light application of non-therapeutic gel

**Outcome Measures**

Visual analogue scale (VAS) of pain on movement, Western Ontario and McMaster Universities Osteoarthritis Index, the knee pain scale, an 11 point numerical VAS for restriction of activity, short form 36 item general health questionnaire (SF-36), assessment of quality of life index, step test, isometric quadriceps strength. Outcome measures were recorded immediately before treatment, immediately after treatment (12 weeks),
and at 24 weeks (12 weeks post treatment).

| Results | The two groups showed similar improvements across all outcome measures. There was a small improvement in step test in both groups. Concluded that the physiotherapy programme tested was no more effective than regular contact with a therapist at reducing pain or disability or improving step test. |
| Notes | Treatment included manual therapy (massage and mobilisation) combined with other physiotherapy treatments. The only outcome measure relating to falls or balance was the step test, a functional dynamic test of standing balance which involves standing on the symptomatic leg and recording the number of times that the other leg can be raised onto a 15cm step in 15 seconds. |
| Methods | Quasi-experimental two group trial – An experimental group with hip osteoarthritis and an age-matched control group without hip osteoarthritis No mention is made of any blinding Hypothesis: Hip osteoarthritis could contribute to a decrease in standing balance abilities and that physiotherapy training could improve postural stability in hip osteoarthritis patients. Losses: No losses reported |
| Participants | Setting: Rehabilitation and Prophylaxis Centre, Wroclaw, Poland N= 110 (All male) Sample: Male hip osteoarthritis patients involved in a research group at a rehabilitation centre and age-matched controls Age: 60-75 years, mean 69 years Inclusion Criteria: Ability to walk and stand independently and general independence in living. Exclusion Criteria: History of neurological, cardiovascular or cerebrovascular disease, neuromuscular disorder, and rheumatoid arthritis, or receiving medications known to affect balance. |
| Interventions | Eighty hip osteoarthritis subjects were included in the experimental group and received physiotherapy treatment 5 times per week for six weeks including exercise therapy, diathermy, laser, cryotherapy and massage. Thirty age-matched controls appeared to receive no intervention. |
| Outcome Measures | Postural stability with eyes open and closed on a force plate measured at baseline and after six weeks of treatment. |
| Results | Significant improvements occurred in all measures of postural stability in the osteoarthritis group following physiotherapy intervention. There was
also a significant difference in postural stability between the osteoarthritis group and controls. Concluded that hip osteoarthritis has an effect on the process of maintaining standing balance and the physiotherapy training programme significantly improved postural stability in the male hip osteoarthritis patients.

Notes
Quasi-experimental design with no apparent blinding and only one manual therapeutic intervention (massage) combined with other physiotherapy treatment approaches and modalities.

Study
Hawk, Cambron et al. (2009)
"Pilot Study of the Effect of a Limited and Extended Course of Chiropractic Care on Balance, Chronic Pain, and Dizziness in Older Adults."

Methods
Randomised pilot study – randomisation was performed using a minimisation algorithm based on age and baseline balance assessment. A failure of randomisation occurred due to some participants refusing to participate in their assigned group and others requesting participation in a certain group. Participants and treatment providers were not blinded but assessors were.

Purpose: To collect preliminary information on the effect of a limited and extended course of chiropractic care on balance, chronic pain, and associated dizziness in a sample of older adults with impaired balance.

Losses: Nine of 34 (26%)

Intention to treat analysis was not used.

Participants
Setting: Primarily a fitness centre catering to older adults, Missouri, United States of America
N= 34 (59% female)
Sample: Older adults (65 years and over) most of whom attended a fitness centre catering to older adults.

Age: Median 80 years (range 65-93)

Inclusion Criteria: 65 years or older, able to attend all scheduled sessions and able to stand steadily without assistance on one leg for an average of less than five seconds.

Exclusion Criteria: Nonambulatory, received chiropractic care or other manual care within the past three months, initiated an exercise program for balance/lower body strength within the past month, contraindications to spinal manipulative therapy or mild-exertion exercise, or absence of indications for spinal manipulative therapy. Unable to understand English adequately to complete study forms, presence of central causes of vertigo.

Interventions
Two groups received chiropractic care including spinal manipulative
therapy using manual manipulation and extravertebral manipulation. Group one (n=13) attended two visits per week for eight weeks and group two (n=15) attended two visits per week for eight weeks followed by one visit per month for 10 months. A brochure containing health recommendations was provided, as was a home hazard checklist and also a pamphlet on balance exercises. The control group (n=6) only received the published material that was provided to the experimental group.

**Outcome Measures**

Outcome measures were recorded at baseline, one, two, six and 12 months. Outcome measures included falls (recorded by the clinician at treatment or assessment visits as well as falls recorded using monthly falls calendars). Balance was measured using the Berg Balance Scale and the One-Leg Standing Test. Other measures included the Pain Disability Index, Geriatric Depression Scale, and Dizziness Handicap Inventory.

**Results**

No significant differences within or between groups in median Berg Balance Scale from baseline to 12 months occurred. For the nine patients with dizziness, clinically significant improvement in Dizziness Handicap Index scores of groups one and two was observed at one month and remained lower than baseline thereafter; this was not true of group three. The small sample size precluded the use of inferential statistics to determine if any other differences between groups were significant. Concluded that further investigation of the possible benefit of chiropractic maintenance care for balance and pain-related disability is feasible and warranted, as well as both limited and extended schedules for patients with idiopathic dizziness.

**Notes**

Small sample size and failure of randomisation limit conclusions that can be drawn

**Study**

Hawk, Pfefer et al. (2007)

"Feasibility study of short-term effects of chiropractic manipulation on older adults with impaired balance."

**Methods**

Randomised controlled feasibility trial – randomisation was performed using a minimisation algorithm based on age and baseline balance assessment.

Participants and treatment providers were not blinded but assessors were. Purpose: To collect preliminary information on the effects of chiropractic spinal manipulation on reducing risk of falls in older adults with impaired balance, as assessed by the Berg Balance Scale.

Losses: Three of 11 (27%)

Intention to treat analysis was not used

**Participants**

Setting: Outpatient health centre of a chiropractic college, Kansas City,
MO, USA
N= 11 (55% female) (26 screened)
Sample: Older adults from the community
Age: Mean 73 years (range 63-92 years)
Inclusion Criteria: Aged 60 years or older, able to stand on one leg for five seconds, and able to attend all sessions
Exclusion Criteria: Nonambulatory, received chiropractic care or any other manual care procedure within the past month, initiated an exercise programme targeting balance and/or lower body strength within past month, contraindications to chiropractic manipulative therapy or mild-exertion exercise, absence of indications for chiropractic manipulative therapy, unable to understand English adequately to complete study forms and questionnaires.

<table>
<thead>
<tr>
<th>Interventions</th>
<th>Chiropractic manipulative therapy group received chiropractic care including spinal manipulative therapy using manual manipulation and extravertebral manipulation. Visit frequency was two visits per week for eight weeks. Exercise group was prescribed balance exercises which were supervised at two visits per week for eight weeks.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcome Measures</td>
<td>Outcome measures were recorded at baseline, four weeks and eight weeks. Outcome measures included falls (recorded by the clinician at treatment or assessment visits as well as falls recorded using monthly falls calendars and also exit and entrance interviews). Balance was measured using the Berg Balance Scale and the One-Leg Standing Test. Other measures included the Pain Disability Index, Geriatric Depression Scale, and Dizziness Handicap Inventory.</td>
</tr>
<tr>
<td>Results</td>
<td>The sample size was too small to allow for the use of inferential statistics. Both groups seemed to show some improvement in Berg Balance Scale score. Concluded that further investigation of the possible role of chiropractic care in reducing fall risk in this population appears feasible.</td>
</tr>
<tr>
<td>Notes</td>
<td>Very small study with no meaningful conclusions possible regarding treatment effects.</td>
</tr>
<tr>
<td>Study</td>
<td>Hoch and McKeon (2011) 'Joint mobilization improves spatiotemporal postural control and range of motion in those with chronic ankle instability'</td>
</tr>
<tr>
<td>Methods</td>
<td>Randomised cross-over trial with at least 24 hours between assessments. Allocation was based on selection of sealed opaque envelopes containing allocation information. Assessors were blinded to participant group allocation but participants</td>
</tr>
</tbody>
</table>
were unaware if they were in the treatment or placebo phase of the trial.

**Purpose:** To examine the effects of a single joint mobilisation treatment on dorsiflexion range of motion, posterior talar glide, and dynamic postural control in individuals with self-reported chronic ankle instability.

**Losses:** No losses occurred

**Participants**

<table>
<thead>
<tr>
<th>Setting</th>
<th>Laboratory setting at the University of Kentucky, United States of America.</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>20 (55% female)</td>
</tr>
<tr>
<td>Sample</td>
<td>Individuals with self-reported chronic ankle instability.</td>
</tr>
<tr>
<td>Age</td>
<td>Mean 23.4 +/-5.4 years</td>
</tr>
</tbody>
</table>

**Inclusion Criteria:** A history of at least one ankle sprain and at least two episodes of ‘giving way’ within the past three months. As well as additional ankle instability and functional loss criteria that were assessed using the Ankle Instability Instrument and the Foot and Ankle Ability Measure.

**Exclusion Criteria:** An acute sprain in the previous six weeks, previous history of lower extremity surgeries or fracture, other lower extremity injuries within the past six months, diabetes, neuropathies or other conditions known to affect balance

**Interventions**

<table>
<thead>
<tr>
<th>Treatment intervention – a single session of joint mobilisation consisting of two, two minute sets of Maitland Grade III anterior to posterior talocrural joint mobilisations with one minute of rest between sets.</th>
<th>Control intervention – the participant lay supine with their foot in a resting position without active contraction for five minutes.</th>
</tr>
</thead>
<tbody>
<tr>
<td>The minimum amount of washout time permitted between interventions was 24 hours but the average time was 6 +/- 1.3 days. All interventions were administered by a Certified Athletic Trainer with 13 years’ experience.</td>
<td></td>
</tr>
</tbody>
</table>

**Outcome Measures**

| Outcomes were measured post-intervention in both sessions. Outcome measures included ankle dorsiflexion range of motion, instrumented arthrometry, dynamic postural control was measured using the Star Excursion Balance Test and static postural control was measured using a computerised forceplate analysis of time-to-boundary variables measured while standing on one leg with eyes open and eyes closed. |

**Results**

Post-intervention outcomes were compared between sessions. The joint mobilisation procedure was associated with improvements in dorsiflexion range of motion and time-to-boundary in the anterior-posterior direction with eyes open. No other significant differences were observed but trends were reported in posterior talar displacement and other time-to-boundary measures.
| Notes | A number of positive trends were reported that didn’t reach statistical significance, indicating a type II error may have occurred. |
| Study | Jones, Fryer et al. (2004)  
“The effect of osteopathic manipulative therapy applied to the lumbar spine on postural stability: A pilot study.” |
| Methods | Randomised controlled trial. Pre / post a single intervention.  
Randomisation was performed via lottery draw.  
Participants and treatment providers were not blinded to group allocation and no mention is made of assessor blinding.  
Aim: To investigate the effects of an osteopathic manipulative therapy treatment protocol applied to the lumbar spine on postural stability as measured by average centre of pressure velocity on a vertical force platform measurement system. |
| Participants | Setting: Appears to be set at Victoria University, Melbourne, Australia  
N= 41 (56% female)  
Sample: Student population at Victoria University, Melbourne, Australia  
Age: Mean 23 years (range 18-29)  
Exclusion Criteria: Free from any spinal pain, history of diagnosed spinal or lower limb pathology, any conditions that affect balance or postural stability. |
| Interventions | Osteopathic manipulative therapy treatment including high velocity low amplitude manipulative thrust to the lumbar spine, muscle energy technique, and myofascial technique, also administered to the lumbar spine.  
Control group received no treatment but were asked to lie flat on a table for three minutes. |
| Outcome Measures | Postural sway measured with eyes open and eyes closed using a vertical force platform that calculated centre of pressure velocity. Three different stance positions were used, static bipedal stance, static bipedal tandem stance and static unipedal stance. |
| Results | Significant reduction in average centre of pressure velocity was reported during tandem stance for the intervention group for both eyes open and eyes closed. No other significant differences were reported.  
Concluded that osteopathic manipulative therapy applied to the lumbar spine may have an effect on postural stability. |
| Notes | Unpublished Master’s thesis |
| Study | Karlberg, Magnusson et al. (1996)  
"Postural and symptomatic improvement after physiotherapy in patients with dizziness of suspected cervical origin." |
| Methods | Randomised controlled trial. |
Method of randomisation was not described.
No mention of blinding is made.

Objective: To assess postural performance in patients with dizziness of suspected cervical origin in whom extracervical causes had been excluded, and to assess the effects of physiotherapy on postural performance and subjective complaints of neck pain and dizziness.

Losses: Five of 22 (23%)

Intention to treat analysis was not used

| Participants | Setting: Primary care centres and a tertiary referral centre in Lund, Sweden  
| N= 17 (88% female) (17 healthy controls (88% female) were also included in order to compare baseline postural stability scores)  
| Sample: Patients with recent onset neck pain and simultaneous complaints of dizziness or vertigo referred by general practitioners to a vestibular laboratory. Healthy controls were age and sex matched.  
| Age: Mean 37 years (range 26-49 years)  
| Exclusion Criteria: Older than 55 years, history of central nervous system disease, central nervous system trauma, neck trauma, ear disease, arteriosclerotic disease, psychiatric disease, or major injuries of the lower limbs. Patients were also excluded if it was felt they may derive medico-legal advantage by participation in the study. |

| Interventions | Treatment group received physiotherapy treatment including soft tissue treatment, stabilisation exercises of the trunk and cervical spine, passive and active mobilisation, relaxation techniques, home training programmes and minor ergonomic changes. Treatment was given over 5-20 weeks with between five and 23 treatments per patient.  
| Delayed treatment group received no treatment for the first eight weeks and then received similar physiotherapy treatment as the treatment group. |

| Outcome Measures | Visual analogue scale for neck pain, five point dizziness or vertigo scale, and postural performance measured on a force platform while undergoing vibration-induced body sway and galvanically-induced body sway with both eyes open and eyes closed. Outcome measures were taken at baseline and following completion of physiotherapy treatment in the treatment group, and at baseline, at eight weeks (pre-physiotherapy treatment) and post physiotherapy treatment for the delayed treatment group. |

| Results | The patients manifested significantly poorer postural performance than did healthy subjects (p<0.05). Physiotherapy treatment was reported to significantly reduce neck pain and intensity and frequency of dizziness (p<0.01), and significantly improve postural performance (p<0.05). Concluded that patients with dizziness of suspected cervical origin are |
characterised by impaired postural performance and that physiotherapy treatment reduces neck pain and dizziness and improves postural performance.

<table>
<thead>
<tr>
<th>Notes</th>
<th>A variety of therapeutic modalities and methods were combined with manual therapy in this trial.</th>
</tr>
</thead>
</table>

### Study

<table>
<thead>
<tr>
<th>Study</th>
<th>Palmgren, Lindeberg et al. (2009)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&quot;Head repositioning accuracy and posturography related to cervical facet nerve blockade and spinal manipulative therapy in healthy volunteers: a time series study.&quot;</td>
</tr>
</tbody>
</table>

### Methods

- **Time series design with randomisation of intervention order.**
- Allocation was based on selection of sealed opaque envelopes containing allocation information.
- Assessors were blinded to participant group allocation.
- **Aim:** To investigate if changes in head repositioning accuracy, and standing balance could be evoked by unilateral facet nerve blockade or spinal manipulative therapy.

### Participants

- **Setting:** The setting appears to be the Scandinavian College of Chiropractic
- **N = 6 (17% female)**
- **Sample:** Healthy volunteers.
- **Age:** Mean 35 years (range 27-43 years)
- **Inclusion Criteria:** 18-45 years of age
- **Exclusion Criteria:** General contraindications for manual treatment, presence of severe musculoskeletal injury, or received manual treatment within four weeks.

### Interventions

- **Bilateral cervical spinal manipulative therapy using a rotary technique to C5-C6**
- **Facet nerve blockade using local anesthetic at C5-C6**
- **Intervention order was randomised. It is not clear what length of time existed between interventions.**

### Outcome Measures

- **Head repositioning accuracy following cervical movements and computerised posturography using a stable force platform to measure static postural sway. A series of baseline measures were taken as well as pre and post intervention measures.**

### Results

- **No significant trends were seen in the subjects over the period of the study.**
- Concluded that there was no uniform response to unilateral facet nerve blockade or to spinal manipulative therapy.

### Notes

- **Very small sample size limits ability to make conclusions.**

### Study

<table>
<thead>
<tr>
<th>Study</th>
<th>Reid, Rivett et al. (2008)</th>
</tr>
</thead>
</table>

85
"Sustained natural apophyseal glides are an effective treatment for cervicogenic dizziness."

<table>
<thead>
<tr>
<th>Methods</th>
<th>Double-blind randomised controlled clinical trial. Allocation was based on selection of sealed opaque envelopes containing allocation information. Assessors were blinded to participant group allocation. Participants were unaware if they were in the treatment or placebo group. Aim: to determine the efficacy of sustained natural apophyseal glides in the treatment of cervicogenic dizziness. Losses: One of 34 (3%), from the sustained natural apophyseal glides group due to previous bad experience with manual therapy. A further two (6%) participants from the placebo group were unable to attend some of the assessment procedures. Intention to treat analysis was used</th>
</tr>
</thead>
<tbody>
<tr>
<td>Participants</td>
<td>Setting: University of Newcastle, Australia. N= 34 (62% female) (59 assessed for eligibility) Sample: People suffering from cervicogenic dizziness Age: Mean 63 years (eligible if aged between 18-90 years) Inclusion Criteria: Diagnosis of cervicogenic dizziness with symptoms present for longer than three months and aged 18-90 years. Exclusion Criteria: A variety of other potential causes of vertigo or contraindications to sustained natural apophyseal glides treatment. Manual therapy or physiotherapy in the past month, pregnancy or inability to read English.</td>
</tr>
<tr>
<td>Interventions</td>
<td>Treatment group – sustained natural apophyseal glides treatment following previously published protocol. Placebo group – Sham treatment using a detuned laser Both groups received the interventions 4-6 times over four weeks. All participants were asked to avoid new co-interventions during the trial and it appears all participants complied with this request.</td>
</tr>
<tr>
<td>Outcome Measures</td>
<td>Severity of dizziness using a visual analogue scale, disability caused by dizziness measured using the Dizziness Handicap Inventory, frequency of dizziness (five point scale), severity of cervical pain and headache, global perceived effect response to intervention (six point scale), balance with eyes open and closed and in cervical extension measured using a computer based dynamic balance system, cervical range of motion measured using a CROM instrument.</td>
</tr>
<tr>
<td>Results</td>
<td>At post treatment, six week and 12 week follow up the sustained natural apophyseal glides group had less dizziness, lower Dizziness Handicap Inventory scores, decreased frequency of dizziness, and less cervical pain.</td>
</tr>
</tbody>
</table>
Balance with the neck in extension improved in the sustained natural apophyseal glides group as did cervical extension range of motion. The placebo group had significant changes at 12 weeks only in severity of dizziness, Dizziness Handicap Inventory and severity of cervical pain.

<table>
<thead>
<tr>
<th>Notes</th>
<th>The sustained natural apophyseal glides group seemed to have immediate clinically significant improvements in a variety of outcome measures.</th>
</tr>
</thead>
</table>
| Study | Vaillant, Rouland et al. (2009)  
"Massage and mobilization of the feet and ankles in elderly adults: effect on clinical balance performance." |
| Methods | Randomised, placebo-controlled cross-over trial.  
Intervention order was randomised but method of randomisation was not described.  
Assessors were blinded to participant group allocation.  
Aim: To evaluate the effects of a session of plantar massage and joint mobilisation of the feet and ankles on clinical balance performance in elderly people.  
Losses: One of 28 (4%) due to lack of interest  
Intention to treat analysis was not used |
| Participants | Setting: The setting is not described but appears to be a university hospital in France or Switzerland  
N= 28 (54% female)  
Sample: Healthy volunteers from three community nursing homes.  
Age: Mean 79 years (Range 65-95 years)  
Inclusion Criteria: Age over 65 and the ability to walk 10m.  
Exclusion Criteria: Severe cognitive impairment, rapidly progressing or terminal illness, acute illness or unstable chronic illness, myocardial infarction or a fracture of the lower limb within the six months prior to inclusion. |
| Interventions | Massage and mobilisation of the feet and ankles  
Application of three demagnetised magnets in the region of the fifth metatarsal for twenty minutes.  
At least one week separated the two sessions |
| Outcome Measures | One Leg Balance test, Timed Up and Go test, and the Lateral Reach test. |
| Results | A significant improvement was reported for the One Leg Balance test and Timed Up and Go test in the treatment group compared to the placebo group. The Lateral Reach test did not improve significantly. |
| Notes | Results were only evaluated immediately post-intervention. |
3.4. Discussion

This systematic review revealed that there is no completed research that adequately investigates the role that manual therapy may play in preventing falls. There is however a limited amount of research that supports a role for manual therapy in improving postural stability and balance.

Although a number of the included trials reported positive findings associated with balance measures following manual therapy interventions, poor methodological quality, low participant numbers, or inadequate follow up times, mean these results must be interpreted with caution when attempting to assess whether they represent clinically significant findings. The manual therapy interventions that were associated with positive results included talocrural joint manipulation, thoracic spine mobilisation with soft tissue massage, physiotherapy treatment including massage, soft tissue treatment or mobilisation, chiropractic care including spinal manipulative therapy and extravertebral manipulation, osteopathic manipulative therapy, sustained natural apophyseal glides, and massage and mobilisation of the feet and ankles (Karlberg, Magnusson et al. 1996, Jones, Fryer et al. 2004, Bennell, Hinman et al. 2005, Giemza, Ostrowska et al. 2007, Hawk, Pfefer et al. 2007, Reid, Rivett et al. 2008, Alburquerque-Sendin, Fernandez-de-las-Penas et al. 2009, Hawk, Cambron et al. 2009, Vaillant, Rouland et al. 2009, Hoch and McKeon 2011).

The positive results that were reported following these interventions included improved postural sway, improvement in functional balance tests, and improvement in measures of dizziness (Karlberg, Magnusson et al. 1996, Jones, Fryer et al. 2004, Bennell, Hinman et al. 2005, Giemza, Ostrowska et al. 2007, Hawk, Pfefer et al. 2007, Reid, Rivett et al. 2008, Alburquerque-Sendin, Fernandez-de-las-Penas et al. 2009, Hawk, Cambron et al. 2009, Vaillant, Rouland et al. 2009, Hoch and McKeon 2011). Only one trial of sound methodological quality and with acceptable participant numbers reported favourable, clinically significant balance outcomes, following a manual therapy intervention (Reid, Rivett et al. 2008). The intervention in this trial was treatment over a four week period using sustained natural apophyseal glides, and the outcomes that improved included measures of dizziness and balance. The improvements reported persisted over the 12 week post treatment follow up period.
When considering the methodological quality of included studies it should be acknowledged that this review judged studies using an assessment tool that is designed to assess the risk of bias in intervention studies. It should also be acknowledged that a basic science study, or feasibility study, may be well designed to answer the questions it poses, but score poorly on an assessment of its risk of bias when considered as a clinical intervention study.

3.4.1. Limitations and future research

The conclusions that can be drawn from this review are limited by a lack of quality trials available for inclusion. Bias due to study design and quality exists as a number of the included trials were basic science studies, or pilot, or feasibility studies. Many of the trials included low participant numbers, or healthy subjects as participants, or investigated outcomes pre and post a single intervention with no long term follow up or control group. The conclusions that can be made from this review are also limited due to a considerable amount of heterogeneity existing between interventions and outcomes, which meant that no meta-analysis was possible.

Selection bias may have occurred in this review as only one person conducted the literature search and article selection phase of the review. However, the search was robust and the list of studies identified by the literature review were analysed on two separate occasions to ensure all eligible studies were included in the data extraction phase of the review. In addition, quality assessment was undertaken by two authors, separately. Although the literature search was robust, the exclusion criteria for this review meant that trials lacking a control group were not included due to the greater chance of bias associated with their study design. This resulted in the omission of some relevant single group studies that assessed manual therapy interventions for balance and falls (Hawk and Cambron 2009, Strunk and Hawk 2009).

3.5. Conclusions of the systematic review

This systematic review summarised the evidence relating to the effects of manual therapies on balance and falls that existed by mid-2011. It is the first systematic review to do so. More recent trials may have been published, but this systematic review was conducted prior to the main trial of this thesis in order to identify a gap in the literature. The key finding from this review was that more well designed controlled trials, with
sufficient participant numbers, were required in order to draw meaningful clinical conclusions about the role that manual therapies may play in preventing falls, or improving postural stability and balance. This review also highlighted the need for future trials to include participants who are at risk of falling, or have reduced postural stability, as opposed to healthy volunteers, in order for the results to be valid for the population at most risk. Therefore, the subsequent randomised controlled trial described later in this thesis was conducted to address this gap in the literature.
CHAPTER 4. CROSS-SECTIONAL STUDY OF FALLS RISK OF OLDER PEOPLE RECEIVING CHIROPRACTIC CARE

4.1. Introduction

As primary care practitioners, chiropractors are expected to engage in health promotion activities as a part of clinical practice (Hawk, Rupert et al. 2005). Identification of fall risk is of major importance as the majority of patients with an increased risk of falling have no symptoms that would alert them, or their healthcare provider, to this increased risk (Carrick 2005). If chiropractors identify these risk factors, and counsel their patients on appropriate strategies to address them, they may reduce their future risk of falling, which may have an impact on their future quality of life (American Geriatrics Society 2001, Rao 2005, Rubenstein and Josephson 2006).

The primary aim of this cross-sectional study was to gain an indication of the prevalence of previous falls, risk factors for falls, and balance deficits amongst older ambulatory adults attending a selection of chiropractic practices. Where possible, these prevalence estimates have been compared with reported population rates. The secondary aim was to investigate the health-related quality of life status of older chiropractic patients and to see whether a history of falling was related to health-related quality of life status.

To our knowledge this is the first study to assess fall risk in older chiropractic patients. It is therefore unknown if older chiropractic patients are representative of the wider community or if they are at an even greater risk of falling. It is hoped that by better understanding the risk of falls in their older patients, this study will help to encourage chiropractors to play a primary role in detection of falls risks and engage in falls prevention strategies.
4.2. Methods

4.2.1. Design and study population

This was a cross-sectional study. Twelve chiropractors in Auckland and Melbourne were contacted by the investigators and invited to participate in the study. Chiropractors were selected based on convenience from the 858 practices listed as being located in either Auckland or Melbourne in the chiropractic registers of New Zealand and Australia (New Zealand Chiropractic Board 2008, Chiropractic Board of Australia 2010). All 12 chiropractors that were approached agreed to participate and were subsequently provided with information about the study to pass onto their older patients. Older patients were approached by the chiropractor, or one of their assistants, during an office visit, or else they were contacted by letter and or telephone and invited to participate in the study. All older adults who were active patients in the practices involved in the study were contacted and invited to participate. An active chiropractic patient was defined as a patient who had presented for chiropractic care within the past six weeks. Any older patients that were interested in taking part in the study were provided with a study information sheet (Appendices 1 and 2) that described the study and the expectations of them if they decided to participate in the study. All participants were required to complete an informed consent form (Appendices 3 and 4) before being included in the study.

4.2.2. Inclusion criteria

Participants were 65 years of age and over and active chiropractic patients. Volunteers who were ambulatory (including the use of walking aids) and were willing to sign an informed consent form were eligible.

4.2.3. Exclusion criteria

Participants were excluded if they were wheel-chair bound or unable to remain standing with eyes open and unassisted for a minimum of one minute. These patients were excluded as they would have been unable to complete the balance assessments included in the study.
4.2.4. Outcome measures and data collection

Each participant underwent a structured interview following informed consent to collect information relating to demographic characteristics, fall history, fall risks, quality of life, and health history. Postural sway was then measured. Assessments were carried out by one of three research assistants who had taken part in a consensus training programme.

4.2.4.1. Structured interview

Demographic information (age and gender), chiropractic care history, fall history, fall risk and health history information were collected using a structured interview format (Appendix 5). Fall risks were identified using a modified version of the Falls Risk for Older People in the Community (FROP-Com) screening tool, which has a relatively good capacity to predict falls and identify people with fall risks that may require further assessment or management (Russell, Hill et al. 2009).

4.2.4.2. Berg Balance Scale

Fall risk was also assessed using the Berg Balance Scale (Appendix 6). The Berg Balance Scale involves 14 functional tasks that are common in everyday life. They include tasks such as sit to stand, single leg stance, and standing with eyes closed. Each item is scored on a five point (0-4) ordinal scale depending on the participant’s ability to complete the task. A score of zero means they were unable to perform the task and a score of four represents independence. The maximum possible score is 56, with a score of 45 or less considered to be the cut-off to indicate a greater risk of falling (Berg, Wood-Dauphinée et al. 1992). The reliability of the Berg Balance Scale has been well documented, as has the validity of the Berg Balance Scale as an effective predictor of falls within community dwelling older adults (Berg, Wood-Dauphinée et al. 1989, Berg, Wood-Dauphinée et al. 1992, Berg, Wood-Dauphinée et al. 1995).

4.2.4.3. Balance confidence

Balance confidence was assessed using the Activities-specific Balance Confidence Scale (Appendix 7). The Activities-specific Balance Confidence Scale is a 16 item questionnaire that is completed by the participant. The participant is asked to rate their confidence that they will not lose their balance, or become unsteady, while performing
activities of daily living. Scores for the Activities-specific Balance Confidence Scale range from 0-100% with zero being no confidence and 100 being full confidence. A cut-off point of 85% has been suggested to indicate an excessive fear of falling (Herman, Inbar-Borovsky et al. 2009). The Activities-specific Balance Confidence Scale has been demonstrated to be reliable and a valid predictor of falls in older adults. It has also been shown to have greater item responsiveness than other similar scales which makes it more suitable to detect loss of balance confidence in more highly functioning older adults (Powell and Myers 1995).

4.2.4.4. Posturographic sway

Posturographic sway was measured using a CAPs Lite computerised posturography system (Vestibular Technologies, Cheyenne, Wyoming, USA). This static balance platform measures the vertical force and the centre of pressure of an individual quietly standing on a perturbing foam cushion (to reduce proprioceptive information) with their eyes closed (to remove visual clues) for 20 seconds. This obliges the individual to rely mostly on the vestibular system to maintain balance. Normative data for the testing protocols have been established and published, and the CAPs Lite has been shown to provide repeatable posturographic measures (Amin 2000, Pagnacco, Oggero et al. 2008). The effectiveness of the CAPs protocol has been validated by several studies that demonstrated that the CAPs eyes closed on a perturbed surface posturographic test was a sensitive test for identifying older adults who have fallen (Amin, Krishna et al. 2001, Girardi, Konrad et al. 2001, Amin, Girardi et al. 2002, Girardi, Amin et al. 2002). The CAPs provides several numerical results based on the statistical analysis of the centre of pressure. In this study the participant’s stability level was used, which is calculated by comparing the amount of the participant’s sway throughout the duration of the test to age-matched norms.

4.2.4.5. Health-related quality of life

Health-related quality of life was measured using a Short Form Health Survey (SF-36) version 1. The SF-36 contains 36 questions measuring health across eight subscales – physical functioning, role limitation because of physical health, social functioning, vitality, bodily pain, mental health, role limitation because of emotional problems and general health. Responses to each question within a dimension are combined to generate
a score from 0 to 100, where 100 indicates "good health". In this study the eight sub-scales were aggregated into two higher order summary scores, the Physical Component Summary and Mental Component Summary, which were calculated using the orthogonal extraction and rotation method described by Tucker et al (Tucker, Adams et al. 2010) using the Australian Bureau of Statistics 1995 National Health Survey means and standard deviations to calculate factor score coefficients (Australian Bureau of Statistics 1995). This method produces summary scores that have been normalised to have a mean of 50 and standard deviation of 10 based on Australian population norms (Tucker, Adams et al. 2010). The Physical Component Summary and Mental Component Summary were used to reduce the number of statistical comparisons, and therefore the role of chance, in hypothesis testing (Ware, Kosinski et al. 1995).

The SF-36 has been shown to be a reliable and valid questionnaire for use in older adult populations, and subscales have also been shown to correlate with performance based measures in community dwelling older adults (Lyons, Perry et al. 1994, Sherman and Reuben 1998).

4.2.4.6. Back pain related disability

Back pain related disability was measured using the Revised Oswestry Disability Index (Appendix 8). The Revised Oswestry Disability Index is comprised of 10 brief sections, each of which focuses on an activity of daily living (pain intensity, personal care, lifting, walking, sitting, standing, sleeping, sex life, social life, and travelling). The participant is asked to rate how affected each of these areas of his or her life has been as a result of low back pain. The scores for each section are combined and scaled to give a disability percentage. A score of 0-20% indicates minimal disability, 20-40% moderate disability, 40-60% severe disability, 60-80% crippled, and 80-100% bedbound or exaggerating (Vianin 2008). The Revised Oswestry Disability Index is a valid and reliable measure of disability associated with low back pain that has previously been used to study back pain related disability in older adults (Fairbank and Pynsent 2000, Becker, Bretschneider et al. 2010, Glassman, Carreon et al. 2010). Participants that reported the presence of back pain were asked to complete the Revised Oswestry Disability Index.
4.2.4.7. Neck pain related disability

Neck pain related disability was measured using the Neck Disability Index Questionnaire (Appendix 9) which was modelled after the Revised Oswestry Disability Index (Vernon and Mior 1991). The Neck Disability Index is comprised of sections including: pain intensity, personal care, lifting, reading, headaches, concentration, work, driving, sleeping, and recreation. Participants choose the statement that best describes the way neck pain has affected their ability to manage in these areas. The Neck Disability Index is scored in a similar fashion to the Revised Oswestry Disability Index. The Neck Disability Index has been well validated and utilised in a number of studies to measure disability associated with neck pain in older people (Peterson, Bolton et al. 2003, American Chiropractic Association 2004, Kwak, Niederklein et al. 2005). Participants that reported the presence of neck pain were asked to complete the Neck Disability Index.

4.2.5. Analysis

Descriptive statistics were calculated for each of the fall risk factors and the other test results described below. Health-related quality of life summary scores were compared between fallers and non-fallers using t-tests. Statistical analysis was performed using SAS version 9.1 (Cary, North Carolina, USA).

4.2.6. Ethical considerations

This study received ethical approval from the New Zealand Northern Regional Y Ethics Committee (Ref NTY/06/12/131), and in Australia ethics approval was obtained from the Bellberry Human Ethics Committee (Ref 66/07).

4.3. Results

One hundred and ten older chiropractic patients were eligible to take part in the study and were invited to participate. Eight of the patients approached declined to participate due to overseas travel, disinterest once the study had been explained to them, or other time commitments. One patient was excluded because he could not remain standing unassisted for one minute, leaving 101 (92%) who consented and completed the study. Sixty-two per cent of participants were female and the average age was 72 years (SD 5.9 years). The age range was 65-92 years. A breakdown of participant age is shown in
Figure 4:1. Fifty-three per cent of participants were from Auckland, New Zealand and the remainder were from Melbourne, Australia.

Figure 4:1 - Age of Participants in Fall Risk Profile Study

4.3.1. Chiropractic care history

Table 4:1 describes the characteristics of participants with respect to length of time under care, number of visits in the past 12 months, and the nature of care they sought. Over 90% of participants had been under chiropractic care for over 12 months and 76% described the nature of their chiropractic care as ‘intermittent for occasional acute care or pain management’. The average number of chiropractic visits that participants had made over the previous 12 months was 17.3 and the median number of visits was 13.
Table 4:1 - Description of Chiropractic Care History of Participants in Fall Risk Profile Study

<table>
<thead>
<tr>
<th>Length of Time under Chiropractic Care</th>
<th>n</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>New (&lt; 4 weeks)</td>
<td>3</td>
<td>(3.0)</td>
</tr>
<tr>
<td>1-12 months</td>
<td>7</td>
<td>(6.9)</td>
</tr>
<tr>
<td>&gt; 12 months</td>
<td>91</td>
<td>(90.1)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Nature of Care</th>
<th>n</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>New to Chiropractic</td>
<td>4</td>
<td>(4.0)</td>
</tr>
<tr>
<td>Regular (Maintenance or wellness)</td>
<td>20</td>
<td>(19.8)</td>
</tr>
<tr>
<td>Intermittent (Occasional acute care or pain management)</td>
<td>77</td>
<td>(76.2)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of visits in last 12 months</th>
<th>n</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-5</td>
<td>17</td>
<td>(16.8)</td>
</tr>
<tr>
<td>6-11</td>
<td>22</td>
<td>(21.8)</td>
</tr>
<tr>
<td>12-23</td>
<td>37</td>
<td>(36.6)</td>
</tr>
<tr>
<td>24+</td>
<td>25</td>
<td>(24.8)</td>
</tr>
</tbody>
</table>

Overall mean number of chiropractic visits in last 12 months | 17.3 |
Overall median number of chiropractic visits in last 12 months | 13 |

4.3.2. Fall risk profile

Table 4:2 describes the fall risks identified in the structured interview process, including the falls history of the patient sample. Where possible, results from other studies investigating community dwelling older adults have been given, so general comparisons can be made. Over the previous 12 months 34.6% of the sample reported suffering at least one fall. The most common falls risk factors present were the presence of osteoarthritis (58.4%) and polypharmacy (41.6%).

Table 4:2 - Fall Risk, Fall History and Neck and Back Pain in Older Chiropractic Patients with Results of Comparable Studies of Normal Community Dwelling Older People

<table>
<thead>
<tr>
<th></th>
<th>Chiropractic Patients</th>
<th>Comparable Samples</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n</td>
<td>%</td>
</tr>
<tr>
<td>Number of Falls in past 12 months</td>
<td></td>
<td></td>
</tr>
<tr>
<td>None</td>
<td>66</td>
<td>65.4</td>
</tr>
<tr>
<td>1</td>
<td>23</td>
<td>22.8</td>
</tr>
<tr>
<td>2 or more</td>
<td>12</td>
<td>11.9</td>
</tr>
<tr>
<td>Any Falls</td>
<td>35</td>
<td>34.6</td>
</tr>
</tbody>
</table>
### Injury Related Fall in last 12 months

<table>
<thead>
<tr>
<th>Category</th>
<th>Percentage</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>None</td>
<td>72.3%</td>
<td>Hill, Kerse et al. 2002, Muir, Berg et al. 2010</td>
</tr>
<tr>
<td>Minor, no medical</td>
<td>14.9%</td>
<td>Shumway-Cook, Ciol et al. 2009</td>
</tr>
<tr>
<td>Minor, medical</td>
<td>10.9%</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>2.0%</td>
<td></td>
</tr>
<tr>
<td>Any injury related falls</td>
<td>27.7%</td>
<td>10-30% (Hill, Kerse et al. 2002, Muir, Berg et al. 2010)</td>
</tr>
</tbody>
</table>

### Polypharmacy (4 or more medications)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Percentage</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Polypharmacy</td>
<td>41.6%</td>
<td>Byles, Heinze et al. 2003, Tiedemann, Sherrington et al. 2005, Muir, Berg et al. 2010</td>
</tr>
</tbody>
</table>

### Psychotropic medication use

<table>
<thead>
<tr>
<th>Condition</th>
<th>Percentage</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Psychotropic medication</td>
<td>20.8%</td>
<td>Byles, Heinze et al. 2003, Tiedemann, Sherrington et al. 2005</td>
</tr>
</tbody>
</table>

### Vestibular disorder / dizziness

<table>
<thead>
<tr>
<th>Condition</th>
<th>Percentage</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vestibular disorder</td>
<td>16.8%</td>
<td>Graafmans, Ooms et al. 1996</td>
</tr>
</tbody>
</table>

### Osteoarthritis

<table>
<thead>
<tr>
<th>Condition</th>
<th>Percentage</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Osteoarthritis</td>
<td>58.4%</td>
<td>Jones, Nguyen et al. 1995, Fletcher and Hirdes 2002, Tiedemann, Sherrington et al. 2005</td>
</tr>
</tbody>
</table>

### Depression (currently treated)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Percentage</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Depression</td>
<td>9.9%</td>
<td>Tiedemann, Sherrington et al. 2005</td>
</tr>
</tbody>
</table>

### Problems with continence

<table>
<thead>
<tr>
<th>Condition</th>
<th>Percentage</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Problems with continence</td>
<td>21.8%</td>
<td>Graafmans, Ooms et al. 1996, Tiedemann, Sherrington et al. 2005</td>
</tr>
</tbody>
</table>

### Use of an assistive device (walking aid)

<table>
<thead>
<tr>
<th>Condition</th>
<th>Percentage</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use of an assistive device</td>
<td>15.8%</td>
<td>Tiedemann, Sherrington et al. 2005, Muir, Berg et al. 2010</td>
</tr>
</tbody>
</table>

### Osteoporosis

<table>
<thead>
<tr>
<th>Condition</th>
<th>Percentage</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Osteoporosis</td>
<td>14.9%</td>
<td>Fletcher and Hirdes 2002, Gill-Body et al. 2003, Hartvigsen, Frederiksen et al. 2005</td>
</tr>
</tbody>
</table>

### Neck pain present

<table>
<thead>
<tr>
<th>Condition</th>
<th>Percentage</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neck pain present</td>
<td>38.6%</td>
<td>Hartvigsen, Frederiksen et al. 2005</td>
</tr>
</tbody>
</table>

### Neck Disability Index – Mean (n=39)

<table>
<thead>
<tr>
<th>Index</th>
<th>Percentage</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neck Disability Index</td>
<td>18.8% (SD 15.2)</td>
<td>-</td>
</tr>
<tr>
<td>Neck Disability Index – Median</td>
<td>16%</td>
<td>-</td>
</tr>
<tr>
<td>Neck Disability Index – Range</td>
<td>2-62%</td>
<td>-</td>
</tr>
</tbody>
</table>

### Back pain present

<table>
<thead>
<tr>
<th>Condition</th>
<th>Percentage</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Back pain present</td>
<td>54% (53.5)</td>
<td>Hartvigsen, Frederiksen et al. 2005</td>
</tr>
</tbody>
</table>

### Oswestry Low Back Pain Disability Questionnaire – Mean (n=54)

<table>
<thead>
<tr>
<th>OsWestry Low Back Pain Disability</th>
<th>Percentage</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oswestry Low Back Pain Disability</td>
<td>22.4% (SD 16.1)</td>
<td>-</td>
</tr>
</tbody>
</table>

### Oswestry Low Back Pain Disability Questionnaire - Median

<table>
<thead>
<tr>
<th>OsWestry Low Back Pain Disability</th>
<th>Percentage</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oswestry Low Back Pain Disability</td>
<td>18%</td>
<td>-</td>
</tr>
</tbody>
</table>

### Oswestry Low Back Pain Disability Questionnaire - Range

<table>
<thead>
<tr>
<th>OsWestry Low Back Pain Disability</th>
<th>Percentage</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oswestry Low Back Pain Disability</td>
<td>0-66%</td>
<td>-</td>
</tr>
</tbody>
</table>

### 4.3.3. Balance, balance confidence and postural sway

Results from the Berg Balance Scale, Activities-specific Balance Confidence Scale, and CAPs eyes closed on a perturbed surface posturographic test are presented in Table 4:3. In general, participants performed well on the Berg Balance Scale (mean = 51.9) and on
average they rated their balance confidence as being high (87.3%) on the Activities-specific Balance Confidence Scale. The CAPs eyes closed on a perturbed surface posturographic test revealed that when participants were challenged to rely mostly on their vestibular system to maintain balance they struggled. Almost 60% of participants were either unable to complete the test (included in the profound category), or they exhibited postural sway that was deemed to be severely or profoundly impaired (Figure 4.2).

Figure 4:2 - CAPs Eyes Closed on a Perturbed Surface Stability Level of Older Chiropractic Patients
Table 4:3 - Balance, Balance Confidence, and Postural Sway of Older Chiropractic Patients with Results of Comparable Studies of Normal Community Dwelling Older People

<table>
<thead>
<tr>
<th>Test</th>
<th>Chiropractic Patients</th>
<th>Comparable Samples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Berg Balance Scale - Mean (out of 56)</td>
<td>51.9</td>
<td>46.5-54.1 ([Hatch, Gill-Body et al. 2003, Herman, Inbar-Borovsky et al. 2009, Muir, Berg et al. 2010])</td>
</tr>
<tr>
<td>Berg Balance Scale – Median (out of 56)</td>
<td>55</td>
<td>-</td>
</tr>
<tr>
<td>Berg Balance Scale – Range (put of 56)</td>
<td>22-56</td>
<td>-</td>
</tr>
<tr>
<td>Berg Balance Scale - Score of less than 45</td>
<td>10.9% (n=11)</td>
<td>18-32% ([Hatch, Gill-Body et al. 2003, Muir, Berg et al. 2008])</td>
</tr>
<tr>
<td>Activities-specific Balance Confidence Scale – Mean</td>
<td>87.3%</td>
<td>79-92% ([Hatch, Gill-Body et al. 2003, Herman, Inbar-Borovsky et al. 2009])</td>
</tr>
<tr>
<td>Activities-specific Balance Confidence Scale – Median</td>
<td>93%</td>
<td>-</td>
</tr>
<tr>
<td>Activities-specific Balance Confidence Scale – Range</td>
<td>36-100%</td>
<td>-</td>
</tr>
<tr>
<td>Activities-specific Balance Confidence Scale – Score of less than 85%</td>
<td>25.7% (n=26)</td>
<td>-</td>
</tr>
<tr>
<td>Poor Postural Sway (Severe or profound CAPs stability level when standing with eyes closed on a foam cushion)</td>
<td>59.4% (n=60)</td>
<td>61.7%* ([Agrawal, Carey et al. 2009])</td>
</tr>
</tbody>
</table>

* This comparison study used the eyes closed on a perturbed surface posturographic test but did not use the CAPs system. A pass/fail system was used based on whether or not participants could complete the test while remaining stable.

4.3.4. Health-related quality of life

Health-related quality of life domains and summary scores of the participants generally compared favourably with average scores from the Australian Bureau of Statistics 1995 National Health Survey (Tucker, Adams et al. 2010). The mean physical component summary of chiropractic patients was 44.4 (SD 10.9) and the mean mental component summary of chiropractic patients was 54.0 (SD 8.2). These results are summarised in Table 4:4.
Table 4:4 - Health-related Quality of Life of Older Chiropractic Patients with Results of Comparable Studies of Normal Community Dwelling Older People

<table>
<thead>
<tr>
<th>SF-36 Entire Chiropractic Sample (n=101)</th>
<th>Chiropractic Sample Score</th>
<th>Comparable Sample</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>(SD)</td>
</tr>
<tr>
<td>Physical Functioning</td>
<td>72.9</td>
<td>(26.2)</td>
</tr>
<tr>
<td>Role Physical</td>
<td>74.1</td>
<td>(36.0)</td>
</tr>
<tr>
<td>Bodily Pain</td>
<td>63.5</td>
<td>(23.8)</td>
</tr>
<tr>
<td>General Health</td>
<td>74.1</td>
<td>(20.3)</td>
</tr>
<tr>
<td>Vitality</td>
<td>61.2</td>
<td>(20.9)</td>
</tr>
<tr>
<td>Social Functioning</td>
<td>89.5</td>
<td>(19.8)</td>
</tr>
<tr>
<td>Role Emotional</td>
<td>86.6</td>
<td>(28.9)</td>
</tr>
<tr>
<td>Mental Health</td>
<td>81.0</td>
<td>(13.4)</td>
</tr>
<tr>
<td>Physical Component Summary</td>
<td>44.4</td>
<td>(10.9)</td>
</tr>
<tr>
<td>Mental Component Summary</td>
<td>54.0</td>
<td>(8.2)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SF-36 Chiropractic Patients Aged 70+ (n=55)*</th>
<th>Chiropractic Sample Score</th>
<th>Comparable Sample (n=488)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean</td>
<td>(SD)</td>
</tr>
<tr>
<td>Physical Functioning</td>
<td>70.3</td>
<td>(26.4)</td>
</tr>
<tr>
<td>Role Physical</td>
<td>73.2</td>
<td>(38.5)</td>
</tr>
<tr>
<td>Bodily Pain</td>
<td>62.6</td>
<td>(23.6)</td>
</tr>
<tr>
<td>General Health</td>
<td>75.6</td>
<td>(19.9)</td>
</tr>
<tr>
<td>Vitality</td>
<td>59.6</td>
<td>(21.6)</td>
</tr>
<tr>
<td>Social Functioning</td>
<td>88.3</td>
<td>(22.7)</td>
</tr>
<tr>
<td>Role Emotional</td>
<td>85.1</td>
<td>(30.5)</td>
</tr>
<tr>
<td>Mental Health</td>
<td>82.7</td>
<td>(14.1)</td>
</tr>
<tr>
<td>Physical Component Summary</td>
<td>43.63</td>
<td>(10.6)</td>
</tr>
<tr>
<td>Mental Component Summary</td>
<td>54.33</td>
<td>(8.9)</td>
</tr>
</tbody>
</table>

*Chiropractic patients aged 70 and over were analysed separately in order to make more appropriate comparisons with the Australian Bureau of Statistics 1995 National Health Survey.

Figure 4:3 compares the quality of life of participants who reported a fall during the last 12 months with those that had not fallen. The SF-36 Physical Component Summary of the fallers (mean = 41.4; SD 11.4) was significantly less than the non-fallers (mean = 46.0; SD 10.3) (p=0.04). The SF-36 Mental Component Summary was also slightly less for the fallers (mean = 52.6; SD 9.4) compared to the non-fallers (mean = 54.8; SD 7.4), but the difference was not statistically significant (p=0.2).
Figure 4:3 - SF-36 Physical and Mental Component Summary Scores of Older Chiropractic Patients that have Fallen Compared to those that have not Fallen

* The SF-36 Physical Component Summary score of the fallers was significantly less than the non-fallers ($p=0.04$).

4.3.5. Neck and back pain

Neck pain was present in 38.6% of participants (n=39), with the majority (72%, n=28) of those considered to have a minimal disability due to neck pain. Back pain was present in 53.5% of participants (n=54), with most considered to have either a minimal (54%, n=29) or moderate (31%, n=17) disability due to back pain.
4.3.6. Medication use

Medication use is summarised in Table 4:5. Of the medications linked to an increased falls risk, the most common ones to be taken in this sample were type 1 antiarrhythmics (13.9%), diuretics (11.9%), and antidepressants (9.9%).

Table 4:5 - Medication Use of Older Chiropractic Patients

<table>
<thead>
<tr>
<th>Number of Medications</th>
<th>n</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>18</td>
<td>17.8</td>
</tr>
<tr>
<td>1</td>
<td>11</td>
<td>10.9</td>
</tr>
<tr>
<td>2</td>
<td>18</td>
<td>17.8</td>
</tr>
<tr>
<td>3</td>
<td>12</td>
<td>11.9</td>
</tr>
<tr>
<td>4+</td>
<td>42</td>
<td>41.6</td>
</tr>
<tr>
<td>Mean</td>
<td>3.2</td>
<td>(SD 2.9)</td>
</tr>
<tr>
<td>Median</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Range</td>
<td>0-20</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Categories of Medication Taken</th>
<th>n</th>
<th>(%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sedatives</td>
<td>3</td>
<td>3.0</td>
</tr>
<tr>
<td>Antidepressants</td>
<td>10</td>
<td>9.9</td>
</tr>
<tr>
<td>Neuroleptics</td>
<td>9</td>
<td>8.9</td>
</tr>
<tr>
<td>Centrally acting analgesics</td>
<td>3</td>
<td>3.0</td>
</tr>
<tr>
<td>Digoxin</td>
<td>2</td>
<td>2.0</td>
</tr>
<tr>
<td>Diuretics</td>
<td>12</td>
<td>11.9</td>
</tr>
<tr>
<td>Type 1 antiarrhythmics</td>
<td>14</td>
<td>13.9</td>
</tr>
<tr>
<td>Vestibular suppressants</td>
<td>2</td>
<td>2.0</td>
</tr>
<tr>
<td>Any psychotropic medication</td>
<td>21</td>
<td>20.8</td>
</tr>
</tbody>
</table>

4.4. Discussion

The older chiropractic patients sampled in this study displayed significant falls risk factors and they were as likely to have experienced a fall in the previous 12 months as the general older population. It is important to note that 90% of participants had been under chiropractic care for at least 12 months. This suggests that chiropractors should regularly assess their older patients for falls risk factors, even when they have been under long term care, as many of the falls risk factors identified are modifiable, and the risk of falling may be reduced if appropriate recommendations are made and followed (American Geriatrics Society 2001, Rao 2005, Rubenstein and Josephson 2006).

One of the most important risk factors for falling is having a history of falls (OR 3.0) (American Geriatrics Society 2001). In this study 35% of the older chiropractic patients
had suffered from at least one fall in the previous 12 months. This is consistent with the expected rate of falls within the general older population, as approximately one third of community dwelling older adults suffer from at least one fall each year (American Geriatrics Society 2001, Gill, Taylor et al. 2005). In the current study, of those participants that had experienced a fall, 80% reported that they had suffered from at least a minor injury, with 37% of fallers requiring medical attention for their falls related injury. Of the 35 patients who had fallen over the previous 12 months, 6% (n=2) suffered severe injuries. This rate of severe injury related to falling lies within the expected range of 5-10% reported in previous studies (Rubenstein and Josephson 2006). Chiropractors should be cognisant of the fact that their long-term older patients may have suffered a falls related injury between visits, which could potentially alter patient management strategies if the injury is a contraindication to chiropractic care.

Besides a history of falling, other falls risk factors assessed in this study included polypharmacy, use of psychotropic medications, presence of a balance disorder, use of assistive device, osteoarthritis, depression, and problems with continence (American Geriatrics Society 2001, Rao 2005, Rubenstein and Josephson 2006, Lord, Sherrington et al. 2007). The prevalence of these risk factors in the chiropractic patients sampled is listed in Table 4:2. Most of these prevalence rates are consistent with published data for community dwelling older adults (Jones, Nguyen et al. 1995, Graafmans, Ooms et al. 1996, American Geriatrics Society 2001, Fletcher and Hirdes 2002, Hill, Kerse et al. 2002, Byles, Heinze et al. 2003, Hatch, Gill-Body et al. 2003, Minassian, Drutz et al. 2003, Gill, Taylor et al. 2005, Tiedemann, Sherrington et al. 2005, Lord, Sherrington et al. 2007, Sturnieks, St George et al. 2008, Shumway-Cook, Ciol et al. 2009, Muir, Berg et al. 2010). When making comparisons with other published data it should be noted that population characteristics may have differed between studies, and the use of different classification systems for conditions such as osteoporosis or osteoarthritis, mean comparisons should be viewed with some caution.

The use of four or more medications, or any use of psychotropic medications, results in a significant increase in the risk of falling (Leipzig, Cumming et al. 1999, American Geriatrics Society 2001). Little is known about the medication use of older chiropractic patients. As users of complementary care they may be less inclined to utilise pharmacological treatments than the general older population (Sarnat, Winterstein et al. 2007). It is possible that this is the case, as the percentage of participants taking four or
more medications (41.6% vs. 53%) and the median number of medications used (3 vs. 4) appeared slightly lower than similar Australian samples, and the percentage of participants taking no medications (17.8% vs. 3.2-5.5%) appeared higher in the chiropractic sample (Byles, Heinze et al. 2003, Pit and Byles 2010). To accurately compare medication use between chiropractic patients and general community dwelling older people requires a study design that includes non-chiropractic patients and a random sampling frame, so again these comparisons need to be viewed with caution. It must be emphasised that almost half of the chiropractic patients in this sample were taking four or more medications, which increases their risk of falling or suffering from an adverse drug interaction (American Geriatrics Society 2001, Byles, Heinze et al. 2003).

In this study older chiropractic patients had a higher prevalence of neck pain (38.6%, n=39) compared with the general older population (20%) (Hartvigsen, Frederiksen et al. 2005). This is of potential concern to chiropractors due to the disturbances that may be caused in balance and sensorimotor control due to neck related disorders (Rubin, Woolley et al. 1995, McPartland, Brodeur et al. 1997, Michaelson, Michaelson et al. 2003, Schieppati, Nardone et al. 2003, Gosselin, Rassoulian et al. 2004, Lord, Sherrington et al. 2007, Boucher, Descarreaux et al. 2008, Poole, Treleaven et al. 2008). Considering the growing body of evidence that supports the role of chiropractic care in influencing sensorimotor function it would be of interest for future studies to investigate whether chiropractic care has a positive impact on sensorimotor function associated with postural control in older adults (Haavik and Murphy 2012).

Computerised posturographic testing revealed that 59.4% (n=60) of participants had severe to profound problems with maintaining their balance when required to stand with their eyes closed on a perturbing foam surface. This result is comparable to the general older population, and is of concern, as poor performance on this test has been shown to be related to a significant increase in falls, even when no history of dizziness exists (Agrawal, Carey et al. 2009). Most participants performed well on the Berg Balance Scale, with only 10.9% (n=11) of participants scoring below the suggested cut-off mark of 45, which corresponds to an increased risk of falling (Berg, Wood-Dauphinée et al. 1992). Just over one quarter (25.7%, n=26) of participants had an excessive fear of falling according to the Activities-specific Balance Confidence Scale. Excessive fear of falling can result in self-imposed activity restrictions, functional decline, depression,
feelings of helplessness, and social isolation (Rubenstein and Josephson 2006). Chiropractors should be mindful of the potential negative consequences of a fear of falling in their older patients and, if appropriate, suggest an intervention strategy that may help reduce the individual’s fear of falling such as an exercise programme or tai chi (Zijlstra, van Haastregt et al. 2007, Zijlstra, van Haastregt et al. 2009).

Health-related quality of life scores of participants compared favourably to age matched norms across most domains and summary scores in the SF-36 survey (Tucker, Adams et al. 2010). Chiropractic patients scored their ‘bodily pain’ lower than age matched norms and their ‘role limitation because of emotional problems’ as slightly lower also. All other domains and summary scores were higher than the population norms. This is in contrast to a previous study which reported that chiropractic patients scored lower than age/sex matched norms across the domains of the SF-36 (Coulter and Shekelle 2005). When comparing the health-related quality of life of fallers verses non-fallers, the fallers reported a significantly lower Physical Component Summary score. This is consistent with previous research that has suggested that falls have a negative impact on health-related quality of life (Michalowska, Fiszer et al. 2005, Stenhagen, Ekstrom et al. in press). However, the difference in Mental Component Summary score between the groups in the current study did not reach statistical significance.

Chiropractors could consider implementing assessment and outcome measures in their practices that are aimed at identifying and tracking fall risks in their older patients. Fall risks can be identified in a variety of ways, including structured interviews or questionnaires, home assessment, functional balance tests, and computerised posturographic analysis (Lord, Menz et al. 2003, Larson and Bergmann 2008). Many of the fall risk assessment procedures used in this study, and other assessment protocols that have been recommended for use in clinical practice, are time consuming and require trained assistants to complete (Lord, Menz et al. 2003, Lord, Sherrington et al. 2007). The usefulness of these tests in a chiropractic office setting may need to be explored in future studies.

When fall risks are identified, chiropractors could provide counsel or consider referring their patients for appropriate interventions. Recommendations for appropriate interventions have been published elsewhere and reviewed in Chapter two (American Geriatrics Society 2001, Rao 2005, Rubenstein and Josephson 2006, Larson and
Bergmann 2008). These recommendations may include medication review in the case of psychotropic drug use or polypharmacy, exercise interventions to improve muscle weakness or balance problems, vision assessment for uncorrected vision problems, vitamin D supplementation for those with low vitamin D levels or in residential care, or various multifactorial interventions when a variety of falls risk factors are present. The chiropractic profession has begun to produce falls prevention information specific to chiropractic practice, and fall prevention educational material is now available from chiropractic organisations (Larson and Bergmann 2008, Kline 2009, Kline, Gleberzon et al. 2009, Kline, Enix et al. 2010, The Canadian Chiropractic Association 2010, American Chiropractic Association 2013). Chiropractors should ensure that they are familiar with this information and consider utilising fall prevention strategies in their practices. Although most of the patients included in this study had been receiving chiropractic care for some time it is possible that their fall risk would reduce if appropriate interventions were recommended. Further research is required to better understand the role chiropractors may play in reducing fall risk in their older patients or whether they can play a role in an integrated falls prevention programme.

4.4.1. Limitations

Twelve chiropractic practices were selected from the 848 practices identified as being located in Auckland or Melbourne, using a convenience sampling frame (New Zealand Chiropractic Board 2008, Chiropractic Board of Australia 2010). The 12 practices selected may not accurately reflect chiropractic practices across the two cities or the region in general. This limits the generalisability of findings. Future prevalence studies involving chiropractic care should consider using a random sampling frame to select practices for inclusion. It should be noted that from the participating practices all active older chiropractic patients were invited to participate and the overwhelming response from patients was positive, with almost 92% of those contacted agreeing to take part in the study. This reduces the likelihood of non-response bias.

The sample size of 101 is small for a study that aims to estimate prevalence across chiropractic practices. If the prevalence of risk factors is low, then a small sample size will result in a standard error that is too large to make accurate prevalence estimates. To gain more generalisable estimates for prevalence of fall risk factors of older chiropractic patients a larger sample size and more rigorous sampling method should be used.
One of the exclusion criteria in this study was being unable to remain standing unassisted for one minute as these patients would have been unable to complete the included assessment procedures. Although only one patient was excluded based on this criterion in the present study, future prevalence studies should consider eliminating this criterion as it may result in errors in estimating falls risk prevalence.

Comparison statistics have been provided for many of the risk factors and other data collected in this study. As has already been mentioned, the design of this study does not allow for accurate comparisons to be made with norms for community dwelling older adults. Comparisons have been made to provide some context for readers and to stimulate further research if deemed to be appropriate.

Estimates of the prevalence of diseases such as osteoarthritis and osteoporosis vary based on the criteria for a diagnosis to be present, or the disease definition used. In this study participants were asked if they were aware that they had a variety of conditions, but strict disease definitions or diagnostic criteria were not used. This should be considered when interpreting the results of this study.

Three research assistants were involved in data collection during this study, which increases the risk of observer bias. Consensus training of research assistants took place, but no comparisons were made to test for inter-observer variability. Also it should be noted that the research assistants employed in this study were all chiropractic students, which may have resulted in a response bias due to participants potentially aiming to please the research assistant who was assessing them.

The design of this study does not allow inferences to be made about the role that chiropractic care plays in reducing fall risk factors, or the effect it may have on health-related quality of life, or the other outcomes evaluated in this study. Participants in this study may not have been representative of the wider community when they initiated chiropractic care. An experimental design is required to test hypotheses that investigate the effect of chiropractic care on these risk factors and other outcomes.

4.5. Conclusions

The older chiropractic patients sampled in this study had, in general, been under long term chiropractic care, yet they displayed significant falls risk factors, and they were as
likely to have experienced a fall in the past 12 months as the general older population. Chiropractors, as primary care practitioners focusing on spinal health, general wellness, and illness prevention, are ideally placed to identify risks and ultimately intervene with patients at risk of falling. They should be aware that their older patients are at risk of falling despite the length of time they have been receiving chiropractic care. Further research is required to establish whether chiropractors can play a positive role in reducing falls risk in their older patients.
CHAPTER 5. RELIABILITY AND VALIDITY OF OUTCOME MEASURES USED TO ASSESS SENSORIMOTOR FUNCTION

5.1. Introduction

Previous chapters of this thesis have identified gaps in the literature that relate to the potential effects of chiropractic care on aspects of sensorimotor function that are thought to contribute to an individual’s risk of falling. A randomised controlled trial was therefore planned that would assess this potential relationship. The falls risk factors that were planned to be assessed in the main trial were proprioception, postural stability, general sensorimotor function, and multisensory integration. These risk factors were selected because they are associated with aspects of sensory and/or motor function that have been linked to an increased risk of falling (Lord, Ward et al. 1994, Lord, Menz et al. 2003, Setti, Burke et al. 2011). To assess these risk factors, commercially available equipment was purchased, or equipment was custom-built based on the designs and specifications described in previous studies. These previous studies had assessed the equipment for reliability and/or validity (Girardi, Konrad et al. 2001, Lord and Fitzpatrick 2001, You 2005, Rosenthal, Shimojo et al. 2009, Schoene, Lord et al. 2011, Setti, Burke et al. 2011). In order to ensure that the devices that had been built for the present study were appropriate for use, reliability and validity testing was performed.

5.2. Objectives

The primary aim of this preliminary testing was to evaluate the test/retest reliability of the equipment that was planned to be used to assess sensorimotor function in the main trial. One piece of equipment, the joint position sense testing device, also had a notable modification compared to the original apparatus on which it was based. A second axis of rotation had been included in the design as opposed to the single axis of rotation in the original device. Therefore a second aim was to evaluate the concurrent validity of the joint position sense device against validated goniometer measures.
5.3. Methods

5.3.1. Study population and setting

This study was conducted in a laboratory at the New Zealand College of Chiropractic. Twenty-five adults were recruited by word of mouth from staff, students, and faculty of the Chiropractic College, as well as from their family, friends, and acquaintances. A sample size of 25 was selected based on an expected intraclass correlation coefficient of 0.8 and a 95% confidence interval that excluded 0.61, which was predefined as the lowest acceptable level of test-retest reliability based on the recommendations made by Shrout (1998). In order to expedite reliability testing it was decided that all adults over the age of 18 would be eligible to participate, but an attempt was made to recruit older adults where possible. A convenience sampling frame was used. Adults over the age of 18, who were able to stand unassisted for one minute and understand the study information and consent processes (Appendices 10 and 12), were eligible to participate. Reliability and validity testing took place during March, 2012.

5.3.2. Outcome measures assessed

5.3.2.1. Proprioception

Joint position sense error was used as the measure of proprioceptive accuracy. Joint position sense error was measured at the ankle using an active/active method based on previously published protocols (You, Saliba et al. 2009). The active/active method of assessing joint position sense involves the participant actively positioning their ankle at a target joint angle, then returning their foot to a neutral position, followed by actively attempting to match the previous target angle.

A custom-made Macroderma Proprioception Test Platform MTP-2 system (Macroderma, Inglewood, South Australia) (Figure 5:1) was built to assess joint position sense error. This system was based on the specifications of the SENSERite device that has been shown to be a valid and reliable apparatus for assessing joint position sense error in older adults (You 2005). The system consists of a swivelling polycarbonate and aluminium platform with two axes of rotation that can be used to measure the angle of the ankle joint in four
different planes. Participants stood with one foot on the swivelling platform and one foot on a stable base. They were then able to actively rotate the platform through the $x$ and $z$ axes of rotation in order to place their ankle into plantar/dorsiflexion or inversion/eversion. Continuous goniometric measurements of ankle angle were collected based on the angle of the platform. The platform was able to swivel through 75° of rotation in the $x$ axis and 45° in the $z$ axis. Two potentiometers were used so the angle of rotation around each axis could be measured. Each potentiometer had a recording capability of 0.01°. The output generated by the potentiometers was processed and digitised (Power 1401 Interface and Signal 4:09 Software, Cambridge Electronics Design, Cambridge England) into a laptop computer.

Figure 5:1 - Macroderma Proprioception Test Platform MTP-2 System Used to Test Joint Position Sense

The main difference between the Macroderma system and the SENSERite device was that the Macroderma system had two axes of rotation instead of one, which meant that participants did not need to be repositioned between trials. This was felt to be important in
order to enhance participant safety and also to reduce the time associated with the assessment, which helped to prevent participant fatigue.

The assessment protocol involved the participant standing on the apparatus with their right foot on the swivelling platform and their left foot on a stable platform. Participants held on to a handrail that was securely attached to the wall and were asked to fix their eyes on a point in front of them to reduce visual feedback from the ankle. Participants started in a neutral ankle position and were then asked to select a specific target ankle joint angle that was within their comfortable functional range. When they had reached the appropriate target angle the assessor placed a marker on the trace that was being recorded on the computer and instructed the participant to hold the target angle for three seconds. Participants were unable to see the trace on the computer screen during testing. They were then instructed to return their ankle to the neutral position, before being asked to reproduce or match the target position. When the participant felt that they had matched the target angle another marker was placed on the trace and the participant was asked to hold the angle for three seconds before returning back to neutral.

The target ankle joint angles that were included were; 10° for inversion, 5° for eversion, 20° for plantar flexion, and 15° for dorsiflexion (Figure 5:2). In the main trial of this thesis it was planned to randomly present each of the four target angles five times, in a random sequence, resulting in a total of 20 trials in each assessment period. Prior feasibility testing had suggested that completing the full joint position sense assessment schedule twice in a relatively short space of time may result in fatigue. Therefore reliability testing involved a total of 10 trials in each assessment period with each of the target angles randomly presented either two or three times. At the start of the assessment, participants were given between four and eight practice trials in order to familiarise themselves with the apparatus and testing procedure. When they felt confident that they understood the procedure the assessment began. Each trial lasted 25 seconds, unless the practice session suggested the participant would struggle to complete each trial within this time frame. If that was the case, a longer frame configuration was used that allowed 35 seconds for each trial.
Computation of ankle joint position sense error was obtained using the average absolute constant error between the target and actual angle across all 10 trials. Absolute constant error is the overall deviation from target and matched angle with no consideration of the direction of deviation. The values for the target and matched angle were based on a two second continuous recording average that was taken immediately following the marks that had been placed on the recording trace.

5.3.2.2. General sensorimotor function

General sensorimotor function was assessed using choice stepping reaction time as the outcome measure. The choice stepping reaction time device used in this study was a custom-built Macroderma Reaction Platform MP-3 device (Macroderma, Inglewood, South Australia) (Figure 5:3). This device was based on similar instruments used in a number of previous studies (Lord and Fitzpatrick 2001, Sturniols, St. George et al. 2008, Zheng, Delbaere et al. 2012). These instruments have been shown to be reliable and valid at identifying those at increased risk of falling amongst older adults (Lord and Fitzpatrick
The choice stepping reaction time device consisted of a low, wooden, black platform that measured 80cm x 80cm x 3cm high. At rest, participants stood on yellow, non-slip footmarks, that were adhered 17 cm apart, to the rear, midline area of the platform. Embedded in the platform were four rectangular panels (32cm x 13 cm) that were back illuminated with LED lights. Two panels were located in front of the participant, one directly in front of each foot, and one panel was located directly lateral to each of the participants feet. One panel per trial was illuminated and the participants were instructed to place their full foot on the lit panel as quickly as possible (Figure 5:3). The left foot only was to be placed on the panels located on the left hand side of the platform, and the right foot only could be placed on the right hand panels. Participants were provided with flat soled shoes to wear when completing the choice stepping reaction time assessment if their footwear was considered to be unsuitable for completing the assessment.

Figure 5:3 - Choice Stepping Reaction Time Device in the Laboratory Setting

After five to 10 practice trials, each individual undertook 20 trials, with five trials per panel. Panels were illuminated in a random order to eliminate anticipatory movements. Choice stepping reaction time was measured as the time period in milliseconds between
the panel being illuminated and when the participant’s foot was placed on the panel. The
time that the foot was placed on the panel was assessed using a light sensor in each panel
that recorded when the foot covered the light sensor. There was no requirement to hold the
foot placement for any set length of time. The average time taken during the 20 trials was
used in the analysis. Following each trial the foot was returned to the resting position in
preparation for the next trial.

Data were recorded on the same laptop computer using the same data acquisition system
used for assessing joint position sense. The system was designed to record foot placement
to within one millisecond accuracy.

5.3.2.3. Postural stability

A computerised balance platform (CAPs Lite Computerised Posturography System by
Vestibular Technologies, Cheyanne, Wyoming, USA) was used to measure postural
stability. Computerised posturography provides a measure of vertical force and the centre
of pressure of an individual while quietly standing on a firm or perturbing foam cushion
(to reduce proprioceptive information) with their eyes either open or closed. By standing
on a foam cushion, the individual is obliged to rely more heavily on the vestibular system
to maintain balance. When standing on the firm surface proprioception associated with
peripheral joint position sense and cutaneous sensation is able to play a larger role in
maintaining postural stability. Computerised posturography has been shown to be a
sensitive tool to identify individuals at risk of falling (Buatois, Gueguen et al. 2006,
Matinolli, Korpelainen et al. 2007, Pajala, Era et al. 2008). In this reliability study the
participants were assessed using an ‘eyes closed on an unstable foam surface’ testing
condition. The effectiveness of the CAPs protocol has been validated by several studies
that have demonstrated it is a sensitive test for identifying patients who have fallen (Amin,
et al. 2002).

The CAPs provides several numerical results based on the statistical analysis of the centre
of pressure, which is also shown on a graph as the path of the participant’s sway, together
with the 95% confidence ellipse (used in all calculations), and the concentric circles indicating the thresholds between the various stability levels. These results are:

- **Theoretical limit of stability,**
- **Maximum sway** the participant exhibited during the test,
- **Predominant direction of sway,** in degrees, as the direction in which the participant swayed the most, with 0° being the medio-lateral direction, and 90° being the sagittal or anterior-posterior direction;
- **Directionality of the participant’s sway,** indicating the significance of the predominant direction of sway: 0% means the predominant direction of sway is actually not significant, since the ellipse is a circle. On the other hand, 100% means the ellipse is a line along which the participant swayed. The values in between 0% and 100% give the relative importance of the direction of sway;
- **Stability score,** calculated by comparing the amount of the participant’s sway throughout the duration of the test to the theoretical limit of stability. It indicates the participant’s ability to maintain balance during the test;
- **Stability level,** calculated by comparing the participant’s results with age and gender matched normative data and then categorised as either normal, mildly, moderately, severely, or profoundly reduced stability;
- **Fatigue and adaptation ratios,** calculated by comparing the participant’s sway in the first and second half of the test. Fatigue occurs if the sway increases during the test, adaptation if it decreases. The numerical value is the % of increase or decrease.

The CAPs ‘eyes closed on an unstable foam surface’ assessment involves the participant standing on a 10 centimetre thick foam cushion that is placed on the balance platform. The participant stands quietly with their feet together and their eyes closed for 20 seconds. The key value from this test that was analysed in the reliability trial was the ‘stability score’, which has been shown to be the most repeatable CAPs posturographic measure (Pagnacco, Oggero et al. 2008).
5.3.2.4. Multisensory integration

Multisensory integration was evaluated using a sound-induced flash illusion following a protocol described by Setti, Burke et al. (2011). As previously mentioned, susceptibility to the sound-induced flash illusion appears to be related to an individual’s ability to combine multisensory input into a single percept (Stevenson, Zemtsov et al. 2012). The illusion is robust and resilient to change (Shams, Kamitani et al. 2002, Rosenthal, Shimojo et al. 2009), with older adults who have had a previous fall being more susceptible to the illusion than younger adults and older adults who had not fallen (Setti, Burke et al. 2011).

Stimuli and apparatus

The apparatus for assessing the sound-induced flash illusion was a custom built Macroderma Sound-Induced Flash Illusion System designed to have the same specifications as the apparatus described by Setti, Burke et al. (2011) (Macroderma, Inglewood, South Australia) (Figure 5:4). A white, disc shaped, visual stimulus with a luminance of 108.86 candela/metre$^2$ and subtending a visual angle of 1.5° was presented against a black background (Figure 5:5). A constantly lit dim blue light was used as a fixation point 5° above the visual stimulus. The visual stimulus was flashed for 12ms either as a single stimulus or with a 190ms stimulus onset asymmetry. Speakers were positioned either side of the visual presentation apparatus and were used to present an auditory stimulus that consisted of a 10ms 3500 hertz beep at 79 decibels. The auditory stimulus was delivered in conjunction with the visual stimulus, with either a single beep presented simultaneously with the first visual stimulus, or two beeps, with the second beep presented simultaneously with the second visual stimulus. The stimulus onset asymmetry of 190ms was selected because it has been shown to differentiate between older adults with a history of falling from those with no history of falling, while remaining challenging to healthy younger adults (Setti, Burke et al. 2011). The experiment was conducted using the same laptop computer and data acquisition system described above, with audio and visual stimuli generated by a Power1401 data acquisition system (Cambridge Electronics Design, Cambridge England).
Procedure
Participants were seated with their chin resting 57cm in front of the Macroderma apparatus. They were asked to maintain visual fixation throughout the trial on the blue fixation light that remained on during the assessment. Participants were informed that they would be presented with brief flashes and beeps and they were asked to report whether they saw one or two flashes when they were presented. They were instructed not to report the number of beeps, but to respond solely based on the number of flashes. Five different combinations of flashes and beeps were possible. Four of these combinations were non-illusion control states and included:

- 1 flash with no beeps
- 1 flash with 1 beep
- 2 flashes with no beeps
- 2 flashes with 2 beeps

The illusory state consisted of one flash being presented with two beeps. Each combination was presented 10 times, at random, within a block of 50 trials, with each trial lasting three seconds. Two trial blocks were presented during each stage of the reliability testing, resulting in 100 stimulus presentations, with 20 of those being illusory combinations. During the main trial it was planned to use four trial blocks during each assessment, but this full testing procedure is fairly time consuming, taking up to 25 minutes to complete. It was therefore decided to only use two trial blocks during reliability testing in order to reduce the chance of fatigue and the time burden for participants. An assessor (blind to group allocation), who was aware of which state was being presented, manually recorded whether the response was correct or incorrect. The outcome that was recorded and used for statistical analysis was the percentage of illusory presentations that were correctly reported.

Prior to the first trial block, participants were allowed a training period that continued until the participant was comfortable with the task and ready to proceed with the assessment.

Figure 5:5 - Sound-Induced Flash Illusion Apparatus During Trial Conditions
5.3.3. **Assessment of reliability**

Test-retest reliability was assessed for each of the primary outcome measures. The initial assessment was completed on each device using the protocols described above. Following the initial assessment, the participants were given a short break of approximately five to 10 minutes before the same assessment protocol was repeated. The two assessments were then analysed and compared to each other in order to assess test-retest reliability.

5.3.4. **Assessment of validity**

The joint position sense device used in the main trial was modified slightly compared to the original device upon which it was based (You 2005). In the Macroderma device built for the main trial a second potentiometer was added to give the device a second axis of rotation. This enabled assessment of all four ankle joint angles without repositioning the patient. This was felt to be important in order to reduce the time associated with the assessment, and therefore the chance of fatigue, and also to enhance participant safety. It was decided that due to this design modification it would be appropriate to assess the concurrent validity of the joint position sense device.

Concurrent validity was assessed by comparing the angular position of the foot plate measured by the potentiometers against a manual goniometer, as well as a previously validated computerised accelerometer-based goniometer (iPhone 4, Apple Inc., Cupertino, CA) (Ockendon and Gilbert 2012). Concurrent angular positions were measured using all three systems in twenty different randomly chosen angles for each of the four ankle motions that were tested (dorsiflexion, plantarflexion, inversion and eversion). The goniometric measurements were obtained in a manner that was blind to the potentiometer measurements. The potentiometer measurements were then compared to the two goniometric measurements in order to assess concurrent validity of the joint position sense device.

**Analysis of reliability and validity trial**

Analysis of reliability and validity was performed using IBM SPSS Statistics Version 21.0.0.0 software (IBM Corp, Armonk, New York, USA). To assess test-retest reliability of the primary outcome measures intraclass correlation coefficients were calculated using
two way mixed models, with consistency as the type and single measurements. Spearman’s correlation coefficients were also calculated to account for the non-parametric nature of some of the data. Scatter plots were also created to visually assess the data. To assess the construct validity of the joint position sense device Pearson’s correlation coefficients were calculated. Bland-Altman plots of the joint position sense potentiometer scores and goniometer scores were presented as an alternative measure of validity.

5.4. Results

5.4.1. Participants

Twenty-five volunteers were screened for eligibility to participate in the reliability trial. All 25 were eligible to participate and were enrolled in the trial in March, 2012. Twelve were female and the average age was 44.3 years (SD 21.0, Range 22-79 years). Seven participants were over the age of 65.

5.4.2. Reliability

Test-retest reliability was moderate to substantial for all primary outcome measures. Intraclass correlation coefficients ($r = 0.79$ to $0.98$) and Spearman’s correlation coefficients ($r = 0.71$ to $0.97$) are presented in Table 5:1. Normality tests and visual inspection of the data revealed that the sound-induced flash illusion and CAP’s data violated normality assumptions, and the joint position sense and choice stepping reaction time data were barely normal. Spearman’s correlation coefficients are presented in addition to intraclass correlation coefficients due to the non-parametric distribution of these data. Post hoc log transformations were performed for the CAP’s, joint position sense, and choice stepping reaction time data to remove skewness and intraclass correlation coefficients were recalculated. Log-transformed Intraclass correlation coefficients were similar to the coefficients reported in
Table 5:1 and ranged from 0.76 to 0.97. Transformations were unable to be performed on sound-induced flash illusion data as there were a large number of perfect scores (n=18) for each trial.

Scatter plots of the data obtained in the test-retest reliability testing for each of the primary outcome measures are depicted in Figures Figure 5:6 to Figure 5:9. All intraclass correlation coefficients and Spearman’s correlation coefficients were moderate to substantial and above the minimum level of acceptable agreement (0.61) (Shrout 1998). Scatter plots revealed that results were generally close to the identity lines. The CAPs and sound-induced flash illusion scatter plots revealed that most results were clustered towards the higher score values, indicating a small number of poor performers may have influenced the correlation results. The trends seen on these plots do however support the test-retest reliability of these assessments.

<table>
<thead>
<tr>
<th>Outcome Measure</th>
<th>n</th>
<th>ICC</th>
<th>P value</th>
<th>Spearman’s correlation coefficients</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sound-induced flash illusion</td>
<td>25</td>
<td>0.98</td>
<td>&lt;0.01</td>
<td>0.82</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>CAPs (Postural stability)</td>
<td>25</td>
<td>0.86</td>
<td>&lt;0.01</td>
<td>0.77</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Joint position sense</td>
<td>25</td>
<td>0.79</td>
<td>&lt;0.01</td>
<td>0.71</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Choice stepping reaction time</td>
<td>25</td>
<td>0.97</td>
<td>&lt;0.01</td>
<td>0.97</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>

*ICC: Intraclass correlation coefficient.
Figure 5:6 - Scatter Plot of Sound-Induced Flash Illusion Test-Retest Results

Includes identity line. SIFI = sound-induced flash illusion.

Figure 5:7 - Scatter Plot of CAPs Test-Retest Results

Includes identity line. CAPs refers to postural stability testing using the eyes-closed on a foam surface test.
Figure 5:8 - Scatter Plot of Joint Position Sense Test-Retest Results

*Includes identity line. JPS = Joint position sense.*

Figure 5:9 - Scatter Plot of Choice Stepping Reaction Time Test-Retest Results

*Includes identity line. CSRT = Choice stepping reaction time*
5.4.3. Validity

Pearson’s correlation coefficients of the joint position sense potentiometer values compared to manual and computerised goniometer measurements are presented in Table 5:2. Pearson’s correlation coefficients are nearly perfect for comparisons made between both potentiometer and manual goniometer ($r = 0.994$ to 0.998) and potentiometer and computerised goniometer ($r = 0.996$ to 1.0).

Mean differences for paired estimates from the potentiometer and manual goniometer were small (0.20 degrees), as were the mean differences for the paired estimates between the potentiometer and computerised goniometer (0.18 degrees). Bland-Altman plots of these differences between potentiometer scores and goniometer scores revealed a narrow spread around the mean which also suggests that concurrent validity of the Macroderma Proprioception Test Platform MTP-2 system is acceptable (Figure 5:10 and Figure 5:11).

<table>
<thead>
<tr>
<th>Potentiometer value</th>
<th>$n$</th>
<th>Manual goniometer</th>
<th>$P$ value</th>
<th>Computerised goniometer</th>
<th>$P$ value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inversion</td>
<td>20</td>
<td>0.997</td>
<td>&lt;0.01</td>
<td>1.000</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Eversion</td>
<td>20</td>
<td>0.998</td>
<td>&lt;0.01</td>
<td>1.000</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Dorsiflexion</td>
<td>20</td>
<td>0.995</td>
<td>&lt;0.01</td>
<td>0.996</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Plantarflexion</td>
<td>20</td>
<td>0.994</td>
<td>&lt;0.01</td>
<td>1.000</td>
<td>&lt;0.01</td>
</tr>
<tr>
<td>Combined Angles</td>
<td>80</td>
<td>0.998</td>
<td>&lt;0.01</td>
<td>1.000</td>
<td>&lt;0.01</td>
</tr>
</tbody>
</table>
Figure 5:10 - Bland-Altman Plot of Combined Potentiometer Values and Manual Goniometer Values for Platform Angle

Figure 5:11 - Bland-Altman Plot of Combined Potentiometer Values and Computerised Goniometer Values for Platform Angle
5.5. Discussion of reliability and validity testing

5.5.1.1. Key findings

The equipment used in this trial demonstrated moderate to substantial test-retest reliability and substantial concurrent validity when compared with reference standards of manual and computerised goniometer measurements (Shrout 1998). All reliability measures exceeded the pre-defined acceptable minimum value of $r = 0.61$, which is considered to be the lower end of the moderate range according to revised terminology for the description of reliability ranges proposed by Shrout (1998). These findings supported the use of these devices to assess outcomes in the main trial.

5.5.1.2. Strengths and limitations of the study

This study assessed same day test-retest reliability of sound-induced flash illusion, CAPs postural stability, joint position sense, and choice stepping reaction time. It also assessed the concurrent validity of joint position sense compared to goniometer measures. The results were all acceptable, which suggests that the results observed in the main trial were more likely to be due to changes in participant performance as opposed to variability caused by equipment error.

Test-retest reliability was carried out on the same day in this study, which meant it is not possible to make conclusions about the consistency of these outcome measures over time. This study could not detect whether these outcome measures are consistent over a 24 hour period for example, which means clinically insignificant fluctuations in participant performance cannot be ruled out.

In order to expedite reliability testing, all adults over the age of 18 were eligible to participate in this study. It is possible that the reliability of some of the outcome measures varied depending on age. It should be noted that a considerable number of participants (n=18) scored 100% on both sound-induced flash illusion tests. This is inconsistent with results seen in older adults (Setti, Burke et al. 2011) and meant that the small number of participants who were susceptible to the illusion in the reliability test played a large role in determining the correlation coefficients that were reported. If more older adults were
included in the reliability testing, it is likely that a fairer indication of sound-induced flash illusion test-retest reliability would be obtained. The CAPs testing was also influenced by a small number of people who failed the testing procedure. If this study involved only older adults, a larger number of participants would have been expected to be unable to complete the testing procedures than the numbers observed in this study which may have influenced the reliability results (Agrawal, Carey et al. 2009).

Validity testing of joint position sense measures was consistent with goniometric measurements; however this says nothing about the predictive validity of the joint position sense measure with respect to future falls in older adults. Predictive validity of this joint position sense evaluation system is still unclear with respect to falling, but it has previously been demonstrated to be a useful and sensitive measure to assess proprioceptive changes related to ageing (You 2005). Until further validity testing of this joint position sense measure is performed, this limits the generalisability of findings with respect to fall risk.

There is little consensus between researchers about the level of test-retest reliability that is considered acceptable (Shrout 1998, Karanicolas, Bhandari et al. 2009). Instead, it has been proposed that acceptable levels of reliability are context specific and are dependent on the raters, subjects, instrument administration and study setting (Karanicolas, Bhandari et al. 2009). This becomes problematic when deciding on acceptable levels of reliability for a project such as this. Landis and Koch (1977) proposed adjectives to describe ranges of reliability for categorical data (0-0.20 = Slight, 0.21-0.4=fair, 0.41-0.60 = moderate, 0.61-0.80 = substantial, 0.81-1.0 = almost perfect) that are often quoted in the literature (Shrout 1998). Shrout (1998) described these labels as being overly generous and revised them in a way that shifts the label to the next level. Although this study used the revised version of moderate reliability as the lowest acceptable level of reliability, it is not clear whether this is appropriate or not based on the context of the study.

5.5.1.3. Relevance to previous research

The findings of this study are similar to those reported elsewhere in the literature (Girardi, Konrad et al. 2001, Lord and Fitzpatrick 2001, You 2005, Rosenthal, Shimojo et al. 2009,
Schoene, Lord et al. 2011, Setti, Burke et al. 2011). The reliability of joint position sense measurements were slightly lower \((r = 0.71-0.79)\) than previously reported values \((r = 0.88-0.99)\) (You 2005), but they still fell well within the acceptable range (Shrout 1998). Joint position sense validity testing revealed near perfect correlation with goniometer measures \((r = 0.996-1.0)\), which was very consistent with previous research \((r = 1.0)\) (You 2005). The outcome measures appear to demonstrate adequate test-retest reliability and validity based on recommendations from the literature (Shrout 1998, Karanicolas, Bhandari et al. 2009).

### 5.5.1.4. Implications and recommendations for future research

The findings of this study supported the use of these devices to measure outcomes in the main trial. The current study did not address test-retest reliability beyond a same day evaluation in a diverse group of adults. To be more comfortable generalising the results of the main trial to older adults, future research should focus on a longer time frame between assessments and include participants with the same inclusion/exclusion criteria as the main trial.

Only concurrent validity of joint position sense was assessed in the validity component of this trial. There is support in the literature for the criterion-related validity of the outcomes that were assessed to detect sensorimotor changes associated with age. However, there is still some doubt about the relationship between assessment scores of some of the instruments and fall risk (Girardi, Konrad et al. 2001, Lord and Fitzpatrick 2001, You 2005, Buatois, Gueguen et al. 2006, Setti, Burke et al. 2011). Future research should further investigate this relationship with fall risk.

### 5.6. Conclusion

Reliability and validity testing demonstrated moderate to substantial test-retest reliability and substantial concurrent validity of the assessed equipment. This supported the use of the assessed devices to measure outcomes in the main trial. Further reliability and validity testing that could involve a longer duration between reliability assessments, only older
adult participants, and assessments of predictive validity, would have enhanced the support for the use of these outcome measures in the main trial.
CHAPTER 6. RANDOMISED CONTROLLED TRIAL OF THE EFFECTIVENESS OF CHIROPRACTIC CARE IN IMPROVING SENSORIMOTOR FUNCTION ASSOCIATED WITH FALLS RISK IN OLDER PEOPLE

6.1. Introduction

This chapter presents the main study of this thesis, the randomised controlled trial that assessed the effect of chiropractic care on sensorimotor function associated with falls risk in older people. This study was conducted after identifying gaps in the literature that relate to the potential effects of chiropractic care on aspects of sensorimotor function that are thought to contribute to an individual’s risk of falling. It was identified that there is a growing body of evidence that suggests chiropractic care may result in improvements in sensorimotor function (Haavik and Murphy 2012), and therefore may have a positive impact on fall risk. The systematic review presented in Chapter three suggested that this potential relationship requires further investigation, which was the rationale for completing this main study. Outcome measures used in this study were discussed in detail in Chapter two, Section 2.6. These primary outcome measures included choice stepping reaction time, joint position sense, postural stability, and the sound-induced flash illusion. These outcome measures assess falls risk factors associated with sensorimotor function and multisensory integration. The reliability and validity of primary outcome measures were evaluated in the study presented in Chapter five and were found to be appropriate for use in the main study. The main study also investigated the effect of chiropractic care on health-related quality of life using the SF-36 Health Survey (Ware 2000). This secondary outcome was included in order to gain a greater understanding of the potential effects of the chiropractic intervention.

6.2. Objectives and hypotheses

The primary objective of this randomised controlled trial was to determine whether chiropractic care was effective in improving sensorimotor function that is related to fall risk in community-dwelling older adults over a 12 week period.
The secondary objective was to determine whether chiropractic care was effective in improving health-related quality of life in community-dwelling older people over a 12 week period.

The study hypotheses associated with these objectives were that:

- 12 weeks of chiropractic care will improve sensorimotor function that is related to fall risk compared with a usual care control in community-dwelling older adults.
- 12 weeks of chiropractic care will improve health-related quality of life compared with a usual care control in community-dwelling older adults.

### 6.3. Methods

#### 6.3.1. Trial design

This was a single-blind, parallel-group, randomised controlled trial that investigated the effect of 12 weeks of chiropractic care on objective neurophysiological markers of sensorimotor function that relate to fall risk in community dwelling older adults living in New Zealand. A pragmatic clinical trial approach was chosen as the nature of the intervention that was evaluated precludes blinding of participants or practitioners (Rosner 2012). A balance between external and internal validity was attempted by following the recommendations of Godwin, Ruhland et al. (2003). External validity was maximised by limiting the number of exclusion criteria, inviting a wide range of chiropractors to deliver the intervention, and by allowing flexibility in the management decisions of chiropractors providing the intervention according to their usual chiropractic care. Internal validity was maximised by decreasing assessment bias by concealing group allocation until after baseline assessment, and blinding outcomes assessors to participant group allocation. The study design embraced a whole systems research approach as recommended by Hawk, Khorsan et al. (2007). This included following a ‘usual practice’ intervention approach, including a ‘real-life’ standard care comparison group, and recording health-related quality of life in order to provide more multifactorial information on the effects of chiropractic care.
The background literature review was conducted, and the study protocol developed, from mid-2008 until data collection commenced in May 2012. During this time, three grant applications were submitted and awarded to help fund the study. The study protocol was refined as outcome assessment equipment was tested and assessed for feasibility, reliability, and validity. Description of the study setting, participants, sample-size calculations, protocol, outcome measures, interventions, data analysis, and external consultation are described below.

6.3.2. Study setting and population

The study was based at the University of Auckland in New Zealand. The study procedures took place at the New Zealand College of Chiropractic located in Auckland, New Zealand, and at chiropractic practices located throughout Auckland, from May 2012 to June 2013. Auckland is the largest city in New Zealand with a population of approximately 1.5 million people spread throughout the 4,894 km² of the Auckland region (Figure 6:1).

Chiropractic care was provided by 12 private chiropractic practices located throughout Auckland. This made up 10% of the 120 practices in the Auckland region listed in the Yellow Pages (Yellow Pages Group 2013). These practices were located in the suburbs of Mount Eden, Orakei, Ponsonby, Glenfield, Hobsonville, Pakuranga, Glen Eden, Howick, Remuera, Grey Lynn, and Takanini, and the town of Pukekohe. Eligibility assessments were performed by the principal investigator in the homes of potential participants throughout Auckland. Chiropractors and participants involved in this study were recruited through word of mouth using a convenience sampling frame.
Eligible participants were all community dwelling adults aged 65 years or older, living in Auckland, New Zealand, who could understand the study information and consent process (Appendices 11 and 13), and wanted to receive chiropractic care. Volunteers were ineligible if they were wheel-chair bound, unable to remain standing unassisted for a minimum of one minute (as they would have been unable to complete the required assessment procedures), or if they were considered to be at risk of suffering an adverse event due to chiropractic care. The list of absolute contraindications to chiropractic care that were used as exclusion criteria was developed based on safety recommendations by consensus panels (Globe, Morris et al. 2008, Farabaugh, Dehen et al. 2010) and included the following contraindications:

- An anomaly of the spine such as dens hypoplasia, unstable os odontoideum
- An acute fracture of the spine
- An acute infection of the spine
- Spinal cord tumour
- Cancer of the spine
• Frank disc herniation
• Basilar invagination of the cervical spine
• Arnold-Chiari malformation
• Dislocation of the spine
• Cauda equina syndrome
• Unstable bleeding disorder
• At high risk of vertebrobasilar insufficiency
• A severe mental or physical disease (e.g. Alzheimer’s Disease, Schizophrenia, terminal cancer, severe cognitive impairment)

Volunteers were also ineligible if they had received spinal manipulation within the previous six months, or upon chiropractic examination there was no evidence of a problem in their spine that a chiropractor may be able to address. Eligibility and risk assessment were evaluated by the principal investigator using a screening questionnaire (Appendix 14).

6.3.4. Interventions

6.3.4.1. Chiropractic Group

Participants were randomised to 12 weeks of chiropractic care or to a usual care ‘control’. Participants who were assigned to the chiropractic group were encouraged to initiate care with their assigned chiropractor as soon as possible following allocation of intervention.

Chiropractic care was provided by 12 chiropractic practices from across Auckland in their usual practice setting. Chiropractors were recruited to provide care in the trial based on their proximity to participants who had enrolled in the trial. Some chiropractors also volunteered to assist with the trial, in which case they helped to recruit participants through their practices and were asked to provide care to new trial participants who resided near their practices. Chiropractors were asked to treat study participants like any other patient presenting to their practice, apart from providing care at no charge.

Chiropractors were not limited to any particular type of care, so chiropractors were able to tailor the care they provided to the participant’s individual clinical needs. This enabled
chiropractors to modify the type and frequency of care throughout the trial, which reflects normal chiropractic clinical practice. This meant that the nature of chiropractic care that was provided varied between participants within the intervention group. Following the participant’s final assessment, their treating chiropractor was asked for a description and frequency of care so a summary of interventions used in the trial could be presented.

Chiropractic care in this trial involved the on-going provision of care, whether a subjective complaint was present or not, with the intention of correcting spinal dysfunction, which is termed vertebral subluxation by chiropractors (Haavik Taylor, Holt et al. 2010, Henderson 2012). Clinical indicators of vertebral subluxation, such as palpable restricted intersegmental range of motion and tenderness to palpation of the joint, can be used to guide the chiropractic clinical decision making process, as opposed to areas of pain or symptoms (Owens 2002, Cooperstein, Haneline et al. 2010, Henderson 2012). When applied in this fashion, the goal of chiropractic care is to enhance health as opposed to treating a specific subjective complaint (de Souza and Ebrall 2008). In this trial, all patients were examined and treated using procedures that are customarily used in chiropractic practice, and that conform to best practice guidelines and the scope of chiropractic practice specified by the New Zealand Chiropractic Board with respect to appropriate management of older chiropractic patients (Gleberzon 2001, Bougie 2005, New Zealand Chiropractic Board 2007, Hawk, Schneider et al. 2010). When these guidelines are followed, chiropractic care for older patients is considered to be safe and effective and associated with high levels of patient satisfaction (Gleberzon 2001, American Chiropractic Association 2004, Killinger 2004).

In general, chiropractic visits lasted from ten to thirty minutes and involved the chiropractor taking a subjective report, before assessing the participant, and providing chiropractic care based on the findings present and care plan recommendations. Chiropractors were asked to inform the principal investigator if any serious adverse events occurred while the participant was under their care.

Chiropractic procedures that were used predominantly consisted of:

1. High velocity, low amplitude spinal and extremity adjustments with direct manual contact, typically resulting in joint cavitation (Evans 2002)
2. Table assisted chiropractic adjustments that involve direct manual contact of the spine and a segmental drop table to enhance the motion force imparted towards the segment or area to be adjusted (Homack 2005).


These procedures fall into a number of named proprietary technique packages that can be used on their own or in an eclectic approach. These named technique packages include Diversified Technique, Gonstead Chiropractic Technique, Activator Methods Chiropractic Technique, Thompson Technique, and Torque Release Technique (Cooperstein and Gleberzon 2004). Chiropractors were also able to include rehabilitative exercises, stretching, and other non-adjustive treatments that are routinely used in chiropractic practice (Coulter and Shekelle 2005, Holt, Kelly et al. 2009).

The researchers chose to leave the decisions regarding the approach to care up to the individual chiropractors, as in the past, chiropractic researchers have been criticised for designing interventions in randomised controlled trials that do not reflect usual chiropractic practice (Hawk, Khorsan et al. 2007). It is thought that this prescriptive approach to trial interventions limits the generalisability of results from chiropractic trials when considered from a whole systems research point of view (Hawk, Khorsan et al. 2007, Rosner 2012).

6.3.4.2. Control group

It was decided not to use a placebo treatment as considerable challenges exist with providing appropriate sham procedures for chiropractic care (Hancock, Maher et al. 2006, Rosner 2012). Therefore participants assigned to the control group continued with any usual health care they required, or wished to engage in, during the course of the study. They were however asked not to see a chiropractor during the time that they were being assessed, but it was reinforced that it was their choice if they did choose to seek chiropractic care. Upon the completion of the study, participants in the control group were offered the same chiropractic care programme undertaken by the participants in the
intervention group. They were also asked if they had visited a chiropractor during the course of the study to assess for contamination of intervention.

An inactive control was chosen due to the inherent difficulties associated with blinding participants to group allocation when a manual therapy intervention is being evaluated (Rosner 2012). It has been suggested that if the aim of a trial is to investigate the overall effectiveness in clinical practice of spinal manipulative therapy then a non-treatment group should be employed (Hancock, Maher et al. 2006, Hawk, Khorsan et al. 2007). It should be acknowledged that this approach limits the ability of researchers to differentiate the effect of spinal manipulative therapy from placebo (Hancock, Maher et al. 2006). This approach was adopted as the trial focused on investigating the effectiveness of chiropractic care for improving sensorimotor function, as opposed to the efficacy of spinal manipulative therapy for the treatment of a specific disease or condition, or falls prevention per se.

6.3.5. Trial outcomes

The primary objective of this study was to determine whether 12 weeks of chiropractic care was effective in improving aspects of sensorimotor function that are related to fall risk in community-dwelling older adults. The primary outcomes that were selected as measures of sensorimotor function were joint positions sense, choice stepping reaction time, postural stability, and multisensory processing. The protocol for assessing primary outcomes was presented in detail in Chapter five, Section 5.3.2 in the methods section of the reliability and validity trial. Variations to the protocol used in the reliability trial are discussed in the following sections.

The secondary objective of the study was to determine whether chiropractic care was effective in improving health-related quality of life in community-dwelling older people over a 12 week period. The secondary outcome that was selected as a measure of health-related quality of life was the SF-36 version 2.0 short-form health survey (QualityMetric Inc, Lincoln, Rhode Island, USA).
All outcomes were measured at baseline, four weeks, and 12 weeks (at the completion of the intervention programme). All assessments were conducted in a laboratory at the New Zealand College of Chiropractic, located in Auckland, New Zealand.

6.3.5.1. Proprioception

Joint position sense error was used as the measure of proprioceptive accuracy. Joint position sense error was measured using the equipment and protocol described in Section 5.3.2.1, with one exception. During the joint position sense assessment in the main study each of the four target angles was presented five times for a total of 20 trials, as opposed to the 10 trials used in each stage of the reliability testing. However, feasibility testing indicated that some participants would feel fatigued if they completed the joint position sense assessment in one go, so they were offered an optional short break after the first 10 sessions before completing the assessment. The target angles were presented in a random sequence, in order to reduce potential biasing effects. This resulted in a total of 20 trials in each assessment period. At the start of each assessment, participants were given between four and eight practice trials in order to familiarise themselves with the apparatus and testing procedure. Computation of ankle joint position sense error was obtained using the average absolute constant error method described in the reliability study. The difference in average absolute constant error between the target and actual angle across all 20 trials was used as the primary outcome measure.

6.3.5.2. Choice stepping reaction time

Choice stepping reaction time was assessed using the same protocol described in Section 5.3.2.2. During each assessment, participants were allowed five to 10 practice trials in order to familiarise themselves with the equipment before completing 20 assessment trials. The average choice stepping reaction time taken during the 20 trials was used in the analysis.

6.3.5.3. Postural stability

Postural stability was assessed using the equipment and protocol described in Section 5.3.2.3. The variation to the protocol used was that three extra aspects of postural stability were tested at each assessment. The complete assessment protocol used in this study was
the modified Clinical Test of Sensory Interaction on Balance (mCTSIB). This assessment protocol is used to ‘filter’ sensory input (Pagnacco, Oggero et al. 2008).

The mCTSIB is a computerised analysis of the patient’s functional balance control and postural sway during four sensory conditions which are:

- Eyes open on a firm surface
- Eyes closed on a firm surface
- Eyes open on an unstable surface (foam)
- Eyes closed on an unstable surface (foam)

The mCTSIB is commonly used in clinical practice to identify patients whose balance is abnormal, and to monitor the effect of interventions (Pagnacco, Oggero et al. 2008). The effectiveness of the CAPs mCTSIB protocol has been validated by several studies that have demonstrated it is a sensitive test for identifying patients who have fallen (Amin, Krishna et al. 2001, Girardi, Konrad et al. 2001, Amin, Girardi et al. 2002, Girardi, Amin et al. 2002).

The CAPs mCTSIB provides the same numerical results based on the statistical analysis of the centre of pressure that were described in Section 5.3.2.3. The CAPs mCTSIB involves the participant standing either directly on the firm computerised balance platform surface, or on a 10 centimetre thick foam cushion that can be placed on the balance platform. The participant stands quietly with their feet together and their eyes either open or closed, depending on the stage of testing, for 20 seconds. The key value from this test that was planned to be analysed as the primary outcome measure of postural stability in this study was the ‘stability score’ from the ‘eyes closed on an unstable surface’ testing condition. The extra testing conditions were also assessed so they could be included in sensitivity analyses. Postural stability assessments that were included in the cross-sectional and reliability studies indicated that a large percentage of participants may struggle to complete the challenging ‘eyes closed on an unstable surface’ assessment. This would potentially have an impact on the statistical analysis of this outcome measure, meaning sensitivity analyses may have been required to be more confident about the results reported for this outcome measure.
6.3.5.4. Multisensory integration

Multisensory integration was evaluated using the sound-induced flash illusion protocol described in Section 5.3.2.4. The exception being that in the main study each participant completed four blocks of 50 trials during each assessment, instead of two. This resulted in 200 stimulus presentations, with 40 of those being illusory combinations. The outcome that was recorded and used for statistical analysis was the percentage of illusory presentations that were correctly reported. Prior to the first trial block of each assessment, participants were allowed a training period that continued until the participant was comfortable with the task and ready to proceed with the assessment. Participants were allowed a break between each of the four trial blocks in order to reduce the effect of fatigue on performance of the task.

6.3.5.5. Secondary outcome – Health-related quality of life

The secondary outcome in this study was health-related quality of life, which was measured using the New Zealand version of the SF-36 version 2.0 short-form health survey (QualityMetric Inc, Lincoln, Rhode Island, USA). The SF-36 is the most widely used survey that measures functional health and health-related quality of life, and has been used extensively in general population surveys and clinical trials (Ware 2000, Ferguson, Robinson et al. 2002, Farivar, Cunningham et al. 2007). The SF-36 has been shown to be a reliable and valid questionnaire for use in older populations and it also correlates with performance based measures in community dwelling older adults (Lyons, Perry et al. 1994, Sherman and Reuben 1998). The survey was self-completed by participants at baseline, and at the four week and 12 week assessments, as per the primary outcome measures. Assistance to complete the survey was provided by a blinded assessor if required.

The SF-36 instrument and scoring method was described in Sections 2.6.5 and 4.2.4.5. The outcomes that were included for statistical analysis in this study were the Physical Component Summary and Mental Component Summary scores. These summary scores are used to reduce the number of statistical comparisons and therefore the role of chance in hypothesis testing (Ware, Kosinski et al. 1995). Summary scores are calculated by
standardising the results of each health domain based on population means, transforming
the standardised scores, and then multiplying the transformed scores using a factor
coefficient that reflects the contribution each domain of health is thought to make to either
physical or mental health. The scores are therefore based on population norms and are
calculated so the population summary scores have a mean of 50 and a standard deviation
of 10. Summary scores can therefore be easily interpreted, as a score of over 50 is
considered to be better than the population mean, and a score that is under 50 is worse
(Taft, Karlsson et al. 2001).

Traditionally, population norms and factor coefficients that are used are based on US
samples, but country specific values are becoming increasingly available and can be
substituted for the US values to reflect differences in health status between countries
(Frieling, Davis et al. 2013). These differences may be actual differences in health
outcomes, or they may relate to different perceptions of health and illness between
countries and cultures (Hawthorne, Osborne et al. 2007, Frieling, Davis et al. 2013). This
has led to a potential issue with the system used to calculate summary scores in the SF-36,
as floor and ceiling effects may influence survey results (Ware 2000, Hawthorne, Osborne
et al. 2007). Standardised scores are calculated based on population means and standard
deviations. If a population has higher mean scores than the U.S. population, the size of the
standard deviations are restricted due to ceiling effects, which may result in the
standardised scores of individuals with moderately poor health being so low that they
appear to be suffering from very poor health. This may then lead to overestimates of
treatment effects in pre-post studies due to small increases in scores of individuals with
moderately poor health (Hawthorne, Osborne et al. 2007).

Due to these issues some debate exists regarding the best method for calculating the
summary scores. In particular, whether local population norms should be substituted for
U.S. norms, if the norms should be broken down into age, gender, or disease specific
groups, if U.S. or country specific factor coefficients should be used, and whether the
traditional orthogonal method used to calculate factor coefficients should be replaced by
an oblique method (Jenkins 1999, Taft, Karlsson et al. 2001, Farivar, Cunningham et al.
2010). The most consistent recommendations for the calculation of summary scores is to
use local population norms and U.S. factor coefficients in order to allow for international comparisons (Jenkinson 1999, Ware 2000, Taft, Karlsson et al. 2001, Frieling, Davis et al. 2013). Due to the lack of consensus concerning the calculation of summary scores it has been recommended that component scores should also be presented in combination with sub-scale scores and interpreted with caution (Taft, Karlsson et al. 2001). This is therefore the approach that was taken in this trial to analyse and present the results of the SF-36 assessment. The summary scores were calculated using New Zealand population norms and U.S. factor coefficients (Frieling, Davis et al. 2013).

6.3.6. Sample size

Sample size calculations were performed using Stata version 12.0 (Stata Corporation, College Station, TX, USA). The trial was adequately powered to detect the estimated change in joint position sense, as statistically significant, as this was the only primary outcome measure that had data available relating to a chiropractic intervention on which to base power calculations (Haavik and Murphy 2011).

Calculations were made based on detecting a difference in a continuous response variable from independent control and experimental subjects with one control per experimental participant. In a previous study of joint position sense error, the response within each subject group had a standard deviation of 1.05 degrees for the absolute constant error with a mean improvement in the experimental group of 0.28 degrees (Haavik and Murphy 2011). This study investigated the effect of a single session of chiropractic care on elbow joint position sense error in 25 participants with subclinical neck pain (mean age 25.7 years) (Haavik and Murphy 2011). To detect a true difference in the experimental and control means of 0.25 degrees, it was calculated that we would need to study 20 experimental subjects and 20 control subjects to be able to reject the null hypothesis that the population means of the experimental and control groups were equal with probability (power) 0.8. The Type I error probability associated with this test of this null hypothesis was 0.05. To allow for attrition during the trial, and relative uncertainty about the expected effect sizes, we aimed to enrol a maximum of 60 participants in this trial.
6.3.7. Randomisation

Allocation of participants was carried out by an independent assistant, at a distant site, using a computer generated list of random numbers. The randomisation sequence was created using Microsoft Excel 2010 (Microsoft Corp., Redmond, WA) with a 1:1 allocation using random permuted block sizes of two, four, or six. The allocation list was prepared by the offsite assistant, who had no clinical involvement in the trial, and was stored on a password protected computer that was inaccessible to all personnel involved in the trial. Blocks were used to ensure equal assignment of participants to the intervention and control groups and to reduce bias that may have occurred if the health status of participants entering the trial varied throughout the recruitment period.

The allocation sequence was concealed from the principal investigator until after the participants baseline assessment had taken place, at which stage he contacted the offsite assistant and was informed of the participant’s group allocation.

6.3.8. Participant recruitment

Initially, participant recruitment took place through participating chiropractic practices, as well as a Facebook page set up by the principal investigator. As the study progressed, recruitment became largely through word of mouth through study participants and involved family, friends and co-workers of participants, as well as members of Lions Clubs, Rotary Clubs, Returned and Services' Associations and other organisations frequented by participants. A convenience sampling frame was used to recruit participants.

6.3.9. Participant enrolment

Volunteers who contacted the principal investigator were provided with a short summary of the study over the phone, and were asked if they were over 65 years of age and whether they had seen a chiropractor, or received spinal manipulation, during the previous six months. These questions were asked upon initial contact as these were the most likely reasons that a volunteer would fail to meet the inclusion/exclusion criteria for the trial. If their answers to these questions meant they were likely to be eligible to participate in the trial, a face to face eligibility assessment was scheduled. These assessments involved the principal investigator travelling to the participant’s home. The eligibility assessments took
approximately 30 minutes each and involved explaining the trial protocol to the volunteer, including what would be required of them, then if the volunteer was still interested in participating and they provided verbal consent, the principal investigator performed the eligibility and risk assessment that is included as Appendix 14. This assessment involved the volunteer answering verbal questions relating to the presence of exclusion criteria, presence of vertebrobasilar artery insufficiency (if neck pain or headache was present), and completing an Abbreviated Mental Test to assess cognitive status. This verbal interview was followed by a brief physical examination, to assess for spinal dysfunction that a chiropractor may address in practice, and functional tests were performed to further assess for vertebrobasilar artery insufficiency.

The brief chiropractic assessment was carried out to ensure that spinal dysfunction was present. For the purposes of this study, spinal dysfunction was defined as both palpable restricted intersegmental range of motion and tenderness to palpation of the joint. Although many of the techniques used by chiropractors and other manual therapists to evaluate the function of the spine have questionable inter-examiner reliability, these criteria were chosen because they are considered to be the most reliable available (Schneider, Erhard et al. 2008, Haneline, Cooperstein et al. 2009, Haneline and Young 2009, Cooperstein, Haneline et al. 2010).

If the volunteer was eligible to participate, and they were interested in enrolling in the study, written informed consent was obtained and a baseline assessment at the New Zealand College of Chiropractic was scheduled. The principal investigator arranged transport to the New Zealand College of Chiropractic if volunteers were unable to make their own way to the assessment. Volunteers who required transport to their assessment were picked up and dropped off by the research assistant who conducted the assessment. If transport was an issue for a volunteer, the principal investigator confirmed that they would be able to make their own way to a local chiropractor as the resources were not available to provide transport to study participants for their chiropractic visits.

6.3.9.1. Baseline assessment

Baseline assessments, and the subsequent four week and 12 week assessments, took place in a research laboratory at the New Zealand College of Chiropractic (Figure 6:2). The
baseline assessment began with a research assistant reminding the volunteer about the study protocol and briefly explaining what the baseline assessment would entail. Baseline demographic data were collected by the research assistant using a written questionnaire (Appendix 15). The assessment procedures were then carried out. The full assessment took approximately 45 minutes to complete. When the assessment was complete, the research assistant booked the participant in for their four week assessment and they were told that the principal investigator would contact them to inform them of their group allocation and arrange for them to see a chiropractor if necessary. The research assistants conducting all assessments remained blinded to group allocation throughout the trial.

Figure 6:2 - New Zealand College of Chiropractic Research Laboratory
6.3.9.2. Group allocation

Following the baseline assessment, the principal investigator was informed, via email, of the group allocation by an offsite assistant. If the participant was in the chiropractic group the principal investigator arranged with a local chiropractor for the provision of chiropractic care through the study period. The participant was then contacted and informed of their group allocation. If they were in the chiropractic group the principal investigator confirmed that the participant was happy to see the chiropractor who they had been assigned to and they were given the chiropractors contact details so they could arrange their first visit. If the participant preferred to see another chiropractor for any reason this was arranged whenever possible.

6.3.9.3. Four and 12 week assessments

The four and 12 week assessments began with the research assistant reminding the participant that they should not reveal their group allocation during the assessment visit. They then asked the participant about any serious adverse events that may have occurred since their baseline assessment. Although this question ran the risk of the participant revealing their group allocation if a treatment injury had occurred, it was felt that participant safety was paramount so the question was included during assessment visits. If any serious adverse events occurred this information was passed to the principal investigator so the Data and Safety Monitoring Committee could be informed.

Assessment procedures were then performed in the same manner as the baseline assessment. Following the week 12 assessment, participants were contacted by unblinded study personnel and asked follow-up questions about their time in the study (Appendix 15). These questions aimed to confirm whether any adverse events occurred during the study that the participant may not have mentioned to the research assistant, and also to assess for non-compliance or contamination. If the participant was in the control group they were also asked if they would like to take advantage of the free 12 weeks of chiropractic care that was available to them, and if so arrangements were made with a local chiropractor.
6.3.10. Participant flow

The overall participant flow throughout the trial is summarised in Figure 6:3. All participants were assessed at baseline, four weeks after group allocation, and at the final 12 week assessment. Participants allocated to the control group were offered 12 weeks of complimentary chiropractic care following their 12 week assessment, but no further assessments were made of these participants.

![Figure 6:3](image)

**Figure 6:3 - Flow of participants through the randomised trial to assess the effect of chiropractic care on sensorimotor function among older adults**

6.3.11. Blinding

Successful blinding of patients or practitioners in a trial involving a physical intervention such as chiropractic care is virtually impossible (Rosner 2012). This is due to the manual nature of the interventions and the challenges associated with providing appropriate sham
procedures (Hancock, Maher et al. 2006, Rosner 2012). Therefore patients and chiropractors allocated to the intervention group were aware of the allocated arm. The principal investigator and an administrative assistant were also aware of the allocated arm as they were responsible for organising patient care and managing participant flow throughout the trial. Outcomes assessors were kept blinded to the participant group allocation. The trial adhered to established procedures to maintain separation between outcomes assessors and chiropractors delivering care. No chiropractors involved in the delivery of care recorded outcome measurements. Blinding was maintained by emphasising to participants that they should not share information relating to their group allocation with outcomes assessors. All investigators not involved in participant assessments, staff, care providers, and participants, were kept masked to outcome measurements and trial results.

6.3.12. Statistical analysis

Descriptive statistics such as unadjusted means, standard deviations, and counts were used to describe the baseline characteristics of the two groups. Mixed models for repeated measures method were used to analyse the effect of chiropractic care on the change scores recorded at week four and week 12 of the continuous primary outcomes. These included joint position sense error, sound-induced flash illusion, and choice stepping reaction time. Baseline covariates were predefined based on previous studies that indicated they may influence the dependent variable that was being analysed. Fixed effects that were included in each model were:

- **Joint position sense error**: age, gender, baseline joint position sense error, intervention group, and the interaction effect of intervention group and time (four or 12 week assessments) (Nagai, Sell, Abt, & Lephart, 2012; You et al., 2009)
- **Sound-induced flash illusion**: age, gender, baseline sound-induced flash illusion error, history of a recent fall, intervention group, and the interaction effect of intervention group and time (Setti et al., 2011)
- **Choice stepping reaction time**: age, gender, baseline choice stepping reaction time error, history of a recent fall, stability score with eyes open on a compliant surface,
depression (assessed using a cut off of 52 on the mental health domain raw score (Silveira, Taft et al. 2005)) intervention group, and the interaction effect of intervention group and time (S. R. Lord & Fitzpatrick, 2001; Pijnappels et al., 2010).

Similar models were also constructed for the change scores of the secondary outcomes of physical and mental component summary scores of the SF-36 health survey, with age, gender, relevant baseline SF-36 summary score, history of a recent fall, intervention group, and the interaction effect of intervention group and time as the fixed effects (Frieling et al., 2013; Michalowska, Fiszer, Krygowska-Wajs, & Owczarek, 2005). Participant effect was included as a random effect and the within-subject errors were modelled using an unstructured (co)variance structure. The Kenward-Roger method was used to estimate the denominator degrees of freedom for fixed effects.

A very high number of individuals failed to complete the CAPs postural stability assessment which resulted in extremely skewed data that could not be appropriately transformed. Therefore instead of using stability scores as planned, CAP’s results were transformed into dichotomous outcomes based on whether or not the participant could complete the test or not. This dichotomous assessment has previously been described in the literature as a test of vestibular function (Agrawal, Carey, Della Santina, Schubert, & Minor, 2009). Dichotomous CAPs outcomes were then assessed using generalised linear mixed effects models with age, gender, history of falling, baseline CAPs outcome, intervention group, and the interaction effect of intervention group and time as the fixed effects (Buatois et al., 2006; Faraldo-Garcia et al., 2012; Krause et al., 2013). Participant effect was included as a random effect and the within-subject errors were modelled using an unstructured (co)variance structure. Binomial distribution with logit link function was used.

All analyses were performed according to the intention-to-treat principle where participants were analysed according to the group they were randomised to, regardless of receipt of intervention. All available data were used and no missing data imputation was performed. Drop-outs were included in the analysis with missing data points accounted for using the mixed models repeated measurements approach.
SAS v9.3 software (Cary, North Carolina, USA) was used to undertake statistical analyses. Two sided p-values less than 0.05 were used to determine statistical significance and all confidence intervals were given at a two-sided 95% level. No adjustments to p-values were planned or made based on a rationalist approach to the statistical analysis that has been recommended in the literature (Feise, 2002; Perneger, 1998; Rothman, 1990).

6.3.13. Sensitivity analyses

Sensitivity analyses were performed to test the robustness of the models used, and to gain a greater understanding of any uncertainty that may have been present in the results, as well as to help guide future trials. Sensitivity analyses that were planned involved:

- Testing for the effect of outliers on the significance of outcome measures.
- Altering pre-planned regression models to account for baseline differences in variables that were not selected as potential explanatory variables prior to data analysis.
- Investigating whether outcomes differed based on using regressor variable models as opposed to change score regression models. Regressor variable models use the raw four week and 12 week scores as dependent variables with the baseline score included in the model as a co-variable.
- Investigating whether using different approaches to calculating SF-36 summary scores influenced the results of the statistical tests.

6.3.14. Data quality, confidentiality, and security

Electronic data were entered, stored and backed-up in a secure manner on the New Zealand College of Chiropractic Research Server. Double data entry procedures by blinded assistants were used to increase data quality (Whitney, Lind et al. 1998). Essential written documents and records were retained in a locked filing cabinet in the offices of the Centre for Chiropractic Research at the New Zealand College of Chiropractic. Participant data were anonymised by ensuring all identifying material was kept separate from confidential study material. Consent forms and eligibility forms, which contain participant names, do not refer to the participants study ID, and were secured separate to participant
data. All documents will remain secured at the New Zealand College of Chiropractic (or with an approved archiver) for at least 10 years following trial closure.

6.3.15. Data and safety monitoring

A Data and Safety Monitoring Committee, comprised of the two study supervisors, was formed to oversee all aspects of data auditing, verify data validity and integrity, and to ensure the safety of participants throughout the trial. Information concerning the occurrence of serious adverse events and falls was sought at the four and 12 week assessments, as well as at each chiropractic visit if participants were in the chiropractic intervention group. Participants were also asked about serious adverse events during a follow-up interview at the conclusion of their involvement in the trial. Any serious adverse events that were identified were reported to the principal investigator who regularly updated the Data and Safety Monitoring Committee concerning identified events. Information regarding serious adverse events was recorded whether they were felt to be associated with the study or not. The principal investigator also regularly updated the Data and Safety Monitoring Committee regarding the status of the trial, data auditing, and integrity.

Serious adverse events were defined as any untoward medical occurrence that (Ministry of Health 2012):

- Resulted in death;
- Was life-threatening (defined as an event in which the participant was at risk of death at the time of the event; it did not refer to an event which hypothetically might have caused death if it were more severe);
- Required in-patient hospitalisation or prolongation of existing hospitalisation;
- Resulted in persistent or significant disability or incapacity;
- Was a malignancy; or
- Any other event representing a significant hazard comparable to the criteria mentioned above (e.g. transient ischaemic attack, hypo, or hyperglycaemia).

A fall was defined as ‘an unexpected event in which the participant comes to rest on the ground, floor, or lower level.’ This definition has been widely adopted as the definition
used in falls related epidemiological research (Lamb, Jorstad-Stein et al. 2005, Hauer, Lamb et al. 2006)

Reporting of adverse events was planned to be restricted to serious adverse events. Potentially serious adverse events were followed to resolution or stabilisation and reported as serious adverse events if they become serious. Although it was not included in the study protocol, the principal investigator also kept the Data and Safety Monitoring Committee informed of any minor adverse events that were reported. The Data and Safety Monitoring Committee planned to notify the regulatory authorities of findings that could adversely affect the safety of subjects as per the ethics committee guidelines (Ministry of Health 2012).

6.3.16. Trial registration

The trial was registered with the Australian New Zealand Clinical Trials Registry. The trial ID was ACTRN12608000333314.

6.3.17. Ethics approval

Ethics approval was obtained from the New Zealand Northern Y Regional Ethics Committee (reference NTY/11/06063). Special consideration was given to the potential risk of harm associated with the provision of chiropractic care in this study. Chiropractic care may involve a variety of manual therapy procedures including manipulation or mobilisation which have a small risk of causing physical harm (Gouveia, Castanho et al. 2009). Adverse events associated with chiropractic care are generally transient and involve mild musculoskeletal soreness (Hurwitz, Morgenstern et al. 2004, Thiel, Bolton et al. 2007, Gouveia, Castanho et al. 2009). The risk of serious adverse events due to chiropractic care is low or very low (Thiel, Bolton et al. 2007, Gouveia, Castanho et al. 2009).

6.3.18. Consultation with Māori

During trial design, consultation took place with Dr Morehu McDonald, Māori Cultural Advisor to the New Zealand College of Chiropractic, to ensure that the trial protocol was appropriate to meet the cultural needs of Māori who may have participated in the study.
It was identified that little is known about the circumstances of falls amongst older Māori in the community, but falls in older adults have not been identified as an area of disparity for Māori. Following this consultation process it was decided that special reference would be made to whanau or kaumatua endorsement of inclusion in the trial. It was also decided that participants would be able to be accompanied by friends, family, and whanau during the trial if they wished. Dr McDonald was provided with the final trial protocol before submission for ethical approval. He then wrote a letter of support for the study that was submitted with the ethics application.

6.4. Results

6.4.1. Recruitment of chiropractors

The main trial was introduced to chiropractors in New Zealand, and in particular chiropractors from Auckland, during a presentation made by the principal investigator during the 2011 New Zealand College of Chiropractic Lyceum seminar. This event is the largest annual chiropractic event in New Zealand, and was attended by over 400 chiropractors, chiropractic students, and other stakeholders. Following this event, two Auckland-based chiropractors volunteered to assist with the study.

When participant recruitment was ready to begin in May of 2012, the principal investigator met with the volunteer chiropractors and explained the role they would be required to play in the study. Both volunteer chiropractors agreed to participate and assist with the study and help with participant recruitment. As participants joined the study from other areas around Auckland the principal investigator contacted the principal chiropractor at the most convenient chiropractic practice for the participant to attend and asked them if they would volunteer their time to assist with the study. If they agreed they were also asked if they would mind seeing more participants for the trial, and if they would assist with participant recruitment in the same manner as the original two volunteer chiropractors.

Throughout the trial, 13 additional chiropractic practices were approached and asked to assist in this way. All 13 agreed to help, resulting in a total of 15 chiropractic practices becoming involved in recruitment and the provision of care throughout the study. Of these
15 practices, three only provided care to participants who were assigned to the control group and were eligible to receive chiropractic care once their involvement in the study had finished.

Therefore 12 chiropractors provided care to participants in the chiropractic group. Chiropractors were eligible to be included in the study if they were registered with the New Zealand Chiropractic Board and they had a permanent practice, either part-time or full-time, in the Auckland region, and they were available to see new patients.

6.4.2. Recruitment of participants

Participant recruitment began in May, 2012 and was completed in March, 2013. Recruitment was stopped when the recruitment target of 60 participants had been met. Follow up continued until June, 2013, when the final participant had completed their 12 week assessment. Recruitment efforts were initially focussed on friends and family of active practice members of participating practices. An advertising flyer was produced for chiropractors to place in their practices and to distribute to their patients (Appendix 16). Since study participants were required to be naïve to chiropractic care for at least six months, the flyers asked if the patients knew of anyone who may be interested in participating in the study, and if they did, requested that they pass on the contact details of the principal investigator to the potential participant and suggest they make contact if they were interested in learning more about the study. The chiropractors then promoted the study by placing copies of the flyer in their offices, distributing them to patients visiting their practices, placing the flyer on their Facebook pages, and mentioning the study when talking to potential patients, and at business groups, and other networking activities.

Additional recruiting methods involved social media (Facebook), presentations to groups, either directly to older adult groups, or to other groups such as classes at the New Zealand College of Chiropractic. As the study progressed, recruitment became almost entirely from word of mouth through study participants, and involved family, friends and co-workers of participants, as well as members of Lions Clubs, Rotary Clubs, Returned and Services' Associations and other organisations frequented by participants.
6.4.3. Participant flow

Figure 6:4 shows the flow of participants through the trial. Sixty-five participants were screened for eligibility, with five being ineligible. Four volunteers did not meet the inclusion criteria. Three of these were due to receiving recent spinal manipulation, and one was under the age of 65. One volunteer declined to participate following a discussion with family members. Sixty participants were randomised to the control group (n=30) or chiropractic group (n=30). Fifty-six participants completed the study (n=26 in each group). The two participants that withdrew from the control group lost motivation to continue with the study, one following group allocation, and one after the four week assessment. One of the participants that withdrew from the chiropractic group was hospitalised due to health reasons unrelated to the intervention, and the other withdrew due to transient soreness that was experienced following chiropractic care.

6.4.4. Baseline characteristics

Baseline demographic information, falls history, and medical history are summarised in Table 6:1. Baseline values for primary and secondary outcome measures are included in Table 6:3. Baseline SF-36 domain scores are presented in Table 6:4. Randomisation resulted in similar groups. However, some group differences occurred in gender distribution, medication use, gait deficits, and vision impairments. Differences were also observed in baseline values of the SF-36 Mental Component Summary, some SF-36 domain scores, sound-induced flash illusion, and joint position sense values. Standard deviations were reasonably large for these variables, which may explain the baseline differences. Tests of baseline homogeneity were not performed as differences in outcome baseline measures and other prognostic baseline variables were taken into account using appropriate regression models (Senn 1994). To help guide future studies and to test the robustness of the results, additional baseline variables that exhibited group differences were incorporated into models included in the sensitivity analyses in case they had an unexpected influence on the outcomes.
Figure 6.4 - Consort diagram of the randomised trial to assess the effect of chiropractic care on sensorimotor function among older adults
### Table 6.1 - Demographic, Fall History and Medical History Baseline Characteristics of Study Participants

<table>
<thead>
<tr>
<th>Demographic Factors</th>
<th>Control (n=30)</th>
<th>Chiropractic (n=30)</th>
<th>Combined (n=60)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>72.7 (6.8)</td>
<td>71.7 (6.2)</td>
<td>72.2 (6.5)</td>
</tr>
<tr>
<td>Age, range</td>
<td>65-89</td>
<td>65-89</td>
<td>65-89</td>
</tr>
<tr>
<td>Female *</td>
<td>20 (66.7)</td>
<td>16 (53.3)</td>
<td>36 (60.0)</td>
</tr>
<tr>
<td>Living alone *</td>
<td>7 (23.3)</td>
<td>7 (23.3)</td>
<td>14 (23.3)</td>
</tr>
<tr>
<td>Fall History</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fall in previous year *</td>
<td>6 (20.0)</td>
<td>5 (16.7)</td>
<td>11 (18.3)</td>
</tr>
<tr>
<td>Recent recurrent falls *</td>
<td>0 (0)</td>
<td>1 (3.3)</td>
<td>1 (1.7)</td>
</tr>
<tr>
<td>Medication Use</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of medications #</td>
<td>3.2 (3.2)</td>
<td>2.4 (2.8)</td>
<td>2.8 (3.1)</td>
</tr>
<tr>
<td>Psychoactive medications #</td>
<td>4 (13.3)</td>
<td>3 (10.0)</td>
<td>7 (11.7)</td>
</tr>
<tr>
<td>Medical Conditions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Previous stroke *</td>
<td>2 (6.7)</td>
<td>1 (3.3)</td>
<td>3 (5.0)</td>
</tr>
<tr>
<td>Muscle weakness *</td>
<td>7 (23.3)</td>
<td>6 (20.0)</td>
<td>13 (21.7)</td>
</tr>
<tr>
<td>Poor balance *</td>
<td>9 (30.0)</td>
<td>10 (33.3)</td>
<td>19 (31.7)</td>
</tr>
<tr>
<td>Gait deficit *</td>
<td>5 (16.7)</td>
<td>10 (33.3)</td>
<td>15 (25.0)</td>
</tr>
<tr>
<td>Poor vision *</td>
<td>17 (56.7)</td>
<td>24 (80.0)</td>
<td>41 (68.3)</td>
</tr>
</tbody>
</table>

* n (%), # mean (SD)

### 6.4.5. Chiropractic care

Chiropractic care was provided to participants in the chiropractic group by 12 different chiropractic practices across Auckland. The practices saw between one and seven study participants each, and more than one chiropractor in each practice may have provided care to participants. The average number of visits to the chiropractor during the study period was 21.9 (SD 8.6) over the 12 weeks, with a range of 2 to 33. The type of care provided varied based on the chiropractors preferred technique approach and the participants case history and examination findings. Chiropractors were asked to summarise the nature of the care they provided by indicating which of the three types of care described in Section 6.3.4.1 they provided to each patient. The categories of care were high velocity, low amplitude spinal and extremity adjustments; table assisted chiropractic adjustments, and instrument assisted adjustments.

Table 6:2 summarises the care that was provided. Instrument and table assisted adjustments were each provided to 22 participants, either as the only form of care (n=8), or in combination with other approaches to care. High velocity, low amplitude approaches
were not used exclusively with any participants, but were used in combination with other approaches with five participants.

Table 6.2 - Type of Care that was Provided to Study Participants

<table>
<thead>
<tr>
<th>Type of Care</th>
<th>Number of Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>High velocity, low amplitude only</td>
<td>0</td>
</tr>
<tr>
<td>Table assisted only</td>
<td>8</td>
</tr>
<tr>
<td>Instrument assisted only</td>
<td>8</td>
</tr>
<tr>
<td>High velocity, low amplitude and table assisted</td>
<td>2</td>
</tr>
<tr>
<td>High velocity, low amplitude and instrument assisted</td>
<td>0</td>
</tr>
<tr>
<td>Table assisted and instrument assisted</td>
<td>9</td>
</tr>
<tr>
<td>All three approaches combined</td>
<td>3</td>
</tr>
</tbody>
</table>

6.4.6. Outcomes and estimation

The following sections describe the results observed for the primary and secondary outcome measures. The primary results of the mixed models for repeated measures analyses were tests for a group effect or a group by time interaction. A significant group effect meant that there was an overall effect of the chiropractic care on the outcome, compared to the control group, over the 12 week period, taking both the four and 12 week change scores into account. A significant group by time interaction meant that the change over time differed between the groups. With only two change scores assessed in the models this meant that between the four and 12 week assessments there was a between group difference in the change that occurred. When a significant overall group effect or group by time interaction occurred, the results have been reported to show whether between group differences also occurred at individual assessment time points. Table 6.3 – presents baseline scores, adjusted change scores, and the significance level of the group effect and group by time interaction for each of the primary and secondary outcomes assessed.
Table 6.3 – Sensorimotor and Quality of Life Outcome Results of Randomised Trial of Chiropractic Care versus Control over 12 weeks amongst Older Adults

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Intervention Group</th>
<th>Significance</th>
<th>Group Effect P value</th>
<th>Group by time interaction P value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Chiropractic</td>
<td>Control</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Base-line</td>
<td>4 wk change</td>
<td>12 wk change</td>
<td>Base-line</td>
</tr>
<tr>
<td>Joint Position Sense</td>
<td>1.90 (0.11)</td>
<td>-0.27 (0.08)</td>
<td>-0.27 (0.08)</td>
<td>1.76 (0.10)</td>
</tr>
<tr>
<td>(degrees) *</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CSRT (ms) *</td>
<td>1163 (36)</td>
<td>-23 (23)</td>
<td>-105 (33)</td>
<td>1178 (38)</td>
</tr>
<tr>
<td>CAPs, % pass #</td>
<td>46.7 (7.3)</td>
<td>60.0 (3.5)</td>
<td>64.3 (3.7)</td>
<td>46.7 (7.3)</td>
</tr>
<tr>
<td>SIFI % correct *</td>
<td>63.0 (7.3)</td>
<td>10.6 (3.5)</td>
<td>15.2 (3.7)</td>
<td>60.3 (7.3)</td>
</tr>
<tr>
<td>SF-36 PCS*</td>
<td>44.6 (1.4)</td>
<td>0.4 (1.1)</td>
<td>2.8 (1.0)</td>
<td>46.1 (1.6)</td>
</tr>
<tr>
<td>SF-36 MCS*</td>
<td>52.7 (1.7)</td>
<td>1.1 (1.2)</td>
<td>0.0 (1.7)</td>
<td>49.5 (1.5)</td>
</tr>
</tbody>
</table>

* mean (SE), # CAPs scores are unadjusted, CSRT = choice stepping reaction time, ms = milliseconds, CAPs = Comprehensive Assessment of Postural Systems postural stability assessment, SIFI = sound-induced flash illusion, PCS = Physical Component Summary, MCS = Mental Component Summary.

6.4.6.1. Proprioception

There was a significant group effect (p=0.045, mean difference 0.20°, 95% CI 0.01-0.39°) of chiropractic care on joint position sense error, with the chiropractic group showing greater improvement than the control group across the combined four and 12 week assessments. No group by time interaction was present (p=0.99), which suggests that joint position sense change scores remained consistent from the week four to the week 12 assessment. This is confirmed by Figure 6:5. When assessed individually, the between group differences at both the four and 12 week assessments were identical, but failed to reach significance (p=0.1, mean difference 0.20°, 95% CI -0.04 to 0.43).
All 60 participants were assessed for joint position sense error at baseline, one control group participant withdrew from the study after the baseline assessment, and one control group participant was unable to complete the four week joint position sense assessment due to ankle pain. Therefore, 28 control group and 30 chiropractic group participants completed the four week assessment. A further one control group participant and two chiropractic group participants withdrew from the study between the four and 12 week assessments, so 28 participants were assessed in each group at the 12 week assessment.

![Figure 6.5 - Change From Baseline in Joint Position Sense Error at 4 and 12 Week Assessments.](image)

*Figure 6.5 - Change From Baseline in Joint Position Sense Error at 4 and 12 Week Assessments.*

*Error bars represent 95% confidence intervals. The overall group effect of chiropractic care on joint position sense was significant (p=0.045). No significant between group differences occurred at individual time point assessments.*

6.4.6.2. Choice stepping reaction time

The group effect of chiropractic care for choice stepping reaction time failed to reach significance (p=0.07), but there was a significant (p=0.01) group by time interaction, with
the chiropractic group improving compared to the control group. Significant group differences occurred between the baseline and 12 week assessment (p=0.01, mean difference 118ms, 95% CI 24 to 212ms), and between the four week and 12 week assessment (p=0.01, mean difference 108ms, 95% CI 25 to 192ms). The difference in change scores at the four week assessment was not significant (p=0.8, mean difference 9ms, 95% CI -56 to 74ms). The chiropractic group improved more than the control group for both of these comparisons.

Figure 6:6 - Change From Baseline in Choice Stepping Reaction Time at 4 and 12 Week Assessments

Error bars represent 95% confidence interval. Change scores are measured in milliseconds. A negative change score represents an improvement in choice stepping reaction time. A significant (p=0.01) group by time interaction occurred, meaning there was a difference in change scores between the four and 12 week assessments. *A significant (p=0.01) between group difference was also present at the 12 week assessment.

Figure 6:6 clearly shows the relatively even results at the four week assessment followed by a large improvement in change score for the chiropractic group between the four and 12 week assessments. All participants remaining in the study completed the choice stepping reaction time task at each assessment.
6.4.6.3. Postural stability

A large number of participants (n=32, 53.3%) were unable to complete the eyes closed on a foam surface posturographic assessment at baseline. Failures to complete were evenly spread between groups (n=16, 53.3%, in each group). Normality assumptions were violated due to this large number of failed tests. Therefore, a binary pass/fail assessment procedure was used instead of the originally intended stability scores. Generalised linear mixed models (GLIMMIX) were fit using likelihood-based techniques to the postural stability outcomes in order to assess for change in the binary outcome. No significant group effect (p=0.90) or group by time interaction (p=0.91) were observed in the postural stability assessment. At the four week assessment 13 (44.83%) participants in the control group, and 12 (40.00%) in the chiropractic group failed to complete the assessment. At the 12 week assessment this reduced further to 11 (39.29%) in the control group and 10 (35.71%) in the chiropractic group (Figure 6:7). One control group participant was unable to complete the four week CAPs assessment due to ankle pain, therefore the number of participants completing each CAPs assessment was the same as those reported for the joint position sense task.

![Figure 6:7 - Percentage of Participants that Passed the CAPs Posturographic Assessment at Each Assessment](image)

To pass the test participants were required to remain standing on a perturbing foam cushion with their eyes closed for 20 seconds. No significant differences were observed between groups for the CAPs assessments.
6.4.6.4. Multisensory integration

There was a significant overall group effect (p=0.02, mean difference 11.3, 95% CI 1.7 to 20.9) of chiropractic care on susceptibility to the sound-induced flash illusion, with the chiropractic group showing greater improvement than the control group across the 12 week period. No group by time interaction was present (p=0.2). This indicates that the improvement in change score in the chiropractic group between the four and 12 week assessment was not significant (Figure 6:8). At the four week assessment the between group mean difference did not reach statistical significance (p=0.07, mean difference 9.1, 95% CI -0.9 to 19.1). The mean difference between groups was however significant at the 12 week assessment (p=0.01, mean difference 13.5, 95% CI 2.9 to 24.0). All participants remaining in the study completed the sound-induced flash illusion task at each assessment.

Figure 6:8 - Change From Baseline in Susceptibility to the Sound-Induced Flash Illusion at 4 and 12 Week Assessments

*Error bars represent 95% confidence intervals. Change scores represent the overall percentage improvement in illusory responses. The overall group effect of chiropractic care on the sound-induced flash illusion was significant (p=0.02). *A significant between group difference also occurred at the 12 week assessment (p=0.01).
6.4.6.5. Secondary outcomes: Health-related quality of life (SF-36)

No group effect was present for the SF-36 Physical Component Summary (p=0.5) or Mental Component Summary scores (p=0.6). No group by time interaction was present for the Mental Component Summary scores (p=0.9). However, a significant (p=0.04) group by time interaction was present for the Physical Component Summary scores. The group by time interaction was significant for the difference between groups from the four week to the 12 week assessment (p=0.047, 2.4, 95% CI 0.04 to 4.8), with the chiropractic group improving more than the control group. The difference between groups at the 12 week assessment failed to reach significance (p=0.09, 2.6, 95% CI -0.4 to 5.6). Component summary score changes are depicted in Figure 6:9 and Figure 6:10.

![Figure 6:9 - Change from Baseline in Health-related Quality of Life (SF-36) Physical Component Summary Scores at 4 and 12 Week Assessments.](image)

Error bars represent 95% confidence intervals. Change scores represent the change in norm based summary score from baseline to each assessment. The group by time interaction for the Physical Component Summary score was significant (p=0.04) with the chiropractic group improving compared to the control group. No significant between group effects were present at individual time points.
One control group participant withdrew from the study after the baseline assessment, and one chiropractic group participant failed to complete one page of the survey form which resulted in no Physical Component Summary score being able to be calculated at their four week assessment. Therefore 29 participants from each group completed the four week assessment for Physical Component Summary, with all 30 members of the chiropractic group, and 29 members of the control group completing the four week assessment for Mental Component Summary. A further one control group participant and two chiropractic group participants withdrew from the study between the four and 12 week assessments, and one more participant in the chiropractic group failed to complete enough of the survey at the 12 week assessment to generate a Physical Component Summary or Mental Component Summary score. Therefore 28 control group participants and 27 chiropractic group participants produced Physical Component Summary and Mental Component Summary scores at the 12 week assessment.

Figure 6:10 - Change from Baseline in Health-related Quality of Life (SF-36) Mental Component Summary Scores at 4 and 12 Week Assessments.

Error bars represent 95% confidence intervals. Change scores represent the change in norm based summary score from baseline to each assessment. No significant changes occurred in the Mental Component Summary scores.
Table 6:4 reports the changes observed in raw mean SF-36 domain scores. Due to the lack of consensus concerning the calculation of Physical Component Summary and Mental Component Summary scores, Taft, Karlsson et al. (2001) recommended that domain scores should be presented in conjunction with summary component scores in order to assist with their interpretation. Differences between groups were observed in baseline scores with the chiropractic group having notably higher scores in vitality (3.8) and mental health (4.3) domain scores. The most notable changes between assessments that are evident in the raw domain scores are an improvement in bodily pain in the chiropractic group of 5.7 between the baseline and 12 week assessment, compared to an improvement of 2.4 in the control group. Exploratory analyses of domain scores were not performed in an attempt to reduce the chance of producing spurious results.

Table 6:4 - Raw Mean Health-related Quality of Life (SF-36) Domain Scores (with SD’s) at Baseline and 4 and 12 Week Assessments

<table>
<thead>
<tr>
<th>SF-36 Domain</th>
<th>Chiropractic Group</th>
<th>Control Group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>Week 4</td>
</tr>
<tr>
<td>Physical functioning</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>47.4</td>
<td>47.0</td>
</tr>
<tr>
<td></td>
<td>(7.0)</td>
<td>(8.6)</td>
</tr>
<tr>
<td>Role physical</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>49.0</td>
<td>48.2</td>
</tr>
<tr>
<td></td>
<td>(8.1)</td>
<td>(8.4)</td>
</tr>
<tr>
<td>Bodily pain</td>
<td></td>
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6.4.7. Sensitivity analyses

The pre-planned sensitivity analyses described in Section 6.3.13 were performed, as well as additional analyses that were deemed to be necessary following a review of the trial outcomes. Additional sensitivity analyses centred on the postural stability testing, as the
statistical analyses of this outcome was altered due to the high number of participants unable to complete the CAPs assessment.

The CAPs data involved a large number of failed tests that were assigned a zero score. These data could not be transformed to approximate a normal distribution, so untransformed raw scores were used in an analysis of the stability score, as opposed to the binary pass/fail result that is described in the primary results. Other components of the modified Clinical Test of Sensor Integration in Balance (mCTSIB) protocol (eyes open on a firm surface, eyes closed on a firm surface, eyes open on an unstable foam) were also analysed as a part of the sensitivity analyses. All CAPs sensitivity analyses confirmed that differences between the intervention and control groups failed to reach statistical significance (p values from 0.2 to 0.95).

Baseline differences between groups were observed in variables that were not included as potential prognostic variables, such as medication use, gait deficits, vision impairments, and SF-36 Mental Component Summary scores. Sensitivity analyses were performed that included these factors as co-variables. Manipulating models to include baseline variables that were not originally included as prognostic variables did not significantly alter the results of the models for the sound-induced flash illusion (group effect p values 0.01 to 0.03). For choice stepping reaction time when alternate baseline co-variables were included the group by time interaction remained consistent with a p value of 0.01. The p value for the group effect also remained greater than 0.05 for all variations of the model apart from when vision impairment was added, which resulted in the group effect becoming significant (p=0.04). Altering models also influenced the joint position sense results. When the baseline Mental Component Summary score was included as a co-variable in the model the p value for the group effect became non-significant (p = 0.08), and when vision was added the p value was 0.051. Model alterations had no significant effect on Physical Component Summary results (p values were consistently 0.04 for group by time interaction), or Mental Component Summary results (p values 0.3 to 0.7).

Change score analyses were used instead of regressor variable methods due to violation of normality assumptions seen in the outcomes. Due to the nature of the models used, the results of regressor variable models should be equivalent, even if normality assumptions
were violated, due to the robust nature of the mixed methods repeated measures approach. Sensitivity analyses confirmed that this was the case.

Outliers were identified as change scores that resulted in a studentised residual of greater than three (Atkinson 1994). Studentised residuals are calculated by dividing a residual by an estimate of its standard deviation and is an accepted technique for identifying outliers in regression analyses (Atkinson 1994). One outlier was identified in the chiropractic group for the sound-induced flash illusion change scores, and one outlier was identified within the control group for the choice stepping reaction time change scores. Removal of these outliers from regression models did not alter the p values associated with these outcome measures.

The pre-planned analysis of SF-36 outcomes involved calculating physical and mental component summary scores using U.S. factor coefficients and New Zealand population norms, which was based on recommendations from the literature (Jenkinson 1999, Ware 2000, Taft, Karlsson et al. 2001). Alternate methods for calculating summary scores exist, including the original approach that involves using U.S. factor coefficients and population norms, or it is also possible to use New Zealand factor coefficients and population norms. Sensitivity analyses were performed using these alternate combinations to investigate whether they had an influence on the results. When U.S. factor coefficients and norms were used to calculate Physical Component Summary scores, the p value for the group by time interaction did not change (p=0.4). However when New Zealand factor coefficients and population norms were used the group by time interaction failed to meet the significance criteria (p=0.051). This suggests that the method used to calculate Physical Component Summary scores is an important factor to consider when planning future trials and introduces some uncertainty into the SF-36 Physical Component Summary results. Sensitivity analyses revealed that the factor coefficients and population norms used to calculate Mental Component Summary scores had little influence on the results with all p-values exceeding 0.3.

The sensitivity analyses performed revealed that the models used were relatively robust. The variation in significance for joint position sense and SF-36 Physical Component
Summary scores indicate that the results from these outcomes were borderline significant, which was evident from the p values that were reported in the primary analyses.

6.4.8. Harms and falls

No serious adverse events were reported that were related to the study interventions or assessments. However, eight participants reported experiencing an unrelated serious adverse event during the time they were involved the study. Three of these participants were in the chiropractic group and five were in the control group. The adverse events all involved inpatient hospitalisation. The participants in the chiropractic group were hospitalised due to unstable angina (n=2), and a viral infection with subsequent diagnosis of a tumour of unknown classification (n=1). Participants in the control group were hospitalised due to a fractured bone in the foot (n=1), a viral infection (n=1), skin cancer removal (n=2), and a myocardial infarction (n=1). Of these participants, the only one to withdraw from the study was the member of the chiropractic group who suffered from the viral infection and subsequently diagnosed tumour.

Minor adverse events were reported by two participants relating to the provision of chiropractic care. This involved transient soreness following chiropractic care. One of these participants withdrew from the trial following their four week assessment, and the other completed the trial assessments but did not adhere to their prescribed chiropractic care plan.

Seven participants reported experiencing a fall while participating in the trial. Five of these participants were in the control group and two were in the chiropractic group. None of these falls resulted in injury that required hospitalisation.

6.5. Discussion

6.5.1. Key findings

The key findings in this study were that improvements were observed in the chiropractic group in joint position sense error, the sound-induced flash illusion, and the choice stepping reaction time compared to the usual care control. Between group differences were also observed in the physical component of health-related quality of life with the
chiropractic group improving compared to the control group between the four and 12 week assessments. These findings provide support for the hypothesis that 12 weeks of chiropractic care improves sensorimotor function in community dwelling older adults. They also provide some support for the hypothesis that 12 weeks of chiropractic care improves health-related quality of life in community dwelling older adults. However, this support should be considered within the context of the changes reported in the health-related quality of life outcomes.

No serious adverse events were reported that related to the provision of chiropractic care. Two participants in the chiropractic group reported transient soreness associated with the chiropractic care they received. These results were consistent with reports of adverse events associated with chiropractic care (Walker, Hebert et al. 2013).

Sensitivity analyses suggested the results observed, and the models used, are relatively robust. The statistical significance of the group effect for joint position sense (p=0.045) and SF-36 Physical Component Summary score group by time interaction (p=0.04) indicated that the between group differences observed were borderline significant. Sensitivity analyses supported this assumption as the statistical significance of these results varied based on the models used and the approach to calculating the Physical Component Summary score that was selected.

6.5.2. Strengths and limitations of the randomised controlled trial

6.5.2.1. Pragmatic study design

This pragmatic randomised controlled trial limited the number of exclusion criteria that were used and provided participating chiropractors with flexibility when it came to making case management decisions. These factors were strengths of the study with respect to enhancing its ecological and external validity. This did however result in a trade-off with respect to internal validity, as few solid conclusions can be made about potential mechanisms of action due to these aspects of the study design.
6.5.2.2. Multiple comparisons

Another strength of the study was the use of a limited number of internationally recommended outcome measures that were pre-specified prior to the trial conduct. This reduced the likelihood of a type I error occurring, due to the small number of comparisons that were made, and it enhanced comparability with other intervention trials. It should be acknowledged that more than one analysis was performed, without making adjustments to $p$ values, which can also be viewed as a limitation. No adjustments were made as it leads to fewer errors of interpretation and is appropriate, particularly when exploring new areas of research (Feise 2002). However, the results of a study such as this that involves multiple comparisons should be evaluated with respect to the quality of the study and amplitude of effect size, and should be regarded as tentative until the results are corroborated by further study (Rothman 1990, Feise 2002).

6.5.2.3. Participant attrition and intention to treat analysis

The low drop-out rate and rate of missing data in the study can also be seen as a strength. Only four out of the 60 participants failed to complete the study, resulting in five missing assessment sessions, with three in the control group and two in the chiropractic group. Missing data affected only three other assessments (two in the chiropractic group, one in the control group) out of the 175 assessments that were performed over the course of the study. Participant attrition and missing data were relatively evenly spread across groups. Utilisation of the mixed models repeated measures approach to statistical analysis of the results meant that the missing data and the data from the participants that withdrew still contributed to the intention-to-treat statistical analysis.

6.5.2.4. Blinding and choice of interventions

The pragmatic approach to the study, with a ‘usual care’ control group, was chosen due to the inherent limitations that are associated with an experimental trial that includes a manual therapeutic intervention. Trials such as this impede blinding of participants and care-givers due to the nature of the chiropractic intervention (Rosner 2012). This results in the possibility of placebo effects, or performance bias associated with the attention received by the chiropractic group that was not received by the control group.
Although the effect of extra attention given to the chiropractic group is unlikely to have a direct effect on the objective outcomes that improved in this study (joint position sense, sound-induced flash illusion, choice stepping reaction time), it is possible that it had an effect on the more subjective SF-36 Physical Component Summary. It is also possible that the effect of attention may have had an indirect influence on joint position sense, sound-induced flash illusion, and choice stepping reaction time, as they may all be influenced based on the participants own attention when completing the assessment (Woollacott and Shumway-Cook 2002, St George, Fitzpatrick et al. 2007, Goble, Mousigian et al. 2011, Magnee, de Gelder et al. 2011).

Therefore, it is possible that participants in the chiropractic group paid more attention when completing the assessments as they were trying harder to ‘repay’ the attention that was paid to them by the chiropractor that was caring for them. As a pragmatic trial this limitation is acknowledged, which limits the internal validity of the trial, and therefore the ability to draw conclusions about potential mechanisms of action. However, the objective of this trial was to investigate the effectiveness, as opposed to efficacy, of chiropractic care. This approach limits the ability to draw conclusions due to potential placebo effects (Hancock, Maher et al. 2006).

Researchers have been developing sham manipulation procedures to use as control interventions in trials that include a spinal manipulation component, with varying degrees of success (Tuchin, Pollard et al. 2000, Vernon, Jansz et al. 2009, Vernon, Triano et al. 2012). Future efficacy trials may benefit from the inclusion of a sham manipulation procedure in the control group if a suitable sham procedure exists (Vernon, Triano et al. 2012). Alternatively, future trials could include an active control intervention and take a comparative effectiveness approach. This was not felt to be necessary in this initial trial as it has been suggested that a no-treatment group is appropriate to use when the research question is to determine the effectiveness of chiropractic care, including the specific and non-specific effects of care (Hancock, Maher et al. 2006).

6.5.2.5. Chiropractor recruitment

Convenience sampling was used to recruit chiropractic practices to assist with the study. This is a limitation as it reduces the generalisability of the results. A convenience
sampling method for recruiting chiropractors was used to reduce the logistical challenges associated with travel for participants in the trial. Participants attended up to 33 chiropractic sessions during the trial, so it was necessary for the chiropractic practice that they attended to be close in proximity to their residence in order to reduce the likelihood of non-compliance due to travel difficulties. When a participant was allocated to the chiropractic group, if a currently enrolled practice was not felt to be suitable, the most convenient chiropractor to their home or work was identified, based on a yellow pages search, and invited to join the study.

The challenge to the generalisability issues associated with this sampling frame could not be overcome by performing a cluster analysis. Many practices (n=7) provided care to only one participant in the trial, and more than one chiropractor provided care in a number of the practices that were involved. When the variable nature of care that was provided by individual chiropractors is considered, in essence there were close to 30 clusters. This meant a cluster analysis would have been equivalent to including a random effect of participants with 30 levels, which is what the regression models did. To compound the challenge of investigating cluster effects was that a cluster would have needed to be assigned to every participant, even though the control group did not attend a chiropractic practice. If an artificially assigned dummy practice cluster was used for the control group the cluster effect would have been confounded with the treatment group. Therefore a cluster analysis was considered impractical, but the potential for a clustering effect should be acknowledged when considering the generalisability of results. Future trials could attempt to incorporate a cluster analysis, or be conducted as a cluster randomised trial, if an active or placebo control is used. However a number of challenges would remain to performing an appropriate cluster analysis as outlined above.

It is improbable that the non-random sampling frame significantly influenced the generalisability of the results, as chiropractors in Auckland are unlikely to be representative of chiropractors in New Zealand, or around the world, due to the preponderance of chiropractors in Auckland who graduated from a single College, the New Zealand College of Chiropractic (New Zealand Chiropractic Board 2008, Holt, Kelly et al. 2009). Bearing this in mind, if a random sampling frame for the recruitment of
chiropractors into the trial was used, or if the study design had allowed for cluster analysis to take place, the internal and external validity of the study would have been enhanced.

6.5.2.6. Participant recruitment

Participants were also recruited based on a convenience sampling method, which is likely to have resulted in selection bias. A convenience sampling frame was used as it was felt that due to the potential for harm associated with the chiropractic intervention, participants should only be eligible if they wanted to receive chiropractic care. Using a random sampling method to recruit eligible participants would therefore have been challenging, as it would have been difficult to identify potential participants who wanted to receive chiropractic care. If potential participants were identified based on patients presenting for care at chiropractic practices, random sampling could have taken place. However, the chance of group contamination occurring would have been greater, as it is likely that the participants would have had a greater desire to receive chiropractic care, in a timely manner, than many of the participants who took part in the present trial.

6.5.2.7. Baseline characteristics

Baseline characteristics were recorded that had previously been identified as being important risk factors for falls, or potential explanatory co-variables for the primary outcomes measures. A potentially significant omission from the list of baseline characteristics that were recorded was participant ethnicity. The cross-cultural validity of the SF-36 has been questioned with respect to measuring Maori and Pacific health, so it would have been appropriate to include ethnicity as an explanatory co-variable for the analysis of SF-36 summary scores (Scott, Sarfati et al. 2000). This is a weakness of the study. Future similar studies should record ethnicity data using the ethnicity classifications included in the national New Zealand Census of Population and Dwellings so they can be incorporated into regression models where appropriate (Statistics New Zealand 2007).

6.5.2.8. Adequacy of randomisation and allocation concealment

A strength of the study was the use of an unpredictable randomisation sequence, and maintaining group allocation concealment until after the baseline assessment (Schulz and Grimes 2002). The random permuted blocks approach to allocation meant investigators...
were unable to predict which group participants would be assigned to. Due to the relatively small sample size, baseline differences did occur between groups. These were accounted for by including appropriate baseline characteristics in the regression models and investigating the effects of other potential co-variables using sensitivity analyses.

6.5.2.9. Sample size

The present study was adequately powered to detect the estimated change in joint position sense as statistically significant. This resulted in a sample size of 60, which is relatively small for a clinical trial. A small sample size may lead to an increased risk of an imbalance of some characteristics of the groups at baseline, as happened in this trial. Small sample sizes may also lead to an increased chance of a type II error occurring (Gurusamy, Gluud et al. 2011). The positive results observed in this trial suggest this was not the case. However, the small sample size may also have increased the chance of a type I error occurring due to the potential effects of a small number of outliers on the overall results (Cousineau 2010). Double data entry procedures were utilised to improve data quality and reduce the chance of outliers occurring due to data entry errors. Sensitivity analyses were also performed after removing outliers. These analyses showed that the small number of outliers present did not significantly influence the reported results of the trial, suggesting that type I errors did not occur due to the presence of outliers. Although the trial was small, the sample size was calculated using plausible estimated effect sizes of chiropractic care on joint position sense error (Haavik and Murphy 2011). So it can therefore be argued that it was adequately sized and powered to achieve the studies primary objective as it relates to joint position sense error.

6.5.2.10. Outcomes assessed

Another potential limitation of the study is that the outcome measures used in this trial may have lacked sensitivity to change or clinical significance. Section 6.5.4 discusses potential issues with the clinical significance of the measure of joint position sense used in this trial. Issues with sensitivity to change, responsiveness, and floor and ceiling effects have also been discussed throughout the thesis in relation to the postural stability measures used in the present study. A number of alternative methods of examining postural stability were reviewed, but there is currently little agreement between authors concerning the most
appropriate method for documenting improvements in postural stability in relatively healthy community dwelling older adults following an intervention (Brauer, Burns et al. 2000, Lord, Castell et al. 2003, Pollock, Eng et al. 2011, Taylor, Ketels et al. 2012, Schoene, Wu et al. 2013). Static posturography was therefore selected as parameters derived from centre of pressure trajectories are considered by many to still be the gold standard for assessing balance performance (Clark, Bryant et al. 2010, Huurnink, Fransz et al. 2013).

6.5.2.11. Follow-up period

The 12 week follow-up period used in this study means this is one of the few trials that has investigated the effect of chiropractic care on sensorimotor function that does not involve a single intervention session (Haavik and Murphy 2012, Barker, Yields et al. 2013). This is a strength of the study. However, a number of the outcomes assessed improved significantly between the four and 12 week assessments. It is unclear if improvements would have continued beyond 12 weeks of care. It should also be considered that the SF-36 involves a four week recall period. Therefore events taking place as far back as eight weeks into the study may have contributed to the 12 week SF-36 results. A longer study follow-up period would have enabled a better understanding of the magnitude of improvements that may have occurred in the outcomes that were assessed.

6.5.3. How the findings relate to previous research

6.5.3.1. Proprioception

The key finding with respect to joint position sense error was that there was a significant group effect (p=0.045, mean difference 0.20˚, 95% CI 0.01-0.39˚) of chiropractic care on joint position sense error, with the chiropractic group showing greater improvement than the control group.

It is difficult to make comparisons between the results of different intervention trials that investigate joint position sense because of the heterogeneity of outcome measures that are used in its assessment. Improvements in joint position sense error of up to 6˚ have been reported following a variety of interventions in a variety of clinical populations (Westlake,
Wu et al. 2007, Hijmans, Zijlstra et al. 2009, You, Saliba et al. 2009, Haavik and Murphy 2011). To put this in perspective, the baseline joint position sense error observed in this study was only 1.83˚ (SD = 0.57˚), meaning a 6˚ improvement would be impossible to achieve. Previous studies that are most relevant to the present study are those performed by Haavik and Murphy (2011), because of the similarities of the interventions, and You, Saliba et al. (2009), because of the similarities between the assessment methods.

Haavik and Murphy (2011) reported a significant 0.28˚ (SD = 0.12˚) overall improvement in the absolute constant elbow joint position sense error in a subclinical neck pain population immediately after cervical chiropractic adjustments. This result is similar to the result observed following 12 weeks of chiropractic care in this trial. In their trial, Haavik and Murphy (2011) used a passive/active approach (the experimenter passively moved the participants elbow to the target joint angle and then the participant actively recreated the angle) and assessed joint position sense error with the participants head in one of four different positions (neutral, rotation, flexion, combined flexion and rotation). They reported greater improvement in joint position sense error following cervical chiropractic adjustments when the head was placed in either the neutral or rotated position, compared to the other two positions. Like most studies that investigate a manual therapy intervention, this study was limited by a lack of blinding of participants to group allocation, and the methodology used may have resulted in bias due to participant fatigue. The authors concluded that the results of their study supported the hypothesis that chiropractic care can have a beneficial neuroplastic effect. The current study adds further support to this theory.

You, Saliba et al. (2009) investigated the effect of biofeedback in combination with circumferential ankle pressure on ankle joint position sense error in a convenience sample of 40 older adults. They used a SENSERite joint position sense system that was very similar to the apparatus used in this study. At baseline You, Saliba et al. (2009) reported slightly worse mean joint position sense error (2.51˚, SD = 0.77˚) compared to the current study (1.83˚, SD = 0.57˚). Following an intervention that included a single 45 minute treatment session that involved either ankle joint position feedback on its own, or in combination with circumferential ankle pressure, joint position sense error was reassessed. A further follow-up assessment took place six to eight days after the initial assessment.
The authors do not provide the actual values of improvement but visual estimation from the graphs that are provided suggest that immediately post the intervention, there was an improvement in joint position sense error of approximately 1.35°, and this increased to 1.60° at the follow up assessment. This trial did not include a control group, and the biofeedback intervention consisted of the participants practicing on the SENSERite system while receiving visual feedback regarding how they were performing. This is a limitation of this study because the impressive improvements that are reported may not reflect improvements in proprioceptive perception, but instead they may represent an improved ability to perform the assessment task due to the effect of practice. The clinical implications of the You, Saliba et al. (2009) study are therefore questionable and the authors’ suggestions that position sense impairment is reversible based on exploiting augmented feedback effects should be viewed with caution.

### 6.5.3.2. Choice stepping reaction time

The key finding for choice stepping reaction time was that there was a significant (p=0.01) group by time interaction, with the chiropractic group improving by 118ms (95% CI 24 to 212ms) compared to the control group at the 12 week assessment.

The four week assessment of choice stepping reaction time in this study showed little change between groups, with the chiropractic group experiencing a very small, non-significant improvement compared to the control group (9ms, p=0.8, 95% CI -56 to 74). This lack of improvement at four weeks may be important as it suggests that longer term chiropractic care may be required to have a significant effect on some physiologically important aspects of sensorimotor function. This hypothesis is supported by a recent study that investigated the effect of 12 weeks of chiropractic care on the cervical flexion relaxation response in patients with chronic neck pain (Barker, Yielder et al. 2013). This study revealed that progressive improvement in the flexion relaxation response occurred over a 12 week period of care, and that it took more than six weeks of chiropractic care before changes approached a significant level in this objective marker of cervical neuromuscular function. However, as this study lacked a control group, the results of this study need to be interpreted with caution.
The baseline choice stepping reaction time values observed in this study (combined mean 1171ms, SD = 200ms) were consistent with those reported in similar populations elsewhere in the literature (993ms, SD = 197ms to 1264ms, SD = 268ms) (Lord and Fitzpatrick 2001, Kvelde, Pijnappels et al. 2010, Pijnappels, Delbaere et al. 2010, Zheng, Delbaere et al. 2012). The between group choice stepping reaction time improvement that resulted following 12 weeks of chiropractic care (118ms) is consistent with, or exceeds, the reported results in other intervention trials involving choice stepping reaction time (Lord, Castell et al. 2003, Rissel, Passmore et al. 2013, Schoene, Lord et al. 2013).

Lord, Castell, et al. (2003) conducted a large scale trial that investigated the effect of six months of group exercise classes on choice stepping reaction time in older adults in Sydney. They reported a significant (p < 0.01) 47ms between group difference, with a 35ms reduction in choice stepping reaction time in the experimental group, compared to a 12ms increase in the control groups.

Two small studies reported similar improvements in choice stepping reaction time to the present study following very distinct interventions. One study recruited 18 older adults (aged 49-72 years) into a 12 week cycling programme (Rissel, Passmore et al. 2013). The authors reported an improvement of 80ms in choice stepping reaction time following the cycling programme. It is unclear if this difference was statistically significant due to the way the authors assessed the results. It should be noted that the choice stepping reaction time device used in this study differs from previously validated devices and no mention was made of any reliability or validity testing that was performed. The lack of a control group, the novel choice stepping reaction time device that was used, and the fact that only 12 participants completed the programme, and an intention to treat analysis was not followed, means that these results should be interpreted with some caution, and comparisons to results of other studies should bear this in mind.

The other small study that reported improvements in choice stepping reaction time involved a two-arm randomised controlled trial that compared eight weeks of step pad training using videogame technology to a no-intervention control (Schoene, Lord et al. 2013). The authors of this study reported a 121ms difference between the groups (p < 0.001). The device used to measure choice stepping reaction time in this study was a
portable step pad that differed from traditional choice stepping reaction time devices. The authors had previously demonstrated the reliability and validity of the device; however on average, participants took 175ms longer to perform choice stepping reaction time on the portable mat compared to a traditional choice stepping reaction time platform (Schoene, Lord et al. 2011). This theoretically allows for a greater scope for improvement, which should be considered when comparing outcomes of different interventions. Conclusions that can be drawn from, and comparisons that can be made with the small study by Schoene, Lord et al. (2013) are also somewhat limited by the sample size (n=37), and the learning effect that may have taken place in their study. Participants in the exercise group were able to practice completing the choice stepping reaction time assessment each week throughout the intervention programme on top of participating in the videogame intervention. When viewed in the light of these intervention studies, the improvement in choice stepping reaction time observed in the present trial appears to be impressive and warrants further investigation.

6.5.3.3. Postural stability

No significant differences were observed between groups in postural stability, suggesting that chiropractic care did not lead to an improvement in postural stability in older adults in this study.

A large number of participants failed to complete the postural stability assessment (n=32, 53.3%) at baseline. At subsequent assessments, the number of participants failing to complete decreased (n=25, 42.4% at the four week assessment, and n=21, 37.5% at the 12 week assessment) but the distribution between groups of those who failed to complete remained fairly consistent throughout the trial. Previously, this test has been used as an overall measure of vestibular function, with individuals failing to complete the test being classified as having vestibular dysfunction (Agrawal, Carey et al. 2009). The percentage of participants who failed to complete the test in the current study is consistent with the results of previous research that investigated postural stability in older adults (Agrawal, Carey et al. 2009). With such a large percentage of older adults failing the test, it is possible that the test is simply too challenging for this population. It may also be
insensitive to small but significant improvements in postural stability that occur following an intervention, if they exist.

The postural stability test that was used was the modified Clinical Test of Sensor Integration in Balance (mCTSIB) protocol, which is the most commonly used variation of centre of pressure static balance testing (Pagnacco, Oggero et al. 2008). The ‘eyes closed on an unstable surface’ assessment was chosen for analysis because it reduces the impact that vision, proprioception from the ankles, and cutaneous receptors on the souls of the feet play in postural stability (Lord and Ward 1994). This choice was made as proprioception was assessed using the joint position sense apparatus, so it was hoped to gain a better understanding of any potential effects of chiropractic care on the vestibular aspect of postural stability.

Data were collected from other aspects of the mCTSIB assessment that incorporated visual and peripheral receptor input into the postural stability assessment. Only one postural stability test was included as a primary outcome measure in order to reduce the number of statistical tests that were carried out, and therefore the chance of making a type I error. It was felt that the other components of the mCTSIB assessment would exhibit a ceiling effect as feasibility and reliability testing revealed that these scores were generally between 85-95% in older adults at baseline. These data from the remaining mCTSIB assessments were analysed as a part of the sensitivity analysis to test the robustness of the conclusions made in the primary analysis, but the results remained consistent.

Stability scores from the ‘eyes closed on an unstable surface’ assessment were also included in the sensitivity analysis even though they violated normality assumptions. There were small, non-significant, average increases in stability score in both groups (chiropractic group improved by 10.2%, control group improved by 7.2%), which reflected the small increase in the number of participants who completed the assessment at the 12 week assessment compared to baseline. The sensitivity analyses did not change the conclusions drawn from the primary analysis of postural stability.

The systematic review included in Chapter three concluded that a limited amount of research has been published that supports a role for manual therapy in improving postural
stability and balance. The findings of this study do not add any further support to this potential role.

6.5.3.4. Multisensory integration

The key finding with respect to multisensory integration was that there was a significant overall group effect (p=0.02, mean difference 11.3%, 95% CI 1.7 to 20.9%) of chiropractic care on the sound induced flash illusion, with the chiropractic group showing greater improvement than the control group. No group by time interaction was present (p=0.2), but the mean difference between groups was slightly larger at the 12 week assessment (mean difference 13.5%, 95% CI 2.9 to 24.0%) compared to the four week assessment (9.1%, 95% CI -0.9 to 19.1%). The difference between groups at the 12 week assessment was also significant (p=0.01).

The overall mean baseline sound-induced flash illusion score was 61.6% (SD=39.81), which was very similar to the mean scores reported by Setti, Burke et al. (2011) in healthy older adults using a similar sound-induced flash illusion protocol. The sound-induced flash illusion is considered to be resistant to change, with only one study published that has reported an improvement in illusion performance following an intervention (Rosenthal, Shimojo et al. 2009). This study is discussed in Chapter two, Section 2.6.4 and reported a similar magnitude of change in susceptibility to the illusion as the present study, following feedback training with the added motivation of a monetary reward based on the participants performance accuracy. However, the authors concluded that the perception of the illusion did not change following feedback training. Instead, participants described subtle phenomenological difference between percepts induced by the illusory and non-illusory conditions that helped them to discriminate between the two conditions. The findings reported by Rosenthal, Shimojo et al. (2009) indicate that feedback training did not change the perception of the illusion, which suggests that the current study is the first to report an improvement in the perception of the sound-induced flash illusion following an intervention. This is also the first study to report improvements in multisensory integration in a group receiving chiropractic care.
6.5.3.5. Health-related quality of life

The key finding related to the SF-36 health-related quality of life outcomes was that a significant (p=0.04) group by time interaction was present for the Physical Component Summary score analysis. No other significant findings were observed for the Mental Component Summary scores of the group effect on Physical Component Summary scores. The significant difference between the groups occurred between the four and 12 week assessments (2.4, p=0.047, 95% CI 0.04 to 4.8). However, the difference between groups at the 12 week assessment time point failed to reach significance (2.6, p=0.09, 95% CI -0.4 to 5.6).

The present study is one of the few well-designed, randomised controlled trials to report the effect of chiropractic care on health-related quality of life in an older adult population. A small number of controlled trials have reported similar findings to those reported here in different study populations (Gudavalli, Cambron et al. 2006, Bishop, Quon et al. 2010, Bronfort, Evans et al. 2012), The small sample size and relatively short duration of the study, combined with uncertainty surrounding the results, suggest caution should be used when interpreting the SF-36 results. The results do however suggest that chiropractic care had a positive influence on the SF-36 Physical Component Summary scores, which warrants further investigation.

6.5.3.6. Interventions

Chiropractic care was provided to participants in the chiropractic group by 12 different chiropractic practices across Auckland, with each practice providing care to between one and seven study participants. The care that was provided in this trial mainly consisted of table assisted and instrument assisted adjustments, with some chiropractors using the more traditional high velocity, low amplitude manual approach to care. In practice, chiropractors routinely provide appropriate public health advice, and prescribe rehabilitative exercises, stretching and other non-adjustive treatments when felt to be appropriate (Coulter and Shekelle 2005, Holt, Kelly et al. 2009). These were all potentially included as a part of the provision of chiropractic care in order to match usual care approaches as much as possible. The technique approaches used by the chiropractors in this study reflect those used by chiropractors across New Zealand (Holt, Kelly et al.
2009). The major difference to the approaches taken in this study, compared to New Zealand chiropractors in general, is that fewer chiropractors used high velocity, low amplitude spinal and extremity adjustments with direct manual contact (Holt, Kelly et al. 2009). The most likely explanation for this is that table assisted and instrument assisted adjustment approaches are often chosen when providing chiropractic care to older adults as they utilise smaller overall force loads that may be more appropriate when adjusting the ageing spine (Gleberzon 2001).

6.5.4. Implications of the findings

This study found that joint position sense error, choice stepping reaction time, and the sound induced flash illusion improved in the older adults receiving 12 weeks of chiropractic care. These outcome measures are associated with an individual’s risk of falling, which opens up the possibility that chiropractic care may play a role in preventing falls in older adults. However, the clinical significance of the changes observed should be considered and are discussed in the following section. It should also be acknowledged that until the results of the study are corroborated, and further research is conducted that investigates the effect of chiropractic care on the rate of falls in older adults, the implications of the study from a policy or public health perspective remain limited.

Due to the lack of clarity regarding the relationship between proprioceptive loss and fall risk, it is difficult to draw any conclusions about the implications and clinical significance of the results of proprioception testing in the present study. As has already been mentioned, results in this area are conflicting in the literature, potentially due to the insensitivity of some of the measures of proprioception to detect subtle deficits in proprioceptive function, and the tendency for investigators to take a disease oriented approach to fall risk as opposed to a physiological approach (Lord, Menz et al. 2003, Westlake and Culham 2006, Sturnieks, St George et al. 2008). Lord et al. (1999) reported a significant difference (p<0.05) of 0.4° between fallers and non-fallers in an active, between limb, joint matching task in older adults. Currently, this is perhaps the best estimate available in relation to a clinically significant difference in joint position sense related to fall risk. However, this should not be viewed as an absolute cut-off to represent clinically significant improvements. It has been suggested that judgements of clinical
significance should not only involve a change score of a large enough magnitude that suggests it is due to real world change, but it should also result in a post test score that is within a range of normal values (Jacobson, Roberts et al. 1999). This range of normal values is somewhat arbitrary, but may be set at one or two standard deviations from the normative mean for example (Ferguson, Robinson et al. 2002). Confounding this estimation further is the fact that there is currently little consensus concerning what constitutes impaired joint position sense, and whether improvements in joint position sense reduce fall risk in an individual who does not have a significant joint position sense impairment (You, Saliba et al. 2009). You, Saliba et al. (2009) proposed a critical value of 2.3˚ to classify an individual as having impaired joint position sense of the ankle. Other authors have suggested alternative critical values of up to 5˚, but again this is dependent on the testing method that has been used and the joint that is being tested (Batavia, Gianutsos et al. 1999).

Although the implications of the joint position sense findings are unclear (p=0.045, mean difference 0.20˚, 95% CI 0.01-0.39˚), they do support previous research that suggests chiropractic care positively influences proprioception (Haavik and Murphy 2011). Potential mechanisms associated with these findings and suggestions for future research are discussed in Sections 6.5.5 and 6.5.6.

When considering the clinical significance of the changes observed in choice stepping reaction time, the 118ms between group improvement that occurred by the 12 week assessment is greater than the between group difference (47ms) that Lord, Castell, et al. (2003) described as ‘particularly important’ in their study that involved a six month group exercise intervention. Lord, Castell, et al. (2003) emphasised the importance of this result as they claimed that the choice stepping reaction time task is similar to the step response that is required to avoid a fall, and it is a useful composite measure of falls risk. The observed improvement approaches the difference between fallers and non-fallers (154ms) reported by Lord and Fitzpatrick (2001) in their large trial that involved 477 retirement-village residents in Sydney. It is also similar to the difference between multiple fallers and non-multiple fallers (109ms) reported by Pijnappels, Delbaere et al. (2010) in their path analysis of 294 retirement village residents. The findings of the present study demonstrated that the group of older adults receiving 12 weeks of chiropractic care
displayed a clinically meaningful improvement in a general measure of sensorimotor function that is a significant, independent predictor of falls (Lord and Fitzpatrick 2001).

The between group change in multisensory integration also appears as though it may be clinically significant. The 12 week change score in the chiropractic group indicates that on average their proportion of correct illusory responses went from 63.0% to 78.2%. This latter value approaches the proportion of correct responses reported by Setti, Burke et al. (2011) in healthy younger adults under the same assessment conditions (Figure 2:6). Although susceptibility to the sound-induced flash illusion has been associated with an increased risk of falling, it is unclear whether an improvement in multisensory integration is also a valid surrogate for an improvement in an individual’s risk of falling (Setti, Burke et al. 2011). The implications associated with the findings of the present study with respect to the influence of multisensory integration on the risk of falling are therefore unclear. It does however open some interesting lines of research that may help gain a greater understanding of the effect of chiropractic care on multisensory integration. This may also be clinically relevant to other populations.

The clinical significance of the improvement in SF-36 Physical Component Summary scores in the chiropractic group between assessments is debatable (difference between groups from the four week to the 12 week assessment p=0.047, 2.4, 95% CI 0.04 to 4.8). To date, no minimum clinically important difference values have been published that are relevant to Physical Component Summary scores in older adults who are not suffering from a particular disease or condition. However, minimum clinically important differences for improvement in Physical Component Summary scores have been published for a variety of clinical populations undergoing treatment, including; scleroderma patients treated in a scleroderma clinic (2.2 points) (Sekhon, Pope et al. 2010), systemic lupus erythematosus patients undergoing treatment (2.1 points) (Colangelo, Pope et al. 2009), patients undergoing lumbar spine surgery (4.9-5.2 points) (Copay, Glassman et al. 2008, Carreon, Bratcher et al. 2013), and neck and arm pain patients undergoing cervical spine fusion (4.1 points) (Carreon, Glassman et al. 2010). The differences reported in the present study are similar to some of these clinically significant differences.
Ferguson, Robinson et al. (2002) proposed using a statistic called the reliable change index to determine whether clinically significant healthcare outcomes have occurred when considering SF-36 domain and summary scores. The reliable change index is calculated by subtracting the post-intervention score from the pre-intervention score and dividing by the standard error of the change score. If the reliable change index is over 1.96 it is said to be clinically significant. Using this method of analysis the reliable change index for the Physical Component Summary change score between the four and 12 week assessments in the chiropractic group was 2.05, suggesting that the change is clinically significant. However, it should be remembered that the overall between group 12 week change score failed to reach statistical significance (2.6, p=0.09, 95% CI -0.4 to 5.6). Further research is required to determine whether chiropractic care results in clinically important differences in health-related quality of life in older adults.

6.5.5. Possible mechanisms and explanations

A number of possible mechanisms of action may have contributed to the changes observed in this study. These mechanisms include:

1. Chiropractic care may influence neuroplastic processes within the central nervous system through altered afferent input related to spinal function.

2. Chiropractic care may have an influence on pain that, in turn, affects cognition, particularly with respect to attentional focus, and physical function.

3. Chiropractic care may have resulted in changes in muscle strength or muscle activation patterns.

4. Placebo effects may have been involved.

As a pragmatic effectiveness trial, with a ‘black-box’ intervention, no firm conclusions can be made regarding which, if any, of these potential mechanisms made a significant contribution to the results that were observed. These mechanisms have been explored in more detail in the following sections, and where appropriate, hypotheses have been made regarding their potential contribution to the results so future research can help to gain a
greater understanding of the mechanisms of action that may have been associated with the results of this study.

6.5.5.1. Chiropractic care may influence neuroplastic processes within the central nervous system

Chapter two, Section 2.4 discussed the literature surrounding the effect of chiropractic care on neural plastic changes in the central nervous system. Many of the results of this study may be explained by the model depicted in Figure 2:4 that is based on this previous research.

The improvements in joint position sense may have been due to changes in central nervous system function that influence processing abilities that play a significant role in proprioceptive acuity in older adults (Goble, Mousigian et al. 2011, Goble, Coxon et al. 2012). Chiropractic care may have resulted in changes in neuroplasticity within the neural networks that are involved in processing and integrating proprioceptive information. A growing body of research has been published that has reported neural plastic changes following chiropractic adjustments in the primary somatosensory and motor cortices, the premotor cortex, the secondary association areas, and within subcortical areas such as the basal ganglia and cerebellum-cortical communication, which are all involved in the processing and integration of proprioceptive information (Haavik Taylor and Murphy 2007, Goble, Coxon et al. 2009, Haavik Taylor and Murphy 2010, Goble, Coxon et al. 2011, Goble, Coxon et al. 2012, Daligadu, Haavik et al. 2013).

If chiropractic care does result in a change in afferent input from muscles and receptors around the spine, this potential mechanism provides a plausible explanation for the changes observed in proprioception. Knox, Cordo et al. (2006) reported that illusory changes in head position induced by neck muscle vibration resulted in reduced joint position sense in the elbow that were related to modulation of central nervous system activity caused by the muscle vibration. The muscle vibration was used to alter muscle spindle excitation and induce the illusion of neck movement. Based on the hypothesised effect of vertebral subluxations on muscle spindles and other receptor activity, it is possible that the muscle vibration can be viewed as an analogue to the neurological manifestations of a vertebral subluxation, and therefore provides support for similar
central neural plastic methods of action (Haavik Taylor, Holt et al. 2010, Haavik and Murphy 2012, Henderson 2012). This theoretical concept requires a great deal of further research to understand whether it is a plausible theory or not.

When considering possible mechanisms of action to explain the improvement seen in choice stepping reaction time it is difficult to make any firm conclusions, as choice stepping reaction time provides such a broad composite measure of neuropsychological, sensorimotor, and balance factors that are important for executing appropriate stepping responses when balance perturbations are encountered (Lord and Fitzpatrick 2001). Therefore, improvements in choice stepping reaction time following a chiropractic intervention may be due to multiple changes in physiology and cognition (Pijnappels, Delbaere et al. 2010).

Choice stepping reaction time is influenced by sensory processing and sensorimotor integration (Lord and Fitzpatrick 2001, Kvelde, Pijnappels et al. 2010, Pijnappels, Delbaere et al. 2010), which may be affected by chiropractic adjustments (Haavik and Murphy 2012). In the present study the only mediating factor that was assessed was standing balance, and no significant differences were seen following chiropractic care in this outcome measure. This may suggest that one of the other mediators of choice stepping reaction time, such as central processing speed or lower limb muscle strength, may have played a greater role in the observed improvement (Pijnappels, Delbaere et al. 2010).

Reaction time and processing speed have been shown to improve following a chiropractic adjustment (Kelly, Murphy et al. 2000). However, with no specific alternate measure of reaction time being included in this study it is unclear if this played a part in the results that were observed. If central processing changes were involved in the improvement in the sound-induced flash illusion performance, they had largely taken place by the four week assessment, while the choice stepping reaction time improved between the four and 12 week assessment. This may suggest a more significant role for a sensory perception or motor function mediating effect over a purely neurological processing or integration based pathway. The same is true for changes that may have been associated with proprioception that relate to choice stepping reaction time.
Reduced proprioceptive feedback results in difficulties with the calibration of limb position in space and the coordination of targeted movements and movements associated with gait (Goble, Coxon et al. 2009). If chiropractic care improves proprioceptive ability, which appears to be the case based on the results of this study, there may be an overlap in the mechanism of action related to improved proprioceptive ability and the improvement in choice stepping reaction time that was observed. Again, the changes in joint position sense that were observed had occurred predominantly in the first four weeks of care. This may suggest that alterations may have taken place to central motor control patterns and that these alterations potentially take longer than changes associated with improvements in proprioceptive ability.

The improvements observed in multisensory processing are not adequately explained by Haavik and Murphy’s proposed model (Haavik and Murphy 2012). The sound-induced flash illusion task assessed in the present trial involves no somatosensory or motor component, which means it does not fit neatly into the model as it stands. However, multisensory integration and sensorimotor integration are closely linked, with previous studies describing parallel processing circuitry associated with sensorimotor and multimodal sensory integration (van der Kooij, Jacobs et al. 1999, Cappe, Rouiller et al. 2012, Kipping, Grodd et al. 2013). If the Haavik and Murphy model is expanded to involve a multimodal sensory integration component, that is modulated, either directly or indirectly, by somatosensory processing, this may provide a potential explanation for the changes in sound-induced flash illusion observed in the present trial (Figure 6:11).

This proposed model will need to be investigated in further trials to ascertain its viability. This model should also be considered when discussing changes in the sound-induced flash illusion observed in this trial as they may be related to the individual’s pre-stimulus brain state (Bolognini, Rossetti et al. 2011, Keil, Muller et al. in press). Haavik Taylor and Murphy (2010) reported that a chiropractic adjustment resulted in an enhanced ability to filter sensory information, potentially through subcortical loops involving the thalamus, which may have an impact on resting brain state. Again, this requires further corroborative work in order to understand the feasibility of this potential mechanism. Further research is also needed to understand whether chiropractic care may result in changes in working memory or attentional load that could be important factors involved in improvement in
Joint position sense, choice stepping reaction time and sound-induced flash illusion results (Mishra, Martinez et al. 2007, Kvelde, Pijnappels et al. 2010, Goble, Mousigian et al. 2011).

**Figure 6:11 - Proposed Expansion to the Haavik and Murphy Model (2012) Depicted in Figure 2:4 that Involves a Multisensory Processing and Integration Component**

6.5.5.2. Chiropractic care may influence pain

It is possible that the changes observed in the present trial were related to changes in pain. A number of studies have reported improvements in a variety of pain syndromes following chiropractic care (Wilkey, Gregory et al. 2008, Haas, Spegman et al. 2010, McMorland, Suter et al. 2010, Thorman, Dixner et al. 2010, Stochkendahl, Christensen et al. 2012). Joint position sense, choice stepping reaction time, and sound-induced flash illusion are all dependent to some degree on the attentional load capacity and/or the working memory capacity of the person that is being assessed (Mishra, Martinez et al. 2007, Kvelde, Pijnappels et al. 2010, Goble, Mousigian et al. 2011).
Pain, attention, and working memory are closely linked at both a neural and behavioural level (Sanchez 2011). Pain may interfere with the ability to recall information, which may be important when completing joint position sense tasks (Sanchez 2011). It has also been suggested that pain operates like an additional processing burden, which may influence attentional capacity relating to other tasks (Sanchez 2011). This provides a simple potential link between a possible pain-based mechanism to explain the improvements observed in the chiropractic group for the joint position sense, choice stepping reaction time, and sound-induced flash illusion outcomes.

Pain may have played a further role in the performance of the joint position sense and choice stepping reaction time tasks as it could have interfered with the physical movements required to complete these tasks. Pain is also an integral component of the SF-36 Physical Component Summary score, which potentially explains the changes seen in this secondary outcome as well (Ware 2000). The bodily pain domain scores of the SF-36 evaluation revealed that the chiropractic group was slightly worse than the control group with respect to pain at the baseline evaluations, and slightly better at the 12 week assessment. This may be associated with the between group differences observed in the joint position sense, choice stepping reaction time, sound-induced flash illusion and SF-36 Physical Component Summary outcome measures. Exploratory analyses were not performed to further investigate this potential relationship in order to avoid reporting spurious results. Specific efficacy trials are required to investigate this hypothesis.

6.5.5.3. Chiropractic care may influence muscle strength or muscle activation patterns.

Improvement in choice stepping reaction time may be related to changes in quadriceps muscle strength, or potentially muscle activation patterns. Quadriceps muscle strength is one of the strongest mediators of choice stepping reaction time and it has been shown to increase following chiropractic care (Lord and Fitzpatrick 2001, Hillermann, Gomes et al. 2006, Kvelde, Pijnappels et al. 2010, Pijnappels, Delbaere et al. 2010). Chapter two, Section 2.5.3 discussed previous research that reported increased quadriceps muscle strength, decreased quadriceps muscle inhibition, and increased quadriceps muscle activation following chiropractic care (Suter, McMorland et al. 1999, Hillermann, Gomes 2000).
et al. 2006). These changes were reported following a single chiropractic adjustment. In contrast, the changes in choice stepping reaction time observed in the present trial did not occur until after the four week assessment. This may suggest that if changes to quadriceps muscle strength play a role in improved choice stepping reaction time they may have been due to a different mechanism than the short term neurological effects on muscle function reported by Hillermann, Gomes et al. (2006) and Suter, McMorland et al. (1999).

Studies that investigate time course adaptations in muscle strength and morphology following strength training have reported that neuromuscular changes in the first weeks of a training programme appear to be dominated by neural factors, with morphological changes, such as muscle protein increases and increased cross-sectional area, occurring during later phases of training (Kraemer, Fleck et al. 1996, Folland and Williams 2007, Kubo, Ikebukuro et al. 2010). It is possible that the improvement in choice stepping reaction time observed in the present trial was due to morphological changes in quadriceps muscles that occurred subsequent to the early neurological changes in quadriceps muscle activity that have been reported following chiropractic adjustments (Suter, McMorland et al. 1999, Hillermann, Gomes et al. 2006). It is also possible that the improvement in choice stepping reaction time was due to increased corticospinal excitability, which has previously been shown to develop over several weeks of skill training and may be of importance for task acquisition that involves motor function (Jensen, Marstrand et al. 2005).

Chapter two Section 2.5.3 also discussed a potential role that alterations in feed forward activation may play in choice stepping reaction time, and the research that has demonstrated positive effects of chiropractic care on feed forward activation of core abdominal muscles. Feed forward activation was not assessed in the present trial but it may be involved in the changes observed in choice stepping reaction time and requires further evaluation.

**6.5.5.4. Placebo effects may have been responsible for the observed changes.**

Placebo effects may have been involved in the changes that were observed in the present trial. Strong placebo effects have been hypothesised to occur following spinal manipulation due to manual contact, care provider attention, and provider enthusiasm
(Ernst and Harkness 2001, Vernon, Triano et al. 2012). It is possible that the 22 contacts on average with the chiropractor over 12 weeks influenced the chiropractic group, either in the effort they placed into completing the assessments, or the way they reported their health-related quality of life.

A systematic review of clinical trials that compared placebo effects with no treatment found that there was no significant effects of placebo on objective outcomes, and only small benefits for continuous subjective outcomes (Hrobjartsson and Gotzsche 2001). This would suggest that placebo effects were unlikely to have a significant impact on the objective outcomes such as joint position sense, choice stepping reaction time, and sound-induced flash illusion. They may however have played a part in the subjective SF-36 assessment. The nature of the study design means placebo effects cannot be excluded as a potential mechanism associated with the observed improvements (Hancock, Maher et al. 2006).

Until further explanatory research is conducted that attempts to ‘unpack’ the black-box approach that was used in the present study, these potential mechanisms of action will remain hypothetical. The following section suggests recommendations for future research that may help to shed some light on these potential mechanisms and that will address some of the limitations of the present study.

**6.5.6. Recommendations for future research**

This study has resulted in a lot of questions being formed that will require further research to answer. Are the results clinically significant? Do they relate to a decrease in fall risk associated with chiropractic care? What mechanisms of action were involved? Are the results reproducible?

Future research in this area will be enhanced if studies that investigate the effect of chiropractic care on sensorimotor function include an active control arm, or an appropriate sham control procedure. This would reduce the potential bias associated with placebo effects and also enable a cluster analysis or randomisation to be performed if a multi-centre trial design is used. It would also enable investigators to make conclusions about the specific and non-specific effects of care (Hancock, Maher et al. 2006).
A number of issues were also identified that relate to the outcome measures used in the present study that future researchers may wish to consider.

If testing joint proprioception, future studies should consider using alternative combinations of active and passive joint position sense tasks, and participant positions, as there is little agreement between authors with respect to the most appropriate assessment procedures for the measurement of joint position sense in different patient populations (Westlake and Culham 2006). If alternative assessments of proprioception are utilised, such as thresholds to velocity or movement, this may also shed further light on the relationship between chiropractic care and proprioception. Basic science studies that investigate potential changes in neural plasticity in relation to changes in proprioceptive acuity will also be beneficial. Future trials should also consider taking changes in pain into account when evaluating potential mechanisms of action between chiropractic care and changes to proprioception, and they should consider restricting eligibility to individuals with predefined impaired joint position sense function so conclusions regarding clinical significance can be made.

If the choice stepping reaction time is evaluated in future research the method of action associated with potential changes could be assessed by including appropriate additional explanatory measures, such as quadriceps muscle strength or activation patterns, simple reaction time, feed forward activation, and visual contrast sensitivity. It may also be useful to include dual task choice stepping reaction time as this may shed further light on the mediating effects of chiropractic care on choice stepping reaction time. This is due to dual task choice stepping reaction time appearing to be mediated more by a neuropsychological path than a sensorimotor/balance mediating path (Zheng, Delbaere et al. 2012). Future researchers may choose to take a largely practice based approach to investigate this relationship further in order to reduce financial costs and logistical challenges. Schoene, Lord et al. (2011) developed a dance mat device that is highly portable, and is valid and reliable when compared to a traditional choice stepping reaction time platform. If used in a practice setting, in conjunction with a number of simple tests included in the Physiological Profile Assessment developed by Lord, Menz et al. (2003), it may be possible to shed further light on many of the unanswered questions that have emerged from the present study relating to chiropractic care and choice stepping reaction time.
Considering that proprioception improved following chiropractic care, and proprioception is known to be an important contributor to postural stability (Sturnieks, St George et al. 2008), it is possible that the postural stability assessments that were used in this study were not sensitive enough to pick up subtle differences if they exist. Future studies that investigate the effect of chiropractic care on balance should consider alternative methods of assessment than static posturography, or if static posturography is used, researchers should consider including populations with significant balance impairment who have greater room for improvement on the aspects of the mCTSIB other than the ‘eyes closed on an unstable surface’ assessment. Based on the results of this trial, which seem to indicate an effect of chiropractic care on central processing, future researchers may wish to also include balance assessments that involve a dual task component, as it is possible that they are more likely to show an improvement following chiropractic care than static posturographic assessments.

A number of mechanisms were discussed in Chapter two, Section 2.6.4 that may relate to the changes observed in multisensory integration. These mechanisms include general cognitive slowing that is seen in older adults, inverse effectiveness associated with sensory deficits, alterations in the time window of integration of multisensory information, inefficient top-down modulation of sensory information, and increased background sensory noise (Mishra, Martinez et al. 2007, Bolognini, Rossetti et al. 2011, Mozolic, Hugenschmidt et al. 2012, Stevenson, Zemtsov et al. 2012, Keil, Muller et al. in press). In order to gain a greater understanding of potential mechanisms associated with the improvement in sound-induced flash illusion performance following chiropractic care in this study, future research should focus on these potential mechanisms.

It may also be of interest to investigate the effect of chiropractic care in other population groups who exhibit alterations in multisensory integration, such as people with autism spectrum disorders, dyslexia, migraine, and schizophrenia (Hairston, Burdette et al. 2005, Foucher, Lacambre et al. 2007, Pearl, Yodashkin-Porat et al. 2009, Foss-Feig, Kwakye et al. 2010, Kwakye, Foss-Feig et al. 2011, Martin, Giersch et al. 2013, Schwedt 2013). Researchers may also wish to explore any potential relationships that may exist between chiropractic care, multisensory integration, and cognition in children, as there is evidence to suggest that enhanced multisensory integration in children is associated with above
average scores on the Wechsler Intelligence Scale for Children, and this association may be related to the child’s ability to filter background noise (Barutchu, Crewther et al. 2011).

Further research that investigates the effect of chiropractic care on health-related quality of life should involve larger sample sizes, longer durations of care, and consider recruiting participants with impaired health status so ceiling effects are avoided that are associated with many instruments that measure health-related quality of life (Haywood, Garratt et al. 2005). The survey should also be interviewer administered in order to reduce the rate of missing responses. The SF-36 is suitable for self-completion or administration by a trained interviewer, with interviewer administered studies reporting slightly lower missing response rates (Hayes, Morris et al. 1995, Ware 2000, Haywood, Garratt et al. 2005). The trade-off for the lower missing response rates in interviewer administered studies is longer completion time (Haywood, Garratt et al. 2005). In the present study, the survey was self-completed by participants, but assistance to complete the survey was provided by a blinded assessor if required. Analysis revealed a number of missing responses, most of which related to questions focusing on ‘work’, but also some respondents skipped an entire page, most likely by accident. These missing responses resulted in subscale and summary scores being unable to be calculated for some individuals. In order to reduce the missing response rate in future studies involving older participants, it is recommended that SF-36 surveys be interviewer administered, or else survey questionnaires should be checked for completion during assessment visits.

The results of this trial also need to be corroborated using similar interventions and outcomes assessment procedures before they can be regarded as anything more than tentative (Feise 2002). Future studies investigating the effect of chiropractic care on health-related quality of life and joint position sense should also consider using a larger sample size, as the results reported in this trial only just met the criteria for statistical significance. There would be a very real risk of making a type II error in any future studies that have similar power to the current study.

This study produced some interesting results that suggest chiropractors could play a role in reducing falls risk in older adults. To enhance the implications of this research on policy and public health practices further studies are required that investigate the effect of
chiropractic care on the incidence of falls in older adults. Chapter three highlights the fact that very little is currently known regarding the potential impact of chiropractic care on the incidence of fall in older adults. The logical next step would be further pilot testing in this area, followed by a well-designed, large scale, randomised controlled clinical trial if felt to be warranted.
CHAPTER 7. CONCLUSIONS

Falls are a major health concern for older adults as they are a significant cause of death, injury, and loss of quality of life (American Geriatrics Society 2001, Taylor and Stretton 2004). Besides the loss to society that results from falls related deaths, there are significant economic, health, and social impacts on the community due to the physical, mental and emotional trauma associated with falls (Taylor and Stretton 2004, Stephenson, Langley et al. 2005). When the social and economic costs of falls are combined it has been estimated that falls in New Zealand cost the country $1.8 billion per year (Collins 2012). Approximately 30-40% of community dwelling older adults suffer from at least one fall per year, with this figure rising to approach 80% when a variety of risk factors are present (Tinetti, Speechley et al. 1988, Dyson 2005, Gill, Taylor et al. 2005). A number of these risk factors are influenced by sensory and/or motor function which are known to decline in older adults (Lord and Ward 1994, Sturnieks, St George et al. 2008, Deandrea, Lucenteforte et al. 2010). A growing body of evidence suggests that chiropractic care may play a role in improving sensorimotor function that is a risk factor for falling (Haavik and Murphy 2012), yet little was known about role that chiropractors and other manual therapists may play in preventing falls in their patients.

Chapter three reviewed the literature relating to the effect of manual therapy on postural stability and falls. This systematic review concluded that no published research adequately investigates the role that manual therapy may play in preventing falls, and that only a limited amount of research exists that supports a role for manual therapy in improving postural stability and balance.

Besides the potential for a positive treatment effect of chiropractic care on fall risk, there is also a general public health role that chiropractors may play in preventing falls. Little was known about the demographics and fall risk status of older chiropractic patients. It was therefore unknown if older chiropractic patients are representative of the wider community or if they are at an even greater risk of falling due to the nature of the complaints that bring them into chiropractic practices. A cross-sectional study was carried out to explore this issue, the results of which were presented in Chapter four. The primary aim of the study was to gain an indication of the occurrence of previous falls, risk factors
for falls, and balance deficits, in older patients attending a group of chiropractic practices in Auckland and Melbourne. It was hoped that by better understanding the risk of falls in their older patients, it would help to encourage chiropractors to play a primary role in detection of falls risks and engage in falls prevention strategies. The study concluded that older chiropractic patients, even those who had been under care for some time, displayed significant falls risk factors and they were as likely to have experienced a fall in the past 12 months as the general older population. The study emphasised that chiropractors should be aware that their older patients are at risk of falling despite the length of time they have been receiving chiropractic care.

The results of the preliminary research reported above suggested that further research was required to establish whether chiropractors can play a positive role in reducing falls risk in their older patients. The main trial of the thesis was therefore planned and carried out in order to address this hole in the literature.

The main trial investigated the effect of 12 weeks of chiropractic care on sensorimotor function in older adults using a pragmatic randomised controlled trial design. The pragmatic approach to the study, with a ‘usual care’ control group, was chosen due to the nature of the chiropractic intervention, which impedes the blinding of participants and care-givers (Rosner 2012). This design limits the conclusions that can be made regarding potential mechanisms of action, and introduces the potential for placebo effects to influence the results. However, the limited number of exclusion criteria that were used and the flexibility given to chiropractors concerning their patient management improved the external validity of the trial.

The results of this trial indicated that aspects of sensorimotor integration and multisensory integration associated with fall risk, improved in a group of community dwelling older adults receiving chiropractic care. The chiropractic group also displayed small statistically significant improvements in health-related quality of life related to physical health when compared to a ‘usual care’ control. These results support previous research that suggests chiropractic care may alter somatosensory processing and sensorimotor integration (Haavik and Murphy 2012). However, the black-box nature of the intervention, the use of a usual care control group, and the lack of blinding in this study mean no firm conclusions
can be made about potential mechanisms of action associated with the improvements that were observed. This study builds on previous research and makes a significant contribution to the literature, as the bulk of this previous research comes from single intervention session basic science trials, in relatively healthy younger people, and often the changes reported do not indicate whether they reflect clinically relevant improvements or not (Haavik and Murphy 2012). This is the first trial to report improvements in multisensory integration in a group receiving chiropractic care. The chiropractic intervention was well tolerated by the older adults in this trial with no serious adverse events being reported that were due to the chiropractic intervention.

Further research is required to investigate which mechanisms were involved in the improvements observed in this trial, and to corroborate the findings that have been presented. Further research should also attempt to investigate whether the improvements in sensorimotor function and multisensory integration observed in the chiropractic group also reflect a reduction in overall fall risk.
APPENDICES

Appendices 1 and 2 – Participant Information Sheets for cross-sectional study.
Information Sheet

Project Title: Falls-risk of chiropractic patients

Principal Investigator: Dr Kelly Holt - Researcher, New Zealand College of Chiropractic. Telephone: 09-526-6789

Introduction:
You are invited to take part in this study which aims to investigate the risk of falling amongst elderly chiropractic patients. After reading this information sheet you will be given at least 24 hours to consider whether or not you wish to take part in this study. Participation in this study is entirely voluntary (your choice) and you may choose not to participate in this study or withdraw from the study at any time without having to give a reason. This will in no way affect your continuing health care.

About the Study:
- This study aims to examine the falls risk profile of chiropractic patients over the age of 65.
- We are seeking 100 volunteers who are over the age of 65 who attend a chiropractor.
- Volunteers will be recruited by holding information evenings for local chiropractors who will then be asking patients in their practices if they would like to participate.
- The study will be based at the New Zealand College of Chiropractic in Newmarket, Auckland. Data collection will take place at a number of chiropractic practices throughout Auckland and Melbourne, Australia.
- If you decide to participate in this study you will only need to be assessed once. This assessment will take about an hour to complete and will be free of charge.
- During this assessment a health and falls history will be taken and you will be asked to complete some questionnaires to establish your balance confidence, quality of life, and disability related to neck pain. You will then be assessed using a functional test that is an established falls risk predictor and includes asking you to complete a number of tasks such as standing with your eyes closed and retrieving an object from the floor.
- The researchers are interested to see if these tasks are difficult for you to complete.
- The final assessment will be conducted using a portable balance platform. This computerised system will assess your postural stability and sway.
These tests will help us to establish how well you can balance on your feet and whether or not you are at risk of having a fall. By collecting this data we hope to establish the falls risk profile of elderly people in Australasia who present to chiropractors. We will also collect valuable data to help plan for future studies that will investigate the effect of chiropractic care on falls risk.

Participant Eligibility
To be eligible to participate in this study you need to be community dwelling and 65 years of age or older and currently be under chiropractic care. If you require a cane, walker or other assistive device to walk will also be eligible but if you are wheelchair bound or are unable to stand unassisted for 1 minute you will be ineligible to participate as you will be unable to complete the required balance testing.

Procedures
- If you agree to take part in this study you will be asked to sign a consent form that indicates you have been informed of what is involved in the study and you are volunteering to participate.
- A trained research assistant will assess you over a single 1 hour period. The assessment will take place at a location convenient to you and will be scheduled at a time convenient to both yourself and the research assistant.
- At the beginning of the assessment the research assistant will discuss the procedures with you and ask you to complete a health and falls history form as well as questionnaires that will assess your quality of life, balance confidence and any neck pain that you may have.
- Your postural sway and balance will then be assessed using the Berg Balance Scale and a computerised balance platform. These assessments will involve you attempting a number of tasks such as standing with your eyes closed, retrieving an object from the floor and moving from a seated to standing position.
- Following the assessment the research assistant will let you know the results of your balance assessment and if you are at an increased risk of falling they will provide you with information and advice to help you to minimise that risk.

Benefits and Risks
During the assessment you will be asked to complete a number of tasks that are designed to test your balance. There is a small possibility that you could lose your balance while completing these tasks. The researcher is trained to observe and assist you if necessary in case you do lose your balance during the test. The assessment procedures have been used on many thousand people similar to yourself and they have an extremely high level of safety. Remember that if at any time during the assessment you feel uncomfortable or unsafe you can withdraw from the study and the assessment will cease.

The benefit to you of participating in this study is that you will be provided with a free report indicating whether or not you are at an increased risk of falling, and if you are, you will be given information and advice to help decrease your risk of having a fall.

Compensation
In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation and Compensation Act. ACC cover is not automatic and your case will need to be assessed by ACC according to the provisions of the 2002 Injury Prevention Rehabilitation and Compensation Act. If your claim is accepted by ACC, you still might not get any compensation. This depends on a number of factors such as whether you are an earner or non-earner. ACC usually provides only partial reimbursement of costs and expenses and there may be no lump sum compensation payable. There is no cover for mental injury unless it is a result of physical injury. If you have ACC cover, generally this will affect your right to sue the investigators.

If you have any questions about ACC, contact your nearest ACC office or the investigator.

**General information**

1. If you require further information about this study please contact the principal investigator Dr Kelly Holt (Contact details at the bottom of this form)
2. If you need an interpreter one will be provided
3. You may have a friend, family or whanau support to help you understand the risks and/or benefits of this study and any other explanation you may require.
4. You may also have a friend, family or whanau accompany you at all times during the study.
5. During the brief health history interview you do not have to answer all the questions, and you may stop the interview at any time.
6. If you have any queries or concerns regarding your rights as a participant in this study you may wish to contact a Health and Disability Advocate:
   
   Telephone: 0800 555 050

7. No reimbursement for your travel costs is available for this study.

**Confidentiality**

Your confidentiality will be respected at all times during this study. No material which could personally identify you will be used in any reports on this study. Your examination findings will be recorded using a confidential code number that will be assigned to you. The record of your examination findings will be recorded initially on paper and then transferred to a secure password encoded computer database. You paper record will be stored in a locked storage cupboard in the office of the Director of Research at the New Zealand College of Chiropractic. All records from this study will be kept for a duration of 10 years following the completion of the study at which time they will be destroyed. Your examination findings and records will be available only to the researchers helping to conduct this study.

**Results**

The results of this study will be presented at the annual New Zealand College of Chiropractic Research Day. You will be invited to attend this presentation. It is expected
that results will be presented at the research day which will be held in October 2008. Results will also be submitted for publication in an appropriate research journal. There is often a significant delay between conducting a research study and publication of the results. If you would like to discuss your individual results please contact the principal investigator Dr Kelly Holt (Contact details at the bottom of this form).

**Ethical Approval**
This study has received ethical approval from the Northern Y Regional Ethics Committee.

Please feel free to contact the principal investigator if you have any questions about this study.

**Principal Investigator:**
Dr Kelly Holt  
Researcher / Lecturer  
New Zealand College of Chiropractic  
6 Harrison Rd, Mt Wellington, Auckland  
Telephone: (09) 526-6789  
Email: spineworks@ihug.co.nz

For any further queries regarding this study, please contact the NZCC Director of Research:

Dr Heidi Taylor  
Director of Research  
New Zealand College of Chiropractic  
6 Harrison Rd, Mt Wellington, Auckland  
Telephone: (09) 526-6789
1. **Study Title**: The Falls-Risk Profile of Elderly Patients Presenting to Private Chiropractic Practices in Auckland and Melbourne.

2. **Investigators**: Dr Paul Noone B.App.Sc(Chiro), PhD, DACNB

3. **Introduction**:

   The following information describes the study and your role if you choose to participate.

   Your chiropractor will answer questions you may have about the study. The information contained in this Information Sheet will help you to understand the possible risks and benefits involved in the study, what alternatives are available and what would happen. Also your rights and responsibilities will be outlined. Please note you **cannot** receive any reward for being a part of this study.

4. **Purpose of the Study**:

   You are invited to participate in a research study which is being conducted in order to establish the falls risk profile of elderly people in Australasia who present to chiropractors. The researchers hope that by collecting this data they can help to educate chiropractors to better care for their elderly patients and they also hope to collect valuable data to help plan for future studies that will investigate the effect of chiropractic care on falls risk.

   This study will take up to 60 minutes of your time and will only require one assessment visit with you. This assessment can take place at your regular chiropractor’s office.

5. **Study Procedures**:

   If you agree to participate in this study you will be asked to come to your chiropractor’s office for a single assessment with a researcher. This assessment will take up to 60 minutes and will involve you:

   - Filling in up to 4 short questionnaires
   - Taking part in a short face to face interview. In this interview the researcher will ask you some questions to help identify whether you have any falls risk factors present and also about any history of falls that you may have had.
   - Performing some manual tasks that are designed to measure how good your balance is. These tasks include activities such as moving from sitting to standing, standing with your eyes closed, standing on one foot. Some of these tasks will take place on a computerised balance platform that will measure the amount you sway.

6. **Risks and Discomforts**:

   This assessment will involve asking you to perform tasks that test your balance. When performing these tasks there is a small chance that you will lose your
balance. The researcher conducting these tests with you has been trained to ensure that the risk to you during this assessment is minimal. Strict guidelines will be followed to minimise any risk there may be of you having a fall while participating in this study.

7. **Possible Benefits:** The benefit to you of taking part in this study is you will receive a free comprehensive falls risk assessment. If you are found to have a high risk of having a fall you will be given information that will help you to reduce your risk of having a fall.

8. **Voluntary Participation/Right to Refuse or Withdraw:**
There is no obligation for you to be involved in this study. If you do not participate your normal treatment plan will be followed. If you decide to participate in the study and later feel that you no longer wish to be part of it, you may withdraw from the study at any time without prejudice to any current or future medical treatment.

9. **Confidentiality:**
Your records relating to this study and any other information received will be kept strictly confidential and will be securely stored for 10 years following the completion of this study. The Director of Research at the New Zealand College of Chiropractic will be responsible for its safe keeping. However staff participating in your care and other agencies authorised by law, may inspect the records related to the study. In the event you are admitted to hospital as a result of an adverse event resulting from this study, your treating doctor may require access to your study records. Your identity will not be revealed and your confidentiality will be protected in any reviews and reports of this study which may be published.

10. **Adverse Events and Compensation for Injury:**
If you should suffer any injury from participating in this study, you will be given appropriate medical treatment however, in the event you do not have private health insurance and you require hospitalisation, you will be admitted to a public hospital. Please note you retain all your legal rights in relation to this study.

Compensation for medical expenses shall not be deemed an admission of fault or liability by the researcher or any other person or institution. By signing the Consent Form, you are not waiving any of the legal rights which you otherwise would have as a participant in a research study, and you are not releasing anyone involved in this research study from liability or negligence.

Information on compensation can be obtained from the Human Research Ethics Committee listed below or at the Medicines Australia website at www.medicinesaustralia.com.au

11. **Payment /Costs**
No reimbursement of costs are available to you for participating in this study. Every attempt will be made to schedule your assessment at the same time as a scheduled visit to see your chiropractor in order to eliminate any travel costs to you.

12. **Investigators Benefits**
The research assistant is being remunerated to conduct this study. He/she will not allow a conflict of interest to compromise their position or this research study.
13. **Consent**

The researcher is required to provide you with all information regarding the nature and purpose of the research study and risks/benefits. You should be given the opportunity to discuss these. It must be stated that you are free to withdraw anytime and that if you do not participate you will not suffer any prejudice.

14. **Advice And Information**

If you have any further questions regarding this study, please do not hesitate to contact

Dr Paul Noone on 3-9802-5942.

The Bellberry Human Research Ethics Committee has reviewed this study. Should you wish to discuss the study or view a copy of the Complaint procedure with someone not directly involved, particularly in relation to matters concerning policies, information or complaints about the conduct of the study or your rights as a participant, you may contact the Chairman, Bellberry Human Research Ethics Committee on 08 8297 2323.

All study participants should be provided with a copy of the Information Sheet and Consent Form for their personal records.
Appendices 3 and 4 – Participant Consent Forms for cross-sectional study
Consent Form

Title: Falls-risk of chiropractic patients

REQUEST FOR INTERPRETER

<table>
<thead>
<tr>
<th>Language</th>
<th>Translation</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>English</td>
<td>I wish to have an interpreter.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maori</td>
<td>E hiahia ana ahau ki tetahi kaiwhakamaori/kaiwhaka pakeha korero.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cook Island</td>
<td>Ka inangaro au i tetai tangata uri reo.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fijian</td>
<td>Au gadreva me dua e vakadewa vosa vei au</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Niuean</td>
<td>Fia manako au ke fakaaga e tahana tagata fakahokohoko kupu.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Samoan</td>
<td>Ou te mana’o ia i ai se fa’amaataa upu.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tokelaun</td>
<td>Ko au e fofo ki he tino ke fakaliliu te gagana Peletania ki na gagana o na</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>motu o te Pahefika</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Tongan</td>
<td>Oku ou fiema’u ha fakatonulea.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other</td>
<td>Other languages to be added following consultation with relevant communities.</td>
<td></td>
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</table>

1. I have read and I understand the information sheet dated 14/4/08 for volunteers taking part in the study designed to investigate the falls risk of elderly chiropractic patients. I have had the opportunity to discuss this study. I am satisfied with the answers I have been given.

2. I have had the opportunity to use whanau support or a friend to help me ask questions and understand the study.

3. I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time and this will in no way affect my continuing health care or academic progress.
4. I understand that my participation in this study is confidential and that no material which could identify me will be used in any reports on this study.

5. I have had time to consider whether to take part.

6. I know who to contact if I have any side effects to the study.

7. I know who to contact if I have any questions about the study.

8. I understand that I will be invited to a presentation of the results of this study which will take place during the annual New Zealand College of Chiropractic Research Day.

I __________________________ (full name) hereby consent to take part in this study.

Signature: ___________________________________ Date: __________________

Researchers: Dr Kelly Holt (Chief Investigator), Dr Paul Noone, Dr Neil Peterson, Nick Garrett.

Contact Number: The researchers involved in this study can be contacted at the New Zealand College of Chiropractic: Telephone: 09-526-6789

<table>
<thead>
<tr>
<th>RESEARCHER TO COMPLETE</th>
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<tbody>
<tr>
<td>Project explained by:</td>
</tr>
<tr>
<td>Project role:</td>
</tr>
<tr>
<td>Signature:</td>
</tr>
</tbody>
</table>
CONSENT FORM

Research Study Title: The Falls-Risk Profile of Elderly Patients Presenting to Private Chiropractic Practices in Auckland and Melbourne.

I ____________________________ the undersigned hereby voluntarily consent to my involvement in the research project titled ‘The Falls-Risk Profile of Elderly Patients Presenting to Private Chiropractic Practices in Auckland and Melbourne.’

I acknowledge that the nature, purpose and risks have been fully explained to my satisfaction by ___________________. I have also been provided with an Information Sheet regarding the research.

Specifically, the details of the following procedure(s) proposed have been explained to me:

- A falls risk assessment will be conducted on me in the office of my regular chiropractor.

- This assessment will involve me:
  - Filling in up to 4 short questionnaires
  - Taking part in a short face to face interview
  - Performing some manual tasks that are designed to measure how good my balance is. These tasks include activities such as moving from sitting to standing, standing with my eyes closed, standing on one foot. Some of these tasks will take place on a computerised balance platform that will measure the amount I sway.

The anticipated length of time it will take for me to complete these activities will be up to 60 minutes. These activities have a very good safety record and should not involve any discomfort. A trained research assistant will be on hand at all times to ensure that the risk to me during my assessment is minimal.

- Although I understand that the purpose of this research study is to improve the quality of chiropractic care, it has also been explained that my involvement may not be of any direct benefit to me.

- I have been given the opportunity to have a member of my family or another person present while the study is explained to me.

- I have been told that no information regarding my medical history will be divulged and the results of any tests involving me will not be published so as to reveal my identity.

- I understand that access will be required to my medical records for the purpose of this study as well as for quality assurance, auditing and in the event of a serious adverse event.

- I understand that I am free to withdraw from the study at any stage without prejudice to future treatment. If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.

- I am 18 years of age or over.

- I consent to my GP being notified of any information deemed necessary as a result of my participation in this study.

- I declare that all my questions have been answered to my satisfaction.

SIGNATURE OF STUDY PARTICIPANT: ____________________________ DATE: ____________________________

NAME OF INVESTIGATOR: ____________________________
SIGNATURE OF INVESTIGATOR: ____________________________ Date: ____________

In the event that a witness is present the following signing clause is to be used.

SIGNED __________________________ DATED __________________________

Witness

ADDRESS __________________________________________________________

I declare that I have been present when the research was explained to the above participant and I believe that the participant has an appreciation and understanding of the explanation given and that the consent was freely given.

Witness: __________________________________________________________
Appendices 5, 6, 7, 8 and 9 – Questionnaires used in the cross-sectional study that are not in common use.

Items include:

- Demographic, Health History and Fall Risk Questionnaire
- Berg Balance Scale
- Activities-specific Balance Confidence Scale
- Revised Oswestry Questionnaire
- Neck Pain Disability Index Questionnaire
Falls Risk Profile of Australasian Chiropractic Patients

Number of Visits Over the Past 12 Months: 219
Falls Risk for Older People Questionnaire

1. Number of falls in the past 12 months:
   - Nil
   - 1
   - 2
   - If yes was an injury sustained:
     - No
     - Minor injury, did not require medical attention
     - Minor, did require medical attention
     - Severe injury (fracture etc)
       - If yes to severe did they require hospitalization

2. List all medications:
   - ____________________  •  ____________________
   - ____________________  •  ____________________
   - ____________________  •  ____________________
   - ____________________  •  ____________________
   - ____________________  •  ____________________
   - ____________________  •  ____________________
   - ____________________  •  ____________________
   - ____________________  •  ____________________
   - ____________________  •  ____________________

     - Sedative
     - Antidepressant
     - Neuroleptic
     - Central acting analgesic
     - Digoxin
     - Diuretics
     - Type 1 antiarrhythmic
     - Vestibular suppressant

3. Do you have any of the following medical conditions:
   - Arthritis
   - Other neurological condition (Problem with your brain or nervous system)
   - Respiratory condition (Breathing problems)
   - Lower limb amputation
   - Parkinson’s Disease
   - Osteoporosis
   - Diabetes
   - Vestibular Disorder (Balance disorder)
   - Dementia
   - Other dizziness
   - Peripheral Neuropathy (Nerve problems in your arms or legs)
   - Lower limb joint replacement
   - Cardiac Conditions (Heart problems)
   - Back Pain (Complete Oswestry)
   - Stroke
   - Neck Pain (Complete NDI)
4. Do you have any uncorrected vision problems
   □ Yes
5. Do you have any uncorrected hearing problems
   □ Yes
6. Do you have any foot problems (corns, bunions, swelling etc)
   □ Yes

7. Cognitive Status – (Abbreviated Mental Test)
   
   QUESTION
   a) What is your age?
   b) What is the time to the nearest hour?
   c) I’m going to give you an address, I’d like you to remember it and I’ll ask you to repeat it back to me later. (Ask to repeat at the end of the test)
   d) What is the year?
   e) What is the name of the clinic that you are currently situated?
   f) Can you recognize two people? (Chiro, CA, 2 photos of well-known people)
   g) What is your date of birth?
   h) In which year did the first world war start?
   i) What is the first name of the Queen of England?
   j) Count backwards from 20 down to 1
   (DON’T FORGET TO REPEAT THE ADDRESS)
8. Do you have any problems with continence? (Do you have any trouble with your bowel and bladder such as not being able to hold on, not making it to the toilet in time, or having an accident in bed?)
   - Yes

9. Do you have to get up to go to the toilet in the night 3 or more times?
   - Yes

10. Has your food intake dropped in the last 3 months due to a loss of appetite, digestive problems, chewing or swallowing difficulties?
    - No
    - Small change, but intake remains good
    - Moderate loss of appetite
    - Severe loss of appetite / poor oral intake

11. Have you had any weight loss in the last 12 months?
    - Nil
    - Minimal (>1kg or unsure)
    - Moderate(1-3kg)
    - Marked (> 3kg)

12. How many alcoholic drinks do you have in a week?
    - Nil
    - 1-3
    - 4-10
    - 11+

13. Do you use a walking aid such as a walker or cane etc?
    - Yes (If yes circle one or both: INDOORS / OUTDOORS)

14. How physically active are you?
    - Very active (exercises 3 times per week)
    - Moderate activity (exercises twice or less per week)
    - Not very active ( rarely leaves the house)
    - Inactive (rarely leaves one room of the house)

15. Do you ever feel faint when you stand up?
    - Yes

IF NO FALLS IN THE LAST 12 MONTHS FINISH QUESTIONNAIRE HERE.

16. Has your physical activity level changed since your last fall?
    - Yes

17. When you had your last fall was there anything in the area around you that contributed to the fall – e.g. loose rug or uneven footpath)
    - Yes

18. Prior to your last fall how much assistance did you require for your personal care activities of daily living (e.g. dressing, grooming)?
    - None
    - Supervision
    - Some assistance required
    - Completely dependent
19. Prior to your last fall how much assistance did you require for instrumental activities of daily living such as shopping, housework, laundry?
   ☐ None
   ☐ Supervision
   ☐ Some assistance required
   ☐ Completely dependent

20. Has this changed since the most recent fall?
   ☐ Yes
BERG BALANCE SCALE*

ITEM DESCRIPTION SCORE (0-4)
1. Sitting to standing _____
2. Standing unsupported _____
3. Sitting unsupported _____
4. Standing to sitting _____
5. Transfers _____
6. Standing with eyes closed _____
7. Standing with feet together _____
8. Reaching forward with outstretched arm _____
9. Retrieving object from floor _____
10. Turning to look behind _____
11. Turning 360 degrees _____
12. Placing alternate foot on stool _____
13. Standing with one foot in front _____
14. Standing on one foot _____
TOTAL _____

GENERAL INSTRUCTIONS
Please demonstrate each task and/or give instructions as written. When scoring, please record the lowest response category that applies for each item. In most items, the subject is asked to maintain a given position for specific time. Progressively more points are deducted if the time or distance requirements are not met, if the subject's performance warrants supervision, or if the subject touches an external support or receives assistance from the examiner. Subjects should understand that they must maintain their balance while attempting the tasks. The choices of which leg to stand on or how far to reach are left to the subject. Poor judgment will adversely influence the performance and the scoring. Equipment required for testing are a stopwatch or watch with a second hand, and a ruler or other indicator of 2, 5 and 10 inches (5, 12.5 and 25 cm). Chairs used during testing should be of reasonable height. Either a step or a stool (of average step height) may be used for item #12.

1. SITTING TO STANDING
INSTRUCTIONS: Please stand up. Try not to use your hands for support.
( ) 4 able to stand without using hands and stabilize independently
( ) 3 able to stand independently using hands
( ) 2 able to stand using hands after several tries
( ) 1 needs minimal aid to stand or to stabilize
( ) 0 needs moderate or maximal assist to stand

2. STANDING UNSUPPORTED
INSTRUCTIONS: Please stand for two minutes without holding.
( ) 4 able to stand safely 2 minutes
( ) 3 able to stand 2 minutes with supervision
( ) 2 able to stand 30 seconds unsupported
( ) 1 needs several tries to stand 30 seconds unsupported
( ) 0 unable to stand 30 seconds unassisted
If a subject is able to stand 2 minutes unsupported, score full points for sitting unsupported. Proceed to item #4.
3. SITTING WITH BACK UNSUPPORTED BUT FEET SUPPORTED ON FLOOR OR ON A STOOL
INSTRUCTIONS: Please sit with arms folded for 2 minutes.
( ) 4 able to sit safely and securely 2 minutes
( ) 3 able to sit 2 minutes under supervision
( ) 2 able to sit 30 seconds
( ) 1 able to sit 10 seconds
( ) 0 unable to sit without support 10 seconds

4. STANDING TO SITTING
INSTRUCTIONS: Please sit down.
( ) 4 sits safely with minimal use of hands
( ) 3 controls descent by using hands
( ) 2 uses back of legs against chair to control descent
( ) 1 sits independently but has uncontrolled descent
( ) 0 needs assistance to sit

5. TRANSFERS
INSTRUCTIONS: Arrange chairs(s) for a pivot transfer. Ask subject to transfer one way toward a seat with armrests and one way toward a seat without armrests. You may use two chairs (one with and one without armrests) or a bed and a chair.
( ) 4 able to transfer safely with minor use of hands
( ) 3 able to transfer safely definite need of hands
( ) 2 able to transfer with verbal cueing and/or supervision
( ) 1 needs one person to assist
( ) 0 needs two people to assist or supervise to be safe

6. STANDING UNSUPPORTED WITH EYES CLOSED
INSTRUCTIONS: Please close your eyes and stand still for 10 seconds.
( ) 4 able to stand 10 seconds safely
( ) 3 able to stand 10 seconds with supervision
( ) 2 able to stand 3 seconds
( ) 1 unable to keep eyes closed 3 seconds but stays steady
( ) 0 needs help to keep from falling

7. STANDING UNSUPPORTED WITH FEET TOGETHER
INSTRUCTIONS: Place your feet together and stand without holding.
( ) 4 able to place feet together independently and stand 1 minute safely
( ) 3 able to place feet together independently and stand for 1 minute with supervision
( ) 2 able to place feet together independently and to hold for 30 seconds
( ) 1 needs help to attain position but able to stand 15 seconds feet together
( ) 0 needs help to attain position and unable to hold for 15 seconds

8. REACHING FORWARD WITH OUTSTRETCHED ARM WHILE STANDING
INSTRUCTIONS: Lift arm to 90 degrees. Stretch out your fingers and reach forward as far as you can. (Examiner places a ruler at end of fingertips when arm is at 90 degrees. Fingers should not touch the ruler while reaching forward. The recorded measure is the distance forward that the finger reach while the subject is in the most forward lean position. When possible, ask subject to use both arms when reaching to avoid rotation of the trunk.)
( ) 4 can reach forward confidently >25 cm (10 inches)
( ) 3 can reach forward >12.5 cm safely (5 inches)
( ) 2 can reach forward >5 cm safely (2 inches)
( ) 1 reaches forward but needs supervision
9. PICK UP OBJECT FROM THE FLOOR FROM A STANDING POSITION
INSTRUCTIONS: Pick up the shoe/slipper which is placed in front of your feet.
( ) 4 able to pick up slipper safely and easily
( ) 3 able to pick up slipper but needs supervision
( ) 2 unable to pick up but reaches 2-5cm (1-2 inches) from slipper and keeps balance independently
( ) 1 unable to pick up and needs supervision while trying
( ) 0 unable to try/needs assist to keep from losing balance or falling

10. TURNING TO LOOK BEHIND OVER LEFT AND RIGHT SHOULDERS WHILE STANDING
INSTRUCTIONS: Turn to look directly behind you over toward left shoulder. Repeat to the right. Examiner may pick an object to look at directly behind the subject to encourage a better twist turn.
( ) 4 looks behind from both sides and weight shifts well
( ) 3 looks behind one side only other side shows less weight shift
( ) 2 turns sideways only but maintains balance
( ) 1 needs supervision when turning
( ) 0 needs assist to keep from losing balance or falling

11. TURN 360 DEGREES
INSTRUCTIONS: Turn completely around in a full circle. Pause. Then turn a full circle in the other direction.
( ) 4 able to turn 360 degrees safely in 4 seconds or less
( ) 3 able to turn 360 degrees safely one side only in 4 seconds or less
( ) 2 able to turn 360 degrees safely but slowly
( ) 1 needs close supervision or verbal cueing
( ) 0 needs assistance while turning

12. PLACING ALTERNATE FOOT ON STEP OR STOOL WHILE STANDING UNSUPPORTED
INSTRUCTIONS: Place each foot alternately on the step/stool. Continue until each foot has touched the step/stool four times.
( ) 4 able to stand independently and safely and complete 8 steps in 20 seconds
( ) 3 able to stand independently and complete 8 steps >20 seconds
( ) 2 able to complete 4 steps without aid with supervision
( ) 1 able to complete >2 steps needs minimal assist
( ) 0 needs assistance to keep from falling/unable to try

13. STANDING UNSUPPORTED ONE FOOT IN FRONT
INSTRUCTIONS: (DEMONSTRATE TO SUBJECT)
Place one foot directly in front of the other. If you feel that you cannot place your foot directly in front, try to step far enough ahead that the heel of your forward foot is ahead of the toes of the other foot. (To score 3 points, the length of the step should exceed the length of the other foot and the width of the stance should approximate the subject's normal stride width)
( ) 4 able to place foot tandem independently and hold 30 seconds
( ) 3 able to place foot ahead of other independently and hold 30 seconds
( ) 2 able to take small step independently and hold 30 seconds
( ) 1 needs help to step but can hold 15 seconds
( ) 0 loses balance while stepping or standing

14. STANDING ON ONE LEG
INSTRUCTIONS: Stand on one leg as long as you can without holding.
( ) 4 able to lift leg independently and hold >10 seconds
( ) 3 able to lift leg independently and hold 5-10 seconds
( ) 2 able to lift leg independently and hold = or >3 seconds
( ) 1 tries to lift leg unable to hold 3 seconds but remains standing independently
( ) 0 unable to try or needs assist to prevent fall
The Activities-specific Balance Confidence (ABC) Scale*

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

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

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

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

PLEASE READ:
This questionnaire has been designed to enable us to understand how much your back pain has affected your ability to manage your everyday activities. Please answer each section by ticking the ONE CHOICE that most applies to you. We realize that you may feel that more than one statement may relate to you, but please just tick the box next to the one choice which most closely describes your problem right now.

SECTION 1 - Pain Intensity
- The pain comes and goes and is very mild.
- The pain is mild and does not vary much.
- The pain comes and goes and is moderate.
- The pain is moderate and does not vary much.
- The pain comes and goes and is severe.
- The pain is severe and does not vary much.

SECTION 2 - Personal Care (Washing, Dressing, etc.)
- I would not have to change my way of washing or dressing in order to avoid pain.
- I do not normally change my way of washing or dressing even though it causes some pain.
- Washing and dressing increases the pain, but I manage not to change my way of doing it.
- Washing and dressing increases the pain and I find it necessary to change my way of doing it.
- Because of the pain, I am unable to do some washing and dressing without help.
- Because of the pain, I am unable to do any washing or dressing without help.

SECTION 3 - Lifting
- I can lift heavy weights without extra pain.
- I can lift heavy weights, but it causes extra pain.
- Pain prevents me from lifting heavy weights off the floor.
- Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently positioned, e.g., on a table.
- Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned.
- I can only lift very light weights at the most.

SECTION 4 - Walking
- Pain does not prevent me from walking any distance.
- Pain prevents me from walking more than one mile.
- Pain prevents me from walking more than ½ mile.
- Pain prevents me from walking more than ¼ mile.
- I can only walk while using a cane or on crutches.
- I am in bed most of the time and have to crawl to the toilet.

SECTION 5 - Sitting
- I can sit in any chair as long as I like without pain.
- I can only sit in my favorite chair as long as I like.
- Pain prevents me from sitting more than one hour.
<table>
<thead>
<tr>
<th>SECTION 6 - Standing</th>
</tr>
</thead>
<tbody>
<tr>
<td>I can stand as long as I want without pain.</td>
</tr>
<tr>
<td>I have some pain while standing, but it does not increase with time.</td>
</tr>
<tr>
<td>I cannot stand for longer than one hour without increasing pain.</td>
</tr>
<tr>
<td>I cannot stand for longer than ½ hour without increasing pain.</td>
</tr>
<tr>
<td>I cannot stand for longer than ten minutes without increasing pain.</td>
</tr>
<tr>
<td>I avoid standing because it increases the pain straight away.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>SECTION 7 - Sleeping</th>
</tr>
</thead>
<tbody>
<tr>
<td>I get no pain in bed.</td>
</tr>
<tr>
<td>I get pain in bed, but it does not prevent me from sleeping well.</td>
</tr>
<tr>
<td>Because of pain, my normal night’s sleep is reduced by less than one-quarter.</td>
</tr>
<tr>
<td>Because of pain, my normal night’s sleep is reduced by less than one-half.</td>
</tr>
<tr>
<td>Because of pain, my normal night’s sleep is reduced by less than three-quarters.</td>
</tr>
<tr>
<td>Pain prevents me from sleeping at all.</td>
</tr>
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<tr>
<th>SECTION 8 – Social Life</th>
</tr>
</thead>
<tbody>
<tr>
<td>My social life is normal and gives me no pain.</td>
</tr>
<tr>
<td>My social life is normal, but increases the degree of my pain.</td>
</tr>
<tr>
<td>Pain has no significant effect on my social life apart from limiting my more energetic interests, e.g., dancing, etc.</td>
</tr>
<tr>
<td>Pain has restricted my social life and I do not go out very often.</td>
</tr>
<tr>
<td>Pain has restricted my social life to my home.</td>
</tr>
<tr>
<td>I have hardly any social life because of the pain.</td>
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<tr>
<th>SECTION 9 – Traveling</th>
</tr>
</thead>
<tbody>
<tr>
<td>I get no pain while traveling.</td>
</tr>
<tr>
<td>I get some pain while traveling, but none of my usual forms of travel make it any worse.</td>
</tr>
<tr>
<td>I get extra pain while traveling, but it does not compel me to seek alternative forms of travel.</td>
</tr>
<tr>
<td>I get extra pain while traveling which compels me to seek alternative forms of travel.</td>
</tr>
<tr>
<td>Pain restricts all forms of travel.</td>
</tr>
<tr>
<td>Pain prevents all forms of travel except that done lying down.</td>
</tr>
</tbody>
</table>

<table>
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<tr>
<th>SECTION 10 – Changing Degree of Pain</th>
</tr>
</thead>
<tbody>
<tr>
<td>My pain is rapidly getting better.</td>
</tr>
<tr>
<td>My pain fluctuates, but overall is definitely getting better.</td>
</tr>
<tr>
<td>My pain seems to be getting better, but improvement is slow at present.</td>
</tr>
<tr>
<td>My pain is neither getting better nor worse.</td>
</tr>
<tr>
<td>My pain is gradually worsening.</td>
</tr>
<tr>
<td>My pain is rapidly worsening.</td>
</tr>
</tbody>
</table>
NECK PAIN DISABILITY INDEX QUESTIONNAIRE

PLEASE READ:
This questionnaire has been designed to enable us to understand how much your neck pain has affected your ability to manage your everyday activities. Please answer each section by ticking the ONE CHOICE that most applies to you. We realize that you may feel that more than one statement may relate to you, but please just tick the box next to the one choice which most closely describes your problem right now.

SECTION 1 - Pain Intensity
- I have no pain at the moment.
- The pain is very mild at the moment.
- The pain is moderate at the moment.
- The pain is fairly severe at the moment.
- The pain is very severe at the moment.
- The pain is the worst imaginable at the moment.

SECTION 2 - Personal Care (Washing, Dressing, etc.)
- I can look after myself normally without causing extra pain.
- I can look after myself normally, but it causes extra pain.
- It is painful to look after myself and I am slow and careful.
- I need some help, but manage most of my personal care.
- I need help every day in most aspects of self-care.
- I do not get dressed, I wash with difficulty and stay in bed.

SECTION 3 - Lifting
- I can lift heavy weights without extra pain.
- I can lift heavy weights, but it gives extra pain.
- Pain prevents me from lifting heavy weights off the floor, but I can manage if they are conveniently positioned, for example, on a table.
- Pain prevents me from lifting heavy weights, but I can manage light to medium weights if they are conveniently positioned.
- I can lift very light weights.
- I cannot lift or carry anything at all.

SECTION 4 - Reading
- I can read as much as I want to with no pain in my neck.
- I can read as much as I want to with slight pain in my neck.
- I can read as much as I want to with moderate pain in my neck.
- I cannot read as much as I want because of moderate pain in my neck.
- I cannot read as much as I want because of severe pain in my neck.
- I cannot read at all.

SECTION 5 - Headaches
- I have no headaches at all.
- I have slight headaches which come infrequently.
- I have moderate headaches which come infrequently.
- I have moderate headaches which come frequently.
- I have severe headaches which come frequently.
- I have headaches almost all the time.

**SECTION 6 - Concentration**
- I can concentrate fully when I want to with no difficulty.
- I can concentrate fully when I want to with slight difficulty.
- I have a fair degree of difficulty in concentrating when I want to.
- I have a lot of difficulty in concentrating when I want to.
- I have a great deal of difficulty in concentrating when I want to.
- I cannot concentrate at all.

**SECTION 7 - Work**
- I can do as much work as I want to.
- I can only do my usual work, but no more.
- I can do most of my usual work, but no more.
- I cannot do my usual work.
- I can hardly do any work at all.
- I cannot do any work at all.

**SECTION 8 – Driving**
- I can drive my car without any neck pain.
- I can drive my car as long as I want with slight pain in my neck.
- I can drive my car as long as I want with moderate pain in my neck.
- I cannot drive my car as long as I want because of moderate pain in my neck.
- I can hardly drive at all because of severe pain in my neck.
- I cannot drive my car at all.

**SECTION 9 – Sleeping**
- I have no trouble sleeping.
- My sleep is slightly disturbed (less than 1 hour sleepless).
- My sleep is mildly disturbed (1-2 hours sleepless).
- My sleep is moderately disturbed (2-3 hours sleepless).
- My sleep is greatly disturbed (3-5 hours sleepless).
- My sleep is completely disturbed (5-7 hours).

**SECTION 10 – Recreation**
- I am able to engage in all of my recreational activities with no neck pain at all.
- I am able to engage in all of my recreational activities with some pain in my neck.
- I am able to engage in most, but not all of my recreational activities because of pain in my neck.
- I am able to engage in a few of my recreational activities because of pain in my neck.
- I can hardly do any recreational activities because of pain in my neck.
- I cannot do any recreational activities at all.
Appendices 10 and 11 – Main trial and reliability/validity trial Participant Information Sheets
Information Sheet
Project Title: Reliability of Tests of Sensorimotor Function

Principal Investigator: Dr Kelly Holt – PhD Student, University of Auckland. Ph: 09-526-6789
Supervisors: Dr Raina Elley, Associate Professor, University of Auckland, and Dr Heidi Haavik, Director of Research, New Zealand College of Chiropractic. Ph: 09-526-2104

You are invited to take part in this study, which aims to investigate the reliability of a number of tests of sensorimotor function. Participation in this study is entirely voluntary (your choice) and you may choose not to participate in this study or withdraw from the study at any time without having to give a reason. This will in no way affect your continuing health care.

About the study:
This study will be conducted at the New Zealand College of Chiropractic in Auckland. We would like to recruit 15 adults to take part in this study. People taking part will be asked to complete 4 different tests that measure your balance, joint movements and ability to respond to lights and sounds. We plan to use these tests in a future clinical trial and we want to make sure that the tests are reliable if we repeat them on the same person twice in a row. All testing will be completed in one session that will last for approximately 40 minutes. During this testing session we will not be asking you to do anything apart from complete the tests. No treatment or other intervention will be applied to you between tests. You are free to stop the assessment at any time. You may have a friend, family or whanau support to help you understand the risks and benefits of this study or accompany you at all times during the study.

Can I take part?
You may be eligible to take part in this study if:
- If you are 18 years of age or older

If it is known that you have one of the following conditions or if any of the following statements apply to you, you will not be able to participate in the study:
- You are unable to stand unassisted for 1 minute (as you will not be able to complete our testing procedures)
- You are unable to understand the study information or consent process

Are there any risks?
There is also a small risk of injury during testing procedures. The balance evaluation we will use has been used for many years with older adults at a high risk of falling and has been proven to be a safe method of evaluating postural stability. To ensure the highest degree of participant safety while performing these tests all examiners are on hand to prevent loss of balance and have been trained to identify risk factors or signs that may indicate you are becoming unsteady. In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation and Compensation Act. If you have any questions about ACC, contact your nearest ACC office or the investigator.

Confidentiality:
Your confidentiality will be respected at all times during this study. No material which could personally identify you will be used in any reports on this study. Your assessment results will be
recorded using a confidential code number that will be assigned to you. The record of your assessment will be recorded initially on paper and then transferred to a secure password encoded computer database. Your paper record will be stored in a locked storage cupboard in the office of the Director of Research at the New Zealand College of Chiropractic. All records from this study will be kept for 10 years after the study at which time they will be destroyed. Your assessment results will be available only to the researchers helping to conduct this study. If you would like the investigators to discuss any information obtained during the course of this trial with your GP, they will be available to do so. However, no information will be passed onto your GP without your consent.

Results:
If you would like to discuss the results of this study, or your individual results, please contact the principal investigator so this can be arranged.

Ethical Approval:
This study has received ethical approval from the Northern Y Regional Ethics Committee. If you have any queries or concerns regarding your rights as a participant in this research study, you can contact an independent Health and Disability Advocate. This is a free service provided under the Health & Disability Commissioner Act: Ph: 0800 555050; Fax: 0800 27877678 (0800 2SUPPORT), Email: advocacy@hdc.org.nz

Please feel free to contact the principal investigator if you have any questions about this study. Kelly Holt, Ph: 09-526-6789

Please keep this sheet for your information
Information Sheet
Project Title: Randomised Controlled Trial of Chiropractic Care to Improve Risk of Falls and Sensorimotor Function in Older People

Principal Investigator: Dr Kelly Holt – PhD Student, University of Auckland. Ph: 09-526-6789
Supervisors: Dr Raina Elley, Associate Professor, University of Auckland, and Dr Heidi Haavik, Director of Research, New Zealand College of Chiropractic. Ph: 09-526-2104

You are invited to take part in this study, which aims to investigate the effects of chiropractic care on risk factors for falls and sensory and motor function in older adults. Participation in this study is entirely voluntary (your choice) and you may choose not to participate in this study or withdraw from the study at any time without having to give a reason. This will in no way affect your continuing health care.

About the study:
This study will be conducted at the New Zealand College of Chiropractic and chiropractic practices around the Auckland area. We would like to recruit 60 adults over the age of 65 to take part in this study. People taking part will be randomly assigned (by chance) to 1 of 2 groups. One group will be offered 12 weeks of chiropractic care once to three times per week at no charge. Chiropractic care will be provided by experienced registered chiropractors at a private practice near where you live. Each visit will take about 20 minutes. During these visits the chiropractor will perform a thorough health assessment, possibly take some x-rays and then check your spine for problems and perform one or more chiropractic adjustments if a problem is found. A chiropractic adjustment may involve spinal manipulation (you may hear a CLICK) or alternative procedures may be used involving a special table or a small mechanical instrument that helps the chiropractor to adjust your spine without using a manipulation procedure. The second group of participants will receive no chiropractic care during the time that they are involved in the study, but when their involvement in the study is complete (after 12 weeks) they will be offered the same programme of chiropractic care at no charge. During the course of the study all participants will be assessed at the beginning of the study, after 4 weeks and after 12 weeks by researchers from the New Zealand College of Chiropractic. Each of these assessments will take approximately 40 minutes to complete and will measure your balance, joint movements and ability to respond to lights and sounds. We will also ask you to fill in a questionnaire that measures your quality of life. You are free to stop the assessment or treatment at any time. You may have a friend, family or whanau support to help you understand the risks and benefits of this study or accompany you at all times during the study.

Can I take part?
You may be eligible to take part in this study if:
- If you are 65 years of age or older
- You are interested in receiving chiropractic care

If it is known that you have one of the following conditions or if any of the following statements apply to you, you will not be able to participate in the study:
- You have received chiropractic care or spinal manipulation within the past six months
- You are unable to stand unassisted for 1 minute (as you will not be able to complete our testing procedures)
• You have a severe illness or a condition that means it is dangerous to provide you with chiropractic care (e.g. cancer of the spine, you are at a high risk of bleeding, you have a fracture in your spine due to osteoporosis)
• You are unable to understand the study information or consent process
• You are suspected of having a problem with the arteries in your neck that could mean it is not safe to adjust your neck.
• A chiropractor finds no problem in your spine that they may be able to help you with.

Are there any risks?
Chiropractic care may involve a variety of manual therapy procedures including manipulation or mobilisation which have a small risk of causing physical harm. Adverse events associated with chiropractic care are generally transient and involve mild musculoskeletal soreness. The risk of serious adverse events due to chiropractic care is very low. A recent study that followed almost 29,000 chiropractic treatment consultations reported no serious adverse events. Serious adverse events that have been linked to spinal manipulation include conditions such as cerebrovascular injury (stroke) and fractures. Recent studies found no association between chiropractic care and stroke in those over the age of 45, however it is possible that a small risk does exist even in older adults. We will undertake an initial assessment to ensure there is minimal risk to you. As a part of your chiropractic examination the chiropractor may be required to take x-rays of your spine to ensure that it is safe to provide chiropractic care. There is a small risk of cancer associated with being x-rayed. If x-rays are required the chiropractor will use modern x-ray techniques to reduce the risk to you but a small risk will remain. You will be examined and adjusted using procedures that are customarily used in chiropractic practice and that conform to best practice guidelines specified by the New Zealand Chiropractic Board with respect to appropriate management of older chiropractic patients. When these guidelines are followed chiropractic care for older patients is considered to be safe and is associated with high levels of patient satisfaction.

Besides the risks associated with the provision of chiropractic care there is also a small risk of injury during testing procedures. The balance evaluation we will use has been used for many years with older adults at a high risk of falling and has been proven to be a safe method of evaluating postural stability. To ensure the highest degree of participant safety while performing these tests all examiners are on hand to prevent loss of balance and have been trained to identify risk factors or signs that may indicate you are becoming unsteady. In the unlikely event of a physical injury as a result of your participation in this study, you may be covered by ACC under the Injury Prevention, Rehabilitation and Compensation Act. If you have any questions about ACC, contact your nearest ACC office or the investigator.

Confidentiality:
Your confidentiality will be respected at all times during this study. No material which could personally identify you will be used in any reports on this study. Your examination findings will be recorded using a confidential code number that will be assigned to you. The record of your examination findings will be recorded initially on paper and then transferred to a secure password encoded computer database. Your paper record will be stored in a locked storage cupboard in the office of the Director of Research at the New Zealand College of Chiropractic. All records from this study will be kept for 10 years after the study at which time they will be destroyed. Your examination findings and records will be available only to the researchers helping to conduct this study. If you would like the investigators or your treating chiropractor to discuss any information obtained during the course of this trial with your GP, they will be available to do so. However, no information will be passed onto your GP without your consent.

Results:
If you would like to discuss the results of this study, or your individual results, please contact the principal investigator so this can be arranged.

**Ethical Approval:**
This study has received ethical approval from the Northern Y Regional Ethics Committee. If you have any queries or concerns regarding your rights as a participant in this research study, you can contact an independent Health and Disability Advocate. This is a free service provided under the Health & Disability Commissioner Act: Ph: 0800 555050; Fax: 0800 27877678 (0800 2SUPPORT), Email: advocacy@hdc.org.nz

Please feel free to contact the principal investigator if you have any questions about this study. Kelly Holt, Ph: 09-526-6789

Please keep this sheet for your information
Appendices 12 and 13 – Main trial and reliability/validity trial Participant Consent Forms
**Consent Form**

**THIS FORM WILL BE HELD FOR A PERIOD OF 10 YEARS**

**Title: Reliability of Tests of Sensorimotor Function**

I have read and I understand the information sheet dated 7/2/2012 for volunteers taking part in the study designed to investigate the reliability of tests of sensorimotor function. I have had the opportunity to discuss this study. I am satisfied with the answers I have been given.

- I have had the opportunity to use whanau support or a friend to help me ask questions and understand the study.
- I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time and this will in no way affect my continuing health care.
- I understand that my participation in this study is confidential and that no material which could identify me will be used in any reports on this study.
- I understand that the investigation will be stopped if it should appear harmful to me.
- I understand the compensation provisions for this study
- I have had time to consider whether to take part.
- I know who to contact if I have any side effects to the study.
- I know who to contact if I have any questions about the study.

I  ___________________________________ (full name) hereby consent to take part in this study.

Signature: ___________________________________  Date:  _____________________

*Researchers: Kelly Holt, PhD Student, Department of General Practice and Primary Healthcare, University of Auckland; Dr Raina Elley, Associate Professor, Department of General Practice and Primary Healthcare, University of Auckland; Dr Heidi Haavik, Director of Research, New Zealand College of Chiropractic*
Contact Number: The researchers involved in this trial can be contacted at the New Zealand College of Chiropractic: Telephone: 09-526-6789, or University of Auckland: Telephone: 09-373-7599 extn 86523

<table>
<thead>
<tr>
<th>RESEARCHER TO COMPLETE</th>
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<td>Project explained by:</td>
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<td>Project role:</td>
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<td>Signature:</td>
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</table>
Consent Form

THIS FORM WILL BE HELD FOR A PERIOD OF 10 YEARS

Title: Randomised Controlled Trial of Chiropractic Care to Improve Risk of Falls and Sensorimotor Function in Older People

I have read and I understand the information sheet dated 2/8/2011 for volunteers taking part in the study designed to investigate the effects of chiropractic care on sensory and motor function in older adults. I have had the opportunity to discuss this study. I am satisfied with the answers I have been given.

• I have had the opportunity to use whanau support or a friend to help me ask questions and understand the study.

• I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time and this will in no way affect my continuing health care.

• I understand that my participation in this study is confidential and that no material which could identify me will be used in any reports on this study.

• I understand that the treatment, or investigation, will be stopped if it should appear harmful to me.

• I understand the compensation provisions for this study

• I have had time to consider whether to take part.

• I know who to contact if I have any side effects to the study.

• I know who to contact if I have any questions about the study.

I ________________________________ (full name) hereby consent to take part in this study.

Signature: ___________________________ Date: ___________________________
Researchers: Kelly Holt, PhD Student, Department of General Practice and Primary Healthcare, University of Auckland; Dr Raina Elley, Associate Professor, Department of General Practice and Primary Healthcare, University of Auckland; Dr Heidi Haavik, Director of Research, New Zealand College of Chiropractic

Contact Number: The researchers involved in this trial can be contacted at the New Zealand College of Chiropractic: Telephone: 09-526-6780, or University of Auckland: Telephone: 09-373-7599 extn 86523

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</table>
Randomised Controlled Trial of Chiropractic Care to Improve Risk of Falls and Sensorimotor Function in Older People: Screening Questionnaire

Participant Name: ___________________________ Date of Birth: _____________

Contact Number: ____________________________

Address:
_______________________________________________________________________
________________________________________________________________________

Eligibility Criteria:

1. Have you had a fall in the past 12 months? A fall is defined as (‘an unexpected event in which the participants come to rest on the ground, floor, or other lower level.)
   - Yes
   - No – (Ineligible to participate)

Details of Fall (including date): ______________________________________________
________________________________________________________________________

2. Do any of the following apply to you:
   - You are unable to remain standing unassisted for a minimum of 1 minute
   - You have been diagnosed with:
     - An anomaly of the spine such as dens hypoplasia, unstable os odontoideum
     - An acute fracture of the spine
     - An acute infection of the spine
     - Spinal cord tumour
     - Cancer of the spine
     - Frank disc herniation
     - Basilar invagination of the cervical spine
     - Arnold-Chiari malformation
     - Dislocation of the spine
     - Cauda equine syndrome
     - High risk of bleeding
     - A severe mental or physical disease (e.g. Alzheimer’s Disease, Schizophrenia, terminal cancer)
   - You will be unavailable for one week or more over the next 4 months due to planned travel or other commitments
   - You have received chiropractic care or other spinal manipulation during the past 6 months.
   - Chiropractic screening exam suggests no problem in the spine

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- **NONE OF THE ABOVE APPLY**
- You have current neck pain (COMPLETE NECK PAIN SCREENING QUESTIONNAIRE)
- You are currently suffering from headaches (COMPLETE HEADACHE QUESTIONNAIRE)

3. **Cognitive Status Assessment— (Abbreviated Mental Test)**

<table>
<thead>
<tr>
<th>QUESTION</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>k) What is your age?</td>
<td></td>
</tr>
<tr>
<td>l) What is the time to the nearest hour?</td>
<td></td>
</tr>
<tr>
<td>m) I’m going to give you an address, I’d like you to remember it and I’ll ask you to repeat it back to me later. (Ask to repeat at the end of the test)</td>
<td></td>
</tr>
<tr>
<td>n) What is the year?</td>
<td></td>
</tr>
<tr>
<td>o) What is the name of the clinic that you are currently situated?</td>
<td></td>
</tr>
<tr>
<td>p) Can you recognize two people? (Chiro, CA, 2 photos of well-known people)</td>
<td></td>
</tr>
<tr>
<td>q) What is your date of birth?</td>
<td></td>
</tr>
<tr>
<td>r) In which year did the first world war start?</td>
<td></td>
</tr>
<tr>
<td>s) What is the first name of the Queen of England?</td>
<td></td>
</tr>
<tr>
<td>t) Count backwards from 20 down to 1</td>
<td></td>
</tr>
</tbody>
</table>

(DON’T FORGET TO REPEAT THE ADDRESS)

Score ____/10 (6 or less requires follow up)
**SCREENING PROTOCOL FOR CERVICAL MANIPULATION - VERTEBRAL/INTERNAL CAROTID ARTERY DISSECTION AND VERTEBROBASILAR STROKE**

**Patient History Questions Relating Headache:**

The following questions relate to relative risks for VAD/VBS

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer/Score</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>What is the location of the pain?</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Where?</strong></td>
<td></td>
</tr>
<tr>
<td><strong>What is the nature of the pain?</strong></td>
<td></td>
</tr>
<tr>
<td><em>eg. lancinating, throbbing, aching, constant, intermittent, progressive etc.</em></td>
<td></td>
</tr>
<tr>
<td><strong>Describe?</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Was the onset abrupt or gradual?</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Describe?</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Does the pain radiate?</strong></td>
<td>(Yes/No)</td>
</tr>
<tr>
<td><strong>Where?</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Does the pain vary in intensity during the day?</strong></td>
<td>(Yes/No)</td>
</tr>
<tr>
<td><strong>When?</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Were there in precipitating factors?</strong></td>
<td></td>
</tr>
<tr>
<td><em>eg. trauma, trivial trauma, neck movements, neck posture etc.</em></td>
<td>(Yes/No)  No/1</td>
</tr>
<tr>
<td><strong>What is the severity of the pain compared to previous headaches?</strong></td>
<td>(VAS/10) &gt;8/10/1</td>
</tr>
<tr>
<td><strong>Describe?</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Is there any neck pain associated with the headache?</strong></td>
<td>(Yes/No) Yes/1</td>
</tr>
<tr>
<td><strong>Describe?</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Has there been any recent history of neck trauma?</strong></td>
<td>(Yes/No) Yes/1</td>
</tr>
<tr>
<td><strong>Describe?</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Is there a previous history of same or similar headaches?</strong></td>
<td>(Yes/No) No/1</td>
</tr>
<tr>
<td><strong>Describe?</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Any family history of stroke or arterial dissection?</strong></td>
<td>(Yes/No) Yes/1</td>
</tr>
<tr>
<td><strong>Describe?</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Is there a history of migraine headache?</strong></td>
<td>(Yes/No) Yes/1</td>
</tr>
<tr>
<td><strong>Describe?</strong></td>
<td></td>
</tr>
<tr>
<td>**Do Valsalva type manoeuvres aggravate the headache? <em>eg. cough, sneeze etc.</em></td>
<td>(Yes/No) Yes/1</td>
</tr>
<tr>
<td><strong>Describe?</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Does the patient suffer from advanced cervical osteoarthritis?</strong></td>
<td>(Yes/No) Yes/1</td>
</tr>
<tr>
<td><strong>Is there any pins &amp; needles or numbness in the limbs?</strong></td>
<td>(Yes/No) Yes/1</td>
</tr>
<tr>
<td><strong>Does the patient smoke or take oral contraceptives?</strong></td>
<td>(Yes/No) Yes/1</td>
</tr>
<tr>
<td><strong>Has there been any recent infection?</strong></td>
<td>(Yes/No) Yes/1</td>
</tr>
<tr>
<td><strong>Describe?</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Any previous history of cancer, bone infection or demineralisation diseases?</strong></td>
<td>(Yes/No) Yes/1</td>
</tr>
<tr>
<td><strong>Describe?</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Is there a history of hypertension/diabetes/atherosclerosis/hyperhomocysteinemia?</strong></td>
<td>(Yes/No) Yes/1</td>
</tr>
<tr>
<td><strong>Describe?</strong></td>
<td></td>
</tr>
</tbody>
</table>

**Total Score**

A total score of 8 or more would place the patient in a high risk category and it is recommended that CSMT should be avoided. A total score of 5 or less will not guarantee that it is safe to proceed with CSMT and clinical judgement is advised.
SCREENING PROTOCOL FOR CERVICAL MANIPULATION - VERTEBRAL/INTERNAL CAROTID ARTERY DISSECTION AND VERTEBROBASILAR STROKE

Patient History & Risk Factor Questions Relating Neck Pain:

The following questions relate to relative risks for VAD/VBS [Answer/Score]

What is the location of the pain?
Where?

What is the nature of the pain?
eg. lancinating, throbbing, aching, constant, intermittent etc.

Was the onset abrupt or gradual?
Describe?

Does the pain radiate?

Where?

Does the pain vary in intensity during the day?

When?

Were there any precipitating factors?

eg. trauma, trivial trauma, neck movements, neck posture etc.

Is there a previous history of same or similar neck pain?

Describe?

What is the severity of the pain compared to previous neck pain?

(VAS/10) [Yes/No] Yes/1

If there is any radicular pain?

Where?

Is there any headache associated with the neck pain?

Yes/1

Describe? [Refer to Headache Questions]

Any family history of stroke or arterial dissection?

Describe?

Any previous history of cancer, bone infection or demineralisation diseases

Describe?

Has there been any recent infection?

Yes/1

Describe?

Is there a history of hypertension/diabetes/atherosclerosis/hyperhemocysteinemia?

Yes/1

Describe?

Dose the patient smoke or take oral contraceptives?

Yes/1

Describe?

Is there a history of migraines headache?

Yes/1

Does the patient suffer from advanced cervical osteoarthritis?

Yes/1

Is there any pins & needles or numbness in the limbs?

Yes/1

Where? dermatomal/non-dermatomal

Total Score

A total score of 6 or more would place the patient in a high risk category and it is recommended that CSMT should be avoided. A total score of 5 or less will not guarantee that it is safe to proceed with CSMT and clinical judgement is advised.
The following questions relate to a high risk of VAD/VBS

Is there any pins & needles numbness in the head, face or mouth? (Yes/No) Yes

Is there any limb weakness, clumsiness, ataxia? (Yes/No) Yes

Is there any visual disturbance? (Yes/No) Yes

Describe?...

Is there any dizziness, light-headedness, disequilibrium? (Yes/No) Yes

Describe?...

Is there any nausea, vomiting? (Yes/No) Yes

Describe?...

Is there a recent onset of tinnitus? (Yes/No) Yes

Describe?...

Are there any episodes of fainting or drop attacks? (Yes/No) Yes

Describe?...

Is there any dysphagia? (Yes/No) Yes

Describe?...

Is there any dysarthria? (Yes/No) Yes

Describe?...

Has there been any recent significant neck trauma? (Yes/No) Yes

Describe?...

Is this pain unusual and severe and unlike previous neck pain and of sudden onset? (Yes/No) Yes

Describe?...

The pain is not aggravated or relieved by head or neck movement? (Yes/No) Yes

Does the pain appear to be non-mechanical in nature? (Yes/No) Yes

Do any neck, arm or shoulder movements cause neurological signs or symptoms? (Yes/No) Yes

What movements?...

Have there been any VBI symptoms with previous neck manipulation? (Yes/No) Yes

Describe?...

Any current use of anti-coagulants, steroids or strong analgesics? (Yes/No) Yes

What medication?...

Any personal history of stroke or arterial dissection? (Yes/No) Yes

Describe?...

Is there any connective tissue disorders? eg. Ehlers-Danlos/Marfan’s syndrome (Yes/No) Yes

Describe?...

Is there a history of Fibromuscular dysplasia? (Yes/No) Yes

Describe?...

Are there any known vascular anomalies? eg. hypoplastic arteries etc. (Yes/No) Yes

Describe?...

Is there a risk of atlanto-axial instability? eg. Down’s syndrome, Os odontoideum (Yes/No) Yes

Describe?...

Is there a history of medial cystic necrosis? (Yes/No) Yes

If the answer to any of these questions is yes then GSMT is contra-indicated and depending on the signs and symptoms the patient may require immediate medical attention.

NB The above questions are only a guide and should not be regarded as complete and they should be used in conjunction with standard patient history questioning and sound clinical judgment.
Appendix 15 – Main trial Baseline Characteristics and Follow-up Questionnaire
Baseline Characteristics and Follow-up Questionnaire

Name: ________________________

Pre

1- Have you had a fall in the past 12 months? For this study a fall is defined as ‘accidentally ended up on the floor or ground’ YES / NO
   - If yes how many falls did you have. ______ # of falls

2- How many medications do you take? ______ # of medications

3- Are you taking any medications to help you sleep, stabilise your moods, treat depression, anxiety or panic attacks? YES / NO
   - If yes, please list them:
     ________________________________________________________________
     ________________________________________________________________
     ________________________________________________________________

4- Have you ever suffered from a stroke? YES / NO

5- Do you live alone? YES / NO

6- Do you suffer from any muscle weakness? YES / NO

7- Do you have any problems with your balance? YES / NO

8- Do you have any gait deficits or problems when you walk? YES / NO

9- Do you have any visual deficits? YES / NO

10- Have you seen a chiropractor in the past? YES / NO
    - If so when was your last visit? ______ time since last visit

Post

1 - Did you have any falls while taking part in the study.

2- Did you see a chiropractor while in the study? YES / NO
   - If so how many visits did you have. ______ # of visits

3- While in the study did you have any hospitalisations (if so what for and how long were you admitted for), or injuries (if so please describe). YES / NO
Appendix 16 – Main trial advertising flyer
VOLUNTEERS NEEDED FOR A CHIROPRACTIC RESEARCH STUDY

At the New Zealand College of Chiropractic we are conducting a research project, in conjunction with the University of Auckland, which is investigating the effects of chiropractic care on balance and fall risk in older adults. Participants in this study will receive 12 weeks of free chiropractic care.

To be eligible to participate in the trial volunteers need to be:

- 65 years of age or older
- Able to stand unassisted for at least 1 minute
- Free from health conditions that will make it unsafe for them to receive chiropractic care
- Not currently receiving chiropractic care

Please call the lead researcher, Kelly Holt, on 526-2104 if you would like more information or you know someone who may be interested in participating in the study.
REFERENCES


Daligadu, J., H. Haavik, P. Yielder, J. Baarbe and B. Murphy (2013). "Alterations in cortical and cerebellar motor processing in subclinical neck pain patients following spinal manipulation." J Manipulative Physiol Ther, IN PRESS.


