Falls risk in older adults: the impact of neck pain, dizziness and manual therapy treatment

A thesis submitted in fulfilment of the requirements for the degree of Doctor of Philosophy

Julie Catherine Kendall

Bachelor of Applied Science (Complementary Medicine) RMIT University

Master of Clinical Chiropractic RMIT University

School of Health and Biomedical Sciences

College of Science, Engineering and Health

RMIT University

September 2018
Declarations

I certify that except where due acknowledgement has been made, the work is that of the author alone; the work has not been submitted previously, in whole or in part, to qualify for any other academic award; the content of the thesis is the result of work which has been carried out since the official commencement date of the approved research program; any editorial work, paid or unpaid, carried out by a third party is acknowledged; and, ethics procedures and guidelines have been followed.

I acknowledge the support I have received for my research through the provision of an Australian Government Research Training Program Scholarship.

Julie Kendall, September 2018
Acknowledgements

I would like to thank the chiropractors in Australia and Denmark who generously funded my stipend and project through the Chiropractors’ Association of Australia (National) and the Foundation for Chiropractic Research and Postgraduate Education of Denmark. Without these financial contributions, I would not have been able to visit the wonderful people and places of Denmark, to run the trial presented in Chapter 6, and to carry out the work in this thesis.

To my supervisors Professor Stephen Robinson, Dr Azharuddin Fazalbhoy, Dr Michael Azari, Professor Jan Hartvigsen and Professor Simon French, thank you for your guidance and mentorship of me, my work, and my transition from clinician to researcher. Michael, thank you for believing in me, and giving me the opportunity to undertake this PhD. Jan, I cannot express to you how much I learned from you and your team in the Department of Sports Science and Clinical Biomechanics at the University of Southern Denmark. I was blown away and inspired by the work you do as a team, and I very much hope to visit again. Thanks to you, Odense in Denmark will forever be in my heart. Simon, thank you for your supportive check-in emails and fine attention to detail in my work; I have learned so much from all your feedback on our publications together. Steve, thank you for picking me up at one of my lowest points; your support and encouragement have meant that I did not give up on this journey, my career is forever indebted to you. Finally, Az, your belief in me never wavered. Thank you for listening through the tears, the tantrums, and the hard-times. You never believed me each time I said I would quit and saw a stronger person inside me that I did not know existed. You made time for me in your schedule that didn’t exist, and for that I am so grateful.

Thank you to my fellow authors of the publications in this thesis: Professor Paolo Caserotti, Associate Professor Eleanor Boyle, Dr Lars Hvid and Matthias Skjødt. Paolo, thank you for providing your expertise for Chapters 3 and 4, and for trusting me with the data from the HANC project. Eleanor, thank you for very, very, very patiently going
through the statistical analysis in Chapter 3; while I may have come to Denmark “knowing nothing”, I left crammed full of knowledge, thanks to you. Lars and Matthias, thank you for humouring every time I did a ‘drop-in’ by your office, and always answering my never-ending emails with questions on the data. You were both so patient and always helpful.

The work in this thesis has further been support by the following people. Simon Brice, thank you for the generous loan of the harness used during force plate data collection (unpublished work related to the trial presented in Chapter 6), and thank you for supporting chiropractic research. Thank you, Franziska Wright for assisting with the participants and data collection (Chapter 6). Thank you, Matthew Wong and Adin Tan for your expertise and generous assistance with data collection (Chapter 6).

To my wonderful PhD colleagues: Kelvin Murray, Sam Harman, Dr Dawn Wong Lit Wan, Dr Jessica Owen, Dr Anna Hyde, Ruth Rossell, Danielle Baxter, Dr Anne Mølgaard Nielsen, Craig Moore, Dr Matt Fernandez and Dr Matthew Stevens. Your support and encouragement has meant so much to me. I would like to give a very special thank you to Kelvin. We started this journey together, and over the last five years we’ve both had our up and downs (and downs... and downs...). Thank you for your friendship and humour, and the work you did treating the participants (Chapter 6). I’ve made it to the end, and I’m waiting here at the finish line for you.

During a particularly tough time, I formed a Facebook group to motivate me to work on this thesis. Thank you to all the KickFINISHers who helped by literally bribing me to finish this thesis: Sarah Jansen, Elise Kumar, Anna Vrancic, Tiffany Waldron, Jess Thatcher, Danni Baxter, Katie Harris, Anna Reissig, Lily Keating, Dawn Wong Lit Wan, Morgan Junor, Kim Armstrong, Matthew Bulman, Megan Lutton, Sharmini Kumar, Vanessa Dingey, Mitchell Clark, Ingrid McCarthy, Matt Dingey, Anne Mølgaard Nielsen, Jessica Owen, Karla Rial, and Pearl Taylor. Your gifts, encouragement, and ‘likes’ made all the difference.
Finally, my biggest thanks of all are for Ramiro Fernandez. Ramiro, you’ve always supported me and encouraged me to live my life on my own terms; even when I make complicated life decisions, like doing a PhD. You’ve never doubted me, even when I doubted myself the most. Thank you for your words of encouragement, generous cuddles, and giving the best pep talks of anyone I know. I love you so much. Thank you.
Table of Contents

Declarations ........................................................................................................................ iii
Acknowledgements .............................................................................................................. iv
List of abbreviations .......................................................................................................... xii
List of figures .................................................................................................................... xiv
List of tables ....................................................................................................................... xv
Summary ........................................................................................................................... xvi
Publications arising from this thesis ................................................................................ xx
Conference presentations .............................................................................................. xxi
Poster presentations ...................................................................................................... xxi
Podium presentations ..................................................................................................... xxi
Chapter 1 - Introduction .................................................................................................... 22
  Statement of the problem ............................................................................................... 22
  Questions investigated by this thesis ............................................................................. 26
  Overview ......................................................................................................................... 27
Chapter 2 – Literature review ............................................................................................ 29
  Balance and stability ...................................................................................................... 29
    Neuroanatomy and physiology .................................................................................... 29
    Degeneration of balance with age ................................................................................. 33
  Instability ....................................................................................................................... 36
    Dizziness and instability in older adults ...................................................................... 36
    Dizziness, instability and concerns of falling ............................................................. 36
    Concerns of falling ...................................................................................................... 37
    Concerns of falling and pain in older adults ............................................................... 39
    Neck pain and instability ............................................................................................ 39
  Interventions for improving instability ........................................................................ 41
    Pharmacological interventions ................................................................................... 41
    Manual therapy ........................................................................................................... 42
    Manual therapy and proposed mechanisms ............................................................ 43
Randomisation .......................................................................................................... 117
Blinding ..................................................................................................................... 117
Analysis ...................................................................................................................... 117
Results ........................................................................................................................... 119
Recruitment ............................................................................................................... 119
Compliance ................................................................................................................ 121
Location ..................................................................................................................... 121
Blinding and overall improvement ............................................................................ 121
Costs ......................................................................................................................... 122
Harms ....................................................................................................................... 122
Clinical outcomes ..................................................................................................... 122
Sample size calculation ............................................................................................. 127
Discussion .................................................................................................................... 127
Recruitment .............................................................................................................. 127
Compliance with outcome assessment ..................................................................... 129
Compliance with the intervention .......................................................................... 129
Location .................................................................................................................... 129
Interventions and blinding ....................................................................................... 129
Costs ......................................................................................................................... 130
Harms ....................................................................................................................... 130
Strengths and limitations ......................................................................................... 130
Conclusions ............................................................................................................... 131
Declarations ................................................................................................................. 132
Chapter 7 – Discussion and conclusion ........................................................................... 134
Main research findings ................................................................................................. 135
   Chapter 3 Bothersome neck pain is associated with increased concerns of falling and poor balance ................................................................................................................. 135
   Chapter 4 Non-pharmacological treatment approaches improve non-specific dizziness and balance in older people ................................................................. 137
   Chapter 5 Neck pain influences balance in older people ....................................... 138
# List of abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AP</td>
<td>Anterior to posterior</td>
</tr>
<tr>
<td>AUD</td>
<td>Australian dollar</td>
</tr>
<tr>
<td>BBS</td>
<td>Berg Balance Scale</td>
</tr>
<tr>
<td>CBT</td>
<td>Cognitive behavioural therapy</td>
</tr>
<tr>
<td>COP</td>
<td>Centre of pressure</td>
</tr>
<tr>
<td>EMG</td>
<td>Electromyography</td>
</tr>
<tr>
<td>DASS</td>
<td>Depression Anxiety Stress Scale</td>
</tr>
<tr>
<td>DHI</td>
<td>Dizziness Handicap Inventory</td>
</tr>
<tr>
<td>FES-I</td>
<td>Falls Efficacy Scale International</td>
</tr>
<tr>
<td>HANC</td>
<td>Healthy Ageing Network of Competence study</td>
</tr>
<tr>
<td>LBP</td>
<td>Low back pain</td>
</tr>
<tr>
<td>MCID</td>
<td>Minimal clinically important difference</td>
</tr>
<tr>
<td>MDI</td>
<td>Major Depression Inventory</td>
</tr>
<tr>
<td>ML</td>
<td>Medial to lateral</td>
</tr>
<tr>
<td>MMSE</td>
<td>Mini-Mental State Examination</td>
</tr>
<tr>
<td>MoCA</td>
<td>Montreal Cognitive Assessment</td>
</tr>
<tr>
<td>NDI</td>
<td>Neck Disability Index</td>
</tr>
<tr>
<td>NP</td>
<td>Neck pain</td>
</tr>
<tr>
<td>NSAIDs</td>
<td>Non-steroidal anti-inflammatory drugs</td>
</tr>
<tr>
<td>NRS</td>
<td>Numerical rating scale</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomised controlled trial</td>
</tr>
<tr>
<td>Abbreviation</td>
<td>Description</td>
</tr>
<tr>
<td>--------------</td>
<td>-------------</td>
</tr>
<tr>
<td>SF12 MCS</td>
<td>SF12 mental health composite score</td>
</tr>
<tr>
<td>SF36 PCS</td>
<td>SF12 physical composite score</td>
</tr>
<tr>
<td>SMT</td>
<td>Spinal manipulative therapy</td>
</tr>
</tbody>
</table>
List of figures

Figure 1 Falls per 100 person-years by age................................................................. 22
Figure 2 Activator II instrument................................................................................. 53
Figure 3 Recruitment and participation................................................................. 59
Figure 4 Identification of included studies............................................................ 78
Figure 5 Neck pain and instability.......................................................................... 101
Figure 6 Low back pain and instability................................................................. 102
Figure 7 Flow of participants through the trial ................................................. 120
List of tables

Table 1 Description of participants ................................................................. 63
Table 2 Neck pain ....................................................................................... 64
Table 3 Concerns of falling and physical performance .................................... 65
Table 4 Characteristics of included studies ................................................. 79
Table 5 Risk of bias assessment of the included studies ......................... 87
Table 6 Clinical relevance assessment ......................................................... 88
Table 7 Group characteristics .................................................................... 100
Table 8 Concerns of falling and COP parameters .................................... 103
Table 9 Descriptions of clinical outcome measures .................................. 124
Table 10 Pre- and post-intervention clinical outcome measures ............. 126
Table 11 Proportion of improvement in primary clinical outcome measures .... 127
Summary

Falls place substantial personal and financial burdens on society, and increase in frequency with age. The proportion of older Australians is increasing, and interventions are needed to reduce the healthcare costs associated with ageing.

Neck pain and dizziness are common conditions presenting in older adults. Musculoskeletal pains, and neck pain in particular, are associated with impaired performance on balance tasks, feelings of instability and dizziness. This cluster of symptoms has been proposed to increase the risk of falls in older people; however, the relationship between neck pain, dizziness and stability has predominantly been examined in younger adult populations. Therefore, this thesis seeks to explore the relationship between neck pain and instability in older adults, to determine whether this population might benefit from manual therapy interventions.

The available literature examining manual therapies, including spinal manipulative therapy, suffers from: a lack of control groups; participant blinding; randomisation; clear inclusion criteria targeting older adults with falls-risk health conditions, such as musculoskeletal pain and/or dizziness; and consistent reporting on the interventions provided. Therefore, this thesis also involves designing and conducting a randomised controlled trial of spinal manipulative therapy to reduce neck pain and dizziness, and improve instability in older adults.

Specifically, this thesis answers four key questions: 1) Is neck pain associated with increased concerns of falling and decreased physical performance in an older community-based cohort? 2) Are non-pharmacological interventions effective for treating dizziness in older people? 3) Is the intensity of spinal pain increased in mobility-limited older adults who have increased concerns of falling and reduced balance performance? 4) Is it feasible to run a large trial to examine the effectiveness of spinal manipulative therapy for neck pain and non-specific dizziness in older people?
To examine the relationship between neck pain and instability in older adults, a cross-sectional study of community dwelling older persons in Denmark was conducted. This study investigated whether neck pain is associated with two common falls risk factors: concerns of falling and physical performance. Neck pain was common in older adults, with one in three participants reporting neck pain in the previous four weeks. Of these people with neck pain, a third had pain that interfered with activities and daily routines (bothersome pain). Bothersome neck pain was associated with significantly greater odds of having reduced physical performance and increased concerns of falling. However, these relationships became non-significant after adjusting for confounding factors. Bothersome neck pain and concerns of falling were confounded by depression, and bothersome neck pain and decreased physical performance were confounded by concerns of falling, depression and previous history of falls. This shows that bothersome neck pain in older people is associated with increased concerns of falling and decreased physical performance, which are two known risk factors for falls in older people. However, this relationship is only evident in people with bothersome pain, and these relationships are complicated by confounders, particularly depression.

A thorough examination was conducted of the literature on non-pharmacological interventions, including manual therapies, for dizziness in older adults. This systematic review found only seven controlled trials. All of these trials used exercise therapies as their main interventions. Trials were limited by their high risk of bias, and therefore, could not determine the effectiveness of these interventions for dizziness in this age group. This outcome highlights the paucity of literature on dizziness interventions in older age groups, and the need for rigorous controlled trials to assess the efficacy of manual therapies, including spinal manipulative therapy, in older adults.

The relationship between musculoskeletal pain and instability was examined further in another cross-sectional study of community-dwelling older Danes. These individuals had limited mobility, defined by a normal gait speed of <0.9m/s. This study showed that
increased intensity of neck pain was significantly associated with reduced balance performance, compared to mild neck pain. Furthermore, intense low back pain was significantly associated with increased concerns of falling compared to individuals without pain. This shows that intense pain, but not mild pain, is associated with a significant loss of stability in people with reduced mobility.

A randomised controlled trial was conducted using spinal manipulative therapy for neck pain and dizziness in older adults. Based on the generally poor quality of previous studies of manual therapy in older adults, due to lack of randomisation, blinding and clear inclusion criteria, this trial addressed these methodological issues, and assessed the feasibility of running larger trials. This trial recruited older adults with chronic neck pain and who had experienced dizziness in at least the last three months. To determine if a large trial could be conducted using this protocol it assessed recruitment rate, compliance, study location, blinding, treatment satisfaction, costs, harms, and adequate sample size. The use of sham instrument-assisted manipulation provided acceptable blinding, compliance and treatment satisfaction, and is feasible for future trials. Mild, transient harms of increased spinal pain or headaches were reported by some participants, which is consistent with previous studies of manual therapies. A fully-powered clinical trial may require modifications to the location and recruitment strategy to increase recruitment rates, to enable the required sample size.

This thesis project answered the four questions initially proposed. Neck pain is associated with increased concerns of falling and decreased physical performance in older adults; however, these relationships are confounded by a multitude of other factors. Future studies examining neck pain and instability in older adults should include measures of mood, physical performance and previous history of falling. There is currently insufficient evidence for the effectiveness of non-pharmacological interventions for treating dizziness in older people. Therefore, future rigorous controlled trials need to be conducted that target older adults. Intense neck pain, but not mild neck pain, is
associated with reduced balance in mobility-limited older adults. Interventions that aim to reduce intensity of musculoskeletal pain need to be applied to older adults. Finally, it is feasible to run a large sham-controlled trial to examine the effectiveness of spinal manipulative therapy for neck pain and non-specific dizziness in older people, with modifications to increase recruitment. These trials should target older adults with bothersome or intense neck pain, to determine if alleviating these factors reduces the associated instability and falls risk.
Publications arising from this thesis


Conference presentations

Poster presentations


Podium presentations


Chapter 1 - Introduction

Statement of the problem

Maintaining physical independence into older age is associated with reduced mortality, even after adjusting for key health status risk factors such as smoking, obesity and social isolation (Kaplan, Strawbridge, Cohen, & Hungerford, 1996; Reiner, Niermann, Jekauc, & Woll, 2013; Samitz, Egger, & Zwahlen, 2011). Therefore, addressing these risk factors to remain healthy and physically independent into older age is vitally important. Losing balance and experiencing a fall can result in trauma, increased hospitalisation and increased risk of death (Campbell et al., 1990; Cripps & Carman, 2001). Once a person experiences one fall, they are at an increased risk of experiencing subsequent falls, with the prevalence dramatically increasing with age (Figure 1). After experiencing a fall, an individual can develop fears and concerns of falling while performing daily activities and social routines (Deandrea et al., 2010). Falls lead to a cycle of reduced independence, loss of physical fitness and reduced social engagement.

Figure 1 Falls per 100 person-years by age.

Data taken from (Campbell et al., 1990), New Zealand. Falls become more prevalent with increasing age. As age increased (x-axis), the number of falls per 100 person years (y-axis) increases.
The number of older Australians is not only increasing, but the age distribution is becoming heavily weighted towards older aged Australians (Australian Bureau of Statistics, 2013). For example, the Australian Bureau of Statistics reported in November 2013 that with current projections, Australia’s population is due to double to 46 million by 2075, according to medium growth rate. This projection also predicts a dramatic change to the age structure, suggesting that the proportion of people aged over 65 years compared to other ages will increase to 22% by 2061, from only 14% of the 2013 population. The median age of the population will also rise from 37.3 years to 44.5 within this time. Older people experience an increased prevalence of multiple chronic conditions, which exponentially increase the cost of healthcare (Lehnert et al., 2011). As the older population continues to expand into the next half-century, it will be important to find strategies that limit the financial burden on the healthcare system. It has been proposed that the reasons for these increased costs include, but are not limited to: greater number of co-morbidities, increased number of physicians, increased hospital admissions and increased medication use (Lehnert et al., 2011).

Health conditions in older people can cascade into a spiral of co-morbidities requiring complex and costly treatment plans. As the number and proportion of older Australians increases, the total healthcare costs of falls in Australia are expected to increase to $1.375 billion per year by 2051 (Moller, 2003) this does not take into consideration indirect healthcare costs. Therefore, it is vital to look at health conditions at the top of this spiral of costly and demanding treatments. Falls can lead to major trauma, such as head injuries. Major trauma increases the likelihood of death, admittance to residential care facilities or rehabilitation facilities (Miu, Curtis, & Balogh, 2016). In older people trauma increases the severity of injuries compared to in younger people, and older people are more likely to be admitted to hospital and spend more time in hospital (Curtis et al., 2014). Injuries in older people become more costly as they often produce poorer functional outcomes, than would be expected in a younger adult. Older adults experience slower and more complicated recovery from trauma injuries due to the increased
incidence of co-morbidities with complications (Grossman, Miller, Scaff, & Arcona, 2002). Indirect consequences of falls in older people include increased fears of future falls and fear avoidance of physical activities (Delbaere, Crombez, Vanderstraeten, Willems, & Cambier, 2004). Fear avoidance of physical activities and fears of falls can prevent older people from leaving their homes, reducing their engagement in exercise and social activities, which are all predictors of developing frailty (Lang, Michel, & Zekry, 2009).

Frail older adults, who can no longer live independently, require costly supportive healthcare workers to visit them within their homes or admittance into round-the-clock care in residential care facilities. Once a person is admitted into residential care, they remain in care for the remainder of their life. Older people who have fallen contribute to major societal and individual burdens in Australia and worldwide (Campbell et al., 1990; Cripps & Carman, 2001). Falls prevention is a growing area of investigation due to the direct individual and societal consequences that we now understand. Increased resources, including research funding, are being prioritised towards falls prevention research. The Australian Federal Government has listed preventative healthcare as a priority area, and are steering towards better falls prevention healthcare, such as treatment and rehabilitation therapies.

Falls prevention can involve a combination of physical, psychological and environmental interventions. Environmental interventions include the installation of ramps, hand rails and non-slip mats. Since this thesis will focus on the risk factors associated with physical function it will not examine environmental contributors to falls risk. Increased physiological risks of falling in older people can be associated with underlying pathologies of the vestibular, cardiovascular and neurological systems or otherwise healthy, but underperforming physiology. This thesis will not examine pathological causes of dizziness and physical instability, rather it will examine physiological risk
factors associated with falls in otherwise healthy independent older people. It will not examine or determine mechanisms underlying falls.

Once an older person has experienced a fall, they suffer not only fractures and soft tissue injuries (Nevitt, Cummings, & Hudes, 1991), but ongoing reduced quality of life (Stenhagen, Ekström, Nordell, & Elmståhl, 2014). Of greater concern, experiencing an injurious fall more than doubles a person’s risk of subsequent falls (Pohl, Nordin, Lundquist, Bergström, & Lundin-Olsson, 2014). Treating these ongoing consequences of falls is difficult, and interventions to reduce falls from the outset are a key strategy of preventative healthcare in older people.

The reasons for experiencing a fall are multifaceted. Therefore, predicting falls in otherwise healthy people is difficult. Known risk factors for falls can be divided into three broad categories: physical limitations, behavioural risk and environmental contributors. The strongest predictor of falls is having a previous history of a fall. Falls are recurrent, and once a person has experienced one fall, it is likely that the reasons for falling in the first place remain unaddressed and continue to put the person at risk. So what are predictors in both previous fallers and people who have not yet fallen, and what are the underlying physical reasons for loss of balance and mobility? These critical questions remain to be answered. Physical function is the second strongest predictor of future falls, after a previous history of falls (Sherrington & Tiedemann, 2015). Physical performance is the ability to walk, sit, step and balance (van Lummel et al., 2015). These capabilities are determined by broad tests that measure a person’s overall mobility and balance, as there is no single measure or battery of tests that can accurately predict falls risk. However, adding more components to the test battery can increase the accuracy of testing.

This thesis focuses on key factors that have been postulated to increase the risk of falls in older people and aims to understand and characterise the effects of these factors on
Musculoskeletal pain is associated with reduced balance performance, an important component of physical performance (Stubbs, Schofield, Patchay, & Leveille, 2015b). Furthermore, neck pain specifically is associated with dizziness and feelings of instability and reduced balance (Treleaven, 2008). These subjective (dizziness) and objective (reduced balance) symptoms of instability have been associated with falls (Ekvall Hansson & Magnusson, 2013). It is not known if neck pain is associated with objective symptoms of instability, such as reduced physical performance and increased concerns of falling. Furthermore, it has not been determined if reducing neck pain and dizziness has a positive impact on physical performance and concerns of falls.

This thesis explores these topics, and provides preliminary data to develop a better understanding of stability in the context of musculoskeletal pain, and more specifically neck pain. Furthermore, this thesis provides preliminary data on developing a protocol for a large randomised controlled trial (RCT) to measure the effectiveness of a manual therapy intervention for neck pain and non-specific dizziness in older people.

Questions investigated by this thesis

- Is neck pain associated with increased concerns of falling and decreased physical performance in an older community-based cohort? (Cross Sectional Study)
- Are non-pharmacological interventions effective for treating dizziness in older people? (Systematic Review)
- Is the intensity of spinal pain increased in mobility-limited older adults who have increased concerns of falling and reduced balance performance? (Cross Sectional Study)
• Is it feasible to run a large trial to examine the effectiveness of spinal manipulative therapy (SMT) for neck pain and non-specific dizziness in older people? (RCT)

Overview

Chapter 1 provides an overview of risk factors for falling, specifically related to ageing, neck pain and dizziness in older people. Furthermore, it describes the rationale for manual therapy interventions to reduce neck pain and dizziness in older people through the presentation of existing literature. Ageing increases the risk of falls and reduced quality of life in people with musculoskeletal pain and dizziness. While there is evidence of the relationship between neck pain, dizziness and stability in younger adults, this overview highlights the need for quality literature that specifically examines older adults.

Chapter 2 is a systematic review of controlled trials for non-pharmacological interventions for dizziness in older people. This chapter examines the evidence supporting the efficacy of exercise, manual therapy and other non-pharmacological interventions for treating dizziness in older adults. While there have been trials in younger populations, this study exclusively examines people aged over 60 years.

Chapter 3 is a cross-sectional study of community-dwelling older Danes and the association between neck pain and physical performance and increased concerns of falling. This chapter examines whether neck pain is associated with two common falls risk factors: concerns of falling and physical performance.

Chapter 5 is a cross-sectional study of mobility-limited older adults with and without neck pain and low back pain. This study compares severe and mild pain intensities and their association with balance performance. Furthermore, this study examines whether pain is associated with increased concerns of falling.

Chapter 6 is a RCT of SMT for neck pain and dizziness in older people. This sham-controlled trial determines feasibility on recruitment rates, compliance with intervention
and outcome assessment, reviewing the study location, blinding, costs and reporting of harms. Additionally, sample size calculations for larger trials are calculated for the use of the dizziness handicap inventory (DHI) or neck disability index (NDI) as the primary outcome measure.

Chapter 7 is a discussion of where these studies sit within the literature, strengths and weaknesses of the thesis and recommendations for future research in this area.
Chapter 2 – Literature review

Balance and stability

Neuroanatomy and physiology

The ability of the human body to maintain an upright posture and counteract the effects of gravity involves the integration of several components of the nervous system, including the vestibular, visual and the proprioceptive senses. These components work together to adjust muscular tone in response to changing external stimuli; if this system of integration is compromised, there will be an under- or over-correction in response to gravity, and a subsequent failure to maintain posture.

The primary sensory organ for balance is the vestibular apparatus, located in the inner ear. The vestibular apparatus is a special proprioceptive sensory organ that is integrally involved in sustaining equilibrium, directing the gaze of the eyes in order to maintain a constant plane of vision. This is achieved through a sensory feedback response system and a motor output to modify muscle tone of the surrounding head and neck musculature to achieve balance (Strominger, Demarest, & Laemle, 2012). The vestibular apparatus is encased in a system of bony tubes and chambers that are situated within the petrous portion of each temporal bone, termed the bony labyrinth (Hall, 2015). This bony labyrinth is lined with a membranous tissue that forms the functional component of the system, termed the membranous labyrinth. The membranous labyrinth is made up of three semicircular canals and two large chambers known as the utricle and saccule. The membranous labyrinth also includes the cochlear, a canal that provides sensory stimulation for hearing, but does not contribute to equilibrium and balance.

The receptor end organs of each ear of the vestibular system include the three cristae ampullaris, the utricle, and the saccule. A crista ampullaris is a cone-shaped sensory organ that responds to rotational movement of fluid (endolymph) within the canal. Movement is detected by specialised nerve fibres that end in hair cells that extend into
the crista ampullaris. These hair fibres are coated in the gelatinous cupula. As rotational movement occurs, the endolymph within the canals moves across the cupula and displaces the hair cells. Movement of the hair cells excites the vestibulocochlear nerve (cranial nerve XIII). The vestibular system also detects acceleration of the head, through the maculae of the utricle and saccule. These maculae are similar to the cristae ampullaris, but are flat instead of cone-shaped. Their gelatinous membrane contains heavy otolith organs that displace the membrane with acceleration. In this way, the macula detects acceleration in the plane of orientation they are in. The maculae of the utricle and saccule detect horizontal and lateral movement, respectively. In this way, the hair cells in the utricle, saccule, and cristae ampullaris are able to detect movement and acceleration in all directions of head movement. These stimuli are integrated into the central nervous system through the vestibulocochlear nerve (cranial nerve VIII).

Information from the eyes is important for maintaining balance. To maintain an upright stance and posture, the eyes need to be level with the horizon. This is achieved through projections from the eyes to the superior colliculus in the midbrain. The superior colliculus integrates visual and vestibular information and mediates reflexes that cause movements of the head and eyes in response to positional changes of the body in space. The primary sense organs for vision are rod and cone cells located in the retina at the back of the eye. The cells are stimulated by light rays. Light rays pass into the eye through the cornea (a protective layer of transparent tissue in front of the pupil), the aqueous humour, the lens, vitreous humour and finally land on the retina. The aqueous and vitreous humours are fluid filled spaces that maintain the shape and pressure of the eye. The lens is the primary source of focusing the light rays onto the back of the retina for clear vision. Information from the rod and cone visual sense organs are transported to the central nervous system by the optic nerve (cranial nerve II). In this way, by keeping the eyes level with the horizon the visual system supports the vestibular system to maintain a sense of equilibrium.
Movement of the musculoskeletal system is detected by the proprioceptive sense organs, particularly the muscle spindles and Golgi tendon organs. Muscle spindles, located in the belly of the skeletal muscles, contain specialised receptors that are stimulated by stretching of the muscle spindle organ. These dynamic stretch receptors respond to stretch when the muscle is lengthened or contracted, activating a reflex arc via the sensory nerve that causes motor neurons to adjust the muscle tone. Golgi tendon organs are located in the tendons of skeletal muscles. An encapsulated receptor is stimulated by changed tension of the tendon, resulting from stretching or contracting the muscle. The stimulation of Golgi tendon organs causes motor neurons to be inhibited, which relaxes muscle fibres and prevents damage to the muscle by decreasing the tension. Additionally, Golgi tendon organs are able to distribute forces evenly across the muscle by inhibiting fibres that are overloaded. Both muscle spindles and Golgi tendon organs play an important role in giving feedback to the central nervous system about muscle stretch, tension and load. This feedback is used to control motor function, including maintaining posture and balance.

Vestibular, visual and proprioceptive senses are integrated through specialised reflexes. The vestibulospinal reflexes are a group of spinal and trunk reflexes that assist to maintain neck and body posture during movement tasks. Vestibular excitation activates spinal, trunk and distal muscles. These reflexes allow the head, body and limbs to respond to changes in head position in the absence of vision, for example during walking or standing in the dark (Fukuda, 1959; Peitersen, 1967). The vestibulo-ocular reflex allows the eyes to make composite movements when the head moves. Rotation of the head, detected through the vestibular system, triggers the vestibulo-ocular reflex, which causes the eyes to turn to the side opposite of movement. This assists the eyes to stay fixated while the head is moving. Similarly, the oculocephalic reflex uses proprioceptive information from the neck muscles to move the eyes and maintain fixed vision during head rotation.
During functional, everyday complex movements, balance and posture are primarily modulated through the three functional zones of the cerebellum (Strominger et al., 2012). The spinocerebellum area integrates proprioceptive and somatosensory information from the body and head, as well as auditory, visual and vestibular information. It plays two roles: i) it controls postural adjustments and eye movements in response to integrated sensory input; ii) it corrects the trajectory of the limbs during a movement to adjust for dynamic changes in body position. Vestibular information is integrated in the vestibulocerebellum (flocculonodular lobe), which receives input from the vestibular nuclei and adjusts the position of the eyes, head and trunk in response to changes in gravity or movement. Both the vestibular cerebellum and the spinocerebellum exert their influence on movement unconsciously. By contrast, the cerebrocerebellum interacts with the cerebral cortex to facilitate the smooth performance of conscious tasks. Conscious movement is initiated in the primary motor cortex of the frontal lobe (pre-central gyrus). Signals from 'upper' motor neurons in the motor cortex travel through the brainstem and down the spinal cord where they activate 'lower' motor neurons. The signal then propagates via the peripheral nerves to the muscles.

The vestibular, ocular, and musculoskeletal systems work together to maintain an upright stance and posture. Small discrepancies between these systems may result in mild impairment of balance and posture; for example, people feel dizzy and unsteady after riding a merry-go-round, or the balance and un-coordination seen with cerebellar impairment from alcohol intoxication (Sullivan, Rosenbloom, Deshmukh, Desmond, & Pfefferbaum, 1995). However, when there are larger or more sustained discrepancies in the synergy of vestibular, ocular, musculoskeletal and cerebellar function, postural balance can be compromised in a significant way (Ekvall Hansson & Magnusson, 2013; Kristjansson & Treleaven, 2009). Such compromises are a major contributor to the increased risk of falls in older people (Kurz, Oddsson, & Melzer, 2013; Muir, Kiel, Hannan, Magaziner, & Rubin, 2013).
Degeneration of balance with age

To work optimally, the vestibular apparatus relies on the maintenance of the receptor end-organs. As the human body ages, the vestibular apparatus undergoes wear and tear of the receptor end organs and neural communication pathways. This degradation affects the hair cell receptors specifically, and the nervous system more generally. The mechanisms responsible for these changes are outlined below.

Ageing is associated with a decreasing number and altering morphology of vestibular hair cells (Rosenhall, 1973; Rosenhall & Rubin, 1975). Whilst the cristae ampullaris are more severely affected, there is general loss of hair cells throughout the vestibular system (Rosenhall, 1973). Neural lysosomes and lipofuscin granules accumulate in the vestibular sensory epithelia with age. Lysosomes are organelles involved in cell waste disposal, and intracellular accumulations of these organelles are associated with increased ageing of cells (Brunk & Terman, 2002; Mindell, 2012). The accumulation of lipofuscin within lysosomes is a sign of oxidative damage and a marker of impaired cellular function (Brunk & Terman, 2002). The accumulation of lysosomes and lipofuscin within vestibular sensory cells has been postulated to contribute to a reduction in metabolism of these cells (Rosenhall & Rubin, 1975; Walther & Westhofen, 2007).

Ageing is also associated with changes in the otoconia, the special membrane with imbedded calcifications that displaces with head movement in the otolith organs (Walther & Westhofen, 2007). With age, the otoconia become fewer in number with pitted and roughened surfaces, particularly in the maculae sacculi (Ross, Johnsson, Peacor, & Allard, 1976). These changes are thought to be associated with otoconia misplacement, where otoconia break off and are swept into the semi-circular canals (Lim, 1973). Loss of otoconia in the semi-circular canals has been postulated to cause benign paroxysmal positional vertigo commonly seen in older adults (Walther & Westhofen, 2007). The displaced otoconia stimulate the hair cells of the cristae ampullaris, creating aberrant vestibular signals that then contribute to balance defects.
Arteriosclerosis of the labyrinth system has been proposed as a damaging mechanism in older adults (Droller & Pemberton, 1953; Wada et al., 2008). During a person’s lifetime, plaque builds up in the arteries of the cardiovascular system. Plaque reduces the blood flow capacity, particularly in small arterioles. This reduced blood flow leads to ischemia, with resulting loss of performance and death of cells (Guyton & Klmp, 1996).

The visual system likewise undergoes degradation with age. The lens often becomes stiffer with age and this loss of elasticity makes focusing on near objects difficult. This results in reading glasses being commonly prescribed to people as they get older. The lens can also become calcified with age; these opaque deposits, known as cataracts, restrict light from reaching the retina. Surgical removal of cataracts reduces the risk of falls (Brannan et al., 2003). The cells of the light-sensitive retina commonly degenerate with age. Age-related macular degeneration, the most common cause of blindness, is associated with the gradual degeneration of neurons at the fovea, the area responsible for high acuity in the centre of our visual field. These deficiencies in visual function impair balance and increase the risk of falls (Wood et al., 2011).

Similarly, the primary sense organs of proprioception degenerate with age. This is evident in older people, who commonly display reduced performance on tests of upper limb position (Herter, Scott, & Dukelow, 2014). Reduced sensitivity to proprioception increases the time needed to perform motor tasks (Helsen et al., 2016). These functional changes are associated with degeneration of the peripheral nerve endings and cell bodies due to ageing processes (Vaughan, Stanley, & Valdez, 2016). Furthermore, increasing age is associated with type 2 diabetes, which is associated with reduced proprioceptive function from diabetic neuropathy (Ettinger, Boucher, & Simonovich, 2018).

As well as degeneration of the nerve cells, control of the musculoskeletal and proprioceptive system adapts to the reduced physiological limitations (Geertsen, Willerslev-Olsen, Lorentzen, & Nielsen, 2017). Movement control in older age is often associated with a shift in locus from the reflex arcs mediated at the level of the spinal
cord, to conscious control, mediated by the cerebral cortex (Baudry, 2016). Thus when older adults stand, the tone of their soleus muscle is less strongly influenced by proprioceptive reflexes and more strongly influenced by descending corticospinal pathways, which show increased activity when compared to younger people. This shift towards cortical control is thought to be due to diminished proprioceptive input, and it results in slower postural corrections and increased cognitive load, both of which contribute to falls risk in older people (Baudry, 2016).

Likewise, the peripheral nervous system also deteriorates with age. Older adults with reduced sensory function in the lower limb display reduced gait speed and increased risk of falls compared to older adults with intact sensory function (Lipsitz et al., 2018).

Diabetes Mellitus is the inability to regulate blood glucose levels and is common in older age groups. Prolonged periods of unstable blood glucose levels lead to degeneration of small blood vessels. This strongly impacts peripheral nerve supply and leads to diabetic peripheral neuropathy. Indeed, older adults with diabetes mellitus have an increased risk of falls (risk ratio 1.64 (95%CI 1.27-2.11)) compared to older adults without diabetes; furthermore, standard diabetic treatment of administration of insulin does not reduce the risk of falls, and may even be associated with an increased risk (Yang, Hu, Zhang, & Zou, 2016). There is preliminary evidence to show that exercise programs targeted at improving lower limb strengthening, balance and aerobic capacity may reduce the risk of falls in these populations, but there is limited long term follow-up data (Gu & Dennis, 2017).

Aging also impacts the musculoskeletal system. Sarcopenia is a combination of low muscle mass and reduced muscle function (Tournadre, Vial, Capel, Soubrier, & Boirie, 2018). While sarcopenia has predominantly been the term used to classify age-related changes in muscles, it is now used to classify any muscle degeneration associated with chronic diseases, physical inactivity, impaired mobility and malnutrition (Tournadre et al., 2018). Due to reduced skeletal muscle mass, and therefore postural muscle function,
sarcopenia is associated with an increase in risk of falling (Norman & Otten, 2018; Waters et al., 2019).

**Instability**

**Dizziness and instability in older adults**

While dizziness in younger adults is generally considered to be caused by specific health conditions, dizziness in older adults is more commonly attributed to multifactorial causes (De Moraes, de Souza Soares, Ferriolli, & Perracini, 2013). Dizziness in older people has been termed a ‘geriatric syndrome’ made up of multiple contributors, including the vestibular system, cardiovascular, gait and balance, psychological state (such as depression) and poly-pharmacy (Gassmann & Rupprecht, 2009; Kao, Nanda, Williams, & Tinetti, 2001; Tinetti, Williams, & Gill, 2000). Treating the symptom of ‘dizziness’ is not possible, rather, treatments should be aimed at reducing the contributing factors that are relevant in each patient.

Around thirty per cent of older people experience dizziness, and the prevalence increases with age (Colledge, Wilson, MacIntyre, & MacLennan, 1994; Gassmann & Rupprecht, 2009; Gopinath, McMahon, Rochtchina, & Mitchell, 2009). The direct costs from dizziness in US emergency department visits have been estimated to be $3.9 billion US dollars per year (Saber Tehrani et al., 2013). This does not take into consideration the indirect costs, and the potential costs associated with the ongoing consequences of dizziness. Dizziness contributes to instability, and has been found to be a risk factor for falls (Deandrea et al., 2010).

**Dizziness, instability and concerns of falling**

The symptoms of dizziness can be distressing and disabling, and people with dizziness often report symptoms of primary or secondary psychological illness, most commonly depression and anxiety (Kroenke, Lucas, Rosenberg, & Scherokman, 1993; Maarsingh et al., 2011).
Older people are at greater risk of multiple health conditions due to physical decline and social isolation (Stuck et al., 1999). It is not surprising that older people with dizziness commonly experience psychological illness and distress (Sloane, Hartman, & Mitchell, 1994). Depression in particular has been shown to be strongly associated with dizziness, leading to decreased functional performance in daily activities, insecurity and anxiety. Older people with dizziness are concerned about falling and losing their independence (Kruschinski, Sheehy, Hummers-Pradier, & Lelorier, 2010). This makes the concern of falling as potentially debilitating as falling.

**Concerns of falling**

Concerns of falling are common, with prevalence estimates of up to 85% in older people (Scheffer, Schuurmans, Van Dijk, Van Der Hooft, & De Rooij, 2008). Being older, female and suffering a previous fall are the biggest risk factors. However, an estimated 50% of non-fallers also suffer concerns of falling. Concerns of falling are associated with progression to frailty and reduced physical performance. Community-dwelling older people who have a fear of falls show an increased avoidance of physical activities (Zijlstra et al., 2009; Zijlstra et al., 2012).

There are various measures to assess the psychological concerns of falling (Jørstad, Hauer, Becker, Lamb, & Group, 2005; Scheffer et al., 2008). These include falls efficacy, balance confidence, mobility efficacy, fear of falls and concerns about the consequences of falling. In this thesis, ‘concerns of falling’ will be used to refer to any self-reported measure of fall-related psychological concerns, unless a particular questionnaire or construct is specified.

Del-Rio-Valeiras and colleagues (del-Rio-Valeiras et al., 2016) explored the association between concerns of falling (short Falls Efficacy Scale International (FES-I) questionnaire) and physical performance. They found that older people with increased concerns of falling took significantly longer to complete the Timed Up and Go Test, and they also took an increased number of steps to complete the task.
Delbaere and colleagues have hypothesised a cycle of frailty, where a fear of falling leads to activity avoidance and decreased physical activity, resulting in decreased muscle strength and balance impairment, which reinforces the fear of falling (Delbaere et al., 2004). However, Hadjistavropoulos and colleagues have questioned the relationship between concerns of falling and activity avoidance (Hadjistavropoulos, Delbaere, & Fitzgerald, 2011; Hadjistavropoulos et al., 2007). In a prospective longitudinal study of 571 community dwelling people aged 69 years and older, they found that while fear of falling was associated with an increased risk of experiencing a fall, activity avoidance was not predictive of future falls (Hadjistavropoulos et al., 2007). Interestingly, fear of pain was also not associated with future activity avoidance. It appears that concerns of falling are a rational concern, and while there may be some association with activity avoidance and physical fitness, there is not a direct causal pathway to falls.

It may be proposed that concerns of falling result in decreased physical performance or vice versa, that is, if a person is concerned about their ability to perform a task, their lack of confidence will detract from performance of that task. However, it does not appear to be that simple. Concerns of falling may not necessarily be in-line with physical performance ability. Scores on anxiety questionnaires make a significant and unique contribution to concerns of falling (as measured by FES-I questionnaire) (Hull, Kneebone, & Farquharson, 2013). So while a person may have adequate physical ability to perform activities, their anxiety prevents them from doing so.

Both young and older adults show altered anterior-to-posterior postural motion when anxiety is produced in an anxious fall environment (Brown, Polych, & Doan, 2006). This is postulated to be a defence mechanism, where the body leans back posteriorly in the face of a falls threat (such as the edge of a cliff), to ameliorate the risk of a fall and injury (Huffman, Horslen, Carpenter, & Adkin, 2009). However, increased anxiety that is not associated with an immediate physical threat is also associated with reduced balance performance, in young and otherwise healthy participants (Hainaut, Caillet, Lestienne, &
Bolmont, 2011; Rahimi & Abadi, 2012). This anterior-posterior postural stiffening associated with anxiety becomes unhelpful in functional balance tasks when there is no physical threat.

Therefore, it is possible that increased concerns of falling may be associated with increased psychological perception of falling, which itself causes the reduction in balance performance due to postural stiffness and inability to modulate normal postural perturbations. Older people with increased concerns of falling may have reduced postural stability related to anxiety, and not necessarily their physical limitations.

**Concerns of falling and pain in older adults**

Pain is an important risk factor in the association between concerns of falling and balance, and therefore falls risk. Older adults who report pain also report increased concerns of falling (Stubbs, Eggermont, Patchay, & Schofield, 2015a; Stubbs, Eggermont, Patchay, & Schofield, 2014a; Stubbs et al., 2015b; Stubbs, West, Patchay, & Schofield, 2014c). Increased concerns of falling are associated with multiple pain sites (Stubbs et al., 2015a; Stubbs et al., 2015b), increased intensity of pain (Stubbs et al., 2015b) and pain interfering with normal activities (Stubbs et al., 2013; Stubbs, Patchay, Soundy, & Schofield, 2014b).

Pain that is of higher intensity or bothersome is more frequently reported in older age groups, highlighting the need for better pain management in older age groups (Dionne, Dunn, & Croft, 2006).

**Neck pain and instability**

Neck pain, specifically, has been shown to be associated with decreased balance performance, reduced motor co-ordination and the sensation of dizziness (Kristjansson & Treleaven, 2009; Treleaven, 2008). This sensorimotor performance impairment observed in people with neck pain is believed to be due to abnormal cervical spine proprioceptive input to these pathways (Treleaven, 2008). Indeed, cervico-ocular
reflexes are altered in people with neck pain (de Vries et al., 2016; Kelders et al., 2005; Montfoort, Van Der Geest, Slijper, De Zeeuw, & Frens, 2008). The cervico-ocular reflex modulates gaze stability during head rotation. Meisingset and colleagues found that people with neck pain showed increased stiffness during head movements compared to people without neck pain (Meisingset et al., 2015). These changes in cervico-ocular reflexes can be induced by cervical spine stiffness, due to the involvement of muscle spindles in the axial muscles of the neck (Montfoort et al., 2008). Muscle spindles are found in high density in the cervical spine (Boyd-Clark, Briggs, & Galea, 2002; Cooper & Daniel, 1963; Liu, Thornell, & Pedrosa-Domellof, 2003). It has been proposed that dizziness is a manifestation of alterations in the integration of cervical spine proprioceptive inputs in people with neck pain (Kristjansson & Treleaven, 2009).

These changes in proprioceptive function are evident in functional movement testing. During a timed 10 metre walk test, people with neck pain walk slower than people who do not have neck pain (Wannaprom, Sungkarat, & Uthaikhup, 2018). Poorly controlled movements of the head, combined with vestibular and visual input as part of a functional motor task, are correlated with poor co-ordination in the horizontal plane in people with increased neck pain intensity and neck pain associated disability (Treleaven, Chen, & Bahat, 2016).

In older people, with vestibular systems failing, cervical proprioception becomes more important for sensorimotor control. As people age, the strength of the vestibulo-ocular reflex decreases (Kelders et al., 2003), and is compensated by an increased gain of the cervico-ocular reflex (Kelders et al., 2003; Schweigart, Chien, & Mergner, 2002). This compensation is impaired by neck pain, and consequently older adults with neck pain experience increased sensations of dizziness and reduced balance (Quek, Treleaven, Clark, & Brauer, 2018). Furthermore, case control studies show impaired sensorimotor performance in older people with neck pain, compared to people without neck pain (Poole, Treleaven, & Jull, 2008; Uthaikhup, Jull, Sungkarat, & Treleaven, 2012).
While these studies collectively suggest that neck pain may contribute to feelings of instability (such as dizziness) and reduced balance in older people, neck pain has not been specifically examined in relation to falls risk factors in older people. Indeed, very few studies have examined non-pharmacological interventions for dizziness in older people (Chapter 4– The effects of non-pharmacological interventions for dizziness in older people: a systematic review). Furthermore, while manual therapies show some effectiveness for reducing neck pain and concomitant dizziness in adults (Lystad, Bell, Bonnevie-Svendsen, & Carter, 2011; Reid & Rivett, 2005; Yaseen, Hendrick, Ismail, Felemban, & Alshehri, 2018), this has not been examined in older populations.

**Interventions for improving instability**

**Pharmacological interventions**
Pharmacological interventions have been linked to an increased risk of falling, especially in people already experiencing instability and dizziness, where one-in-three older people with dizziness are prescribed three or more medications that increase the risk of falls (Maarsingh, Schellevis, & van der Horst, 2012). Likewise, pharmacological interventions for pain in older people are associated with increased mobility limitations compared to older people who do not use pharmaceuticals (Karttunen et al., 2012). The most commonly used pharmaceuticals for pain in older people are paracetamol/acetaminophen and non-steroidal anti-inflammatories (NSAIDs) (Nawai, Leveille, Shmerling, van der Leeuw, & Bean, 2017). An Evidence-based guideline for the management of pain in older people recommend paracetamol as first line treatment, and NSAIDs only in low doses (Abdulla et al., 2013). However, since the publication of this guideline a systematic review has concluded that there is high quality evidence that paracetamol is ineffective for reducing pain intensity or improving quality of life for people low back pain; and high quality evidence that it provides a significant effect on pain and disability from osteoarthritis of the hip or knee, however not of enough of an improvement to be clinically important (Machado et al., 2015). Likewise, in another systematic review NSAIDs have shown significant, but minimal, clinically-important
improvements in spinal pain compared to placebo (Machado et al., 2017). Thus the available evidence indicates that common pharmacological treatments do not adequately reduce pain in older people, and polypharmacy is associated with increased dizziness and risk of falls.

**Manual therapy**

Manual therapies are techniques that involve moving the joints and soft tissue structures of the body. Manual therapies are primarily applied with the hands of the practitioner to passively move body structures. Manual therapies can involve movement of bones and joints quickly (high velocity thrusts), slowly (low velocity mobilisations) or sustained pressure on soft tissue structures (massage). Manual therapies are principally performed for musculoskeletal conditions of the spine and the extremities (Gross et al., 2015; Page et al., 2014; Rubinstein, Terwee, Assendelft, de Boer, & van Tulder, 2012; Rubinstein, van Middelkoop, Assendelft, de Boer, & van Tulder, 2011) and can be classified into manipulations (high velocity, low amplitude thrusts) or mobilisations (low velocity, high amplitude movements) (Bialosky, Bishop, Price, Robinson, & George, 2009).

The proposed mechanisms for the therapeutic benefits of manual therapies have included a wide variety of physiological responses, from local peripheral tissue responses to centrally mediated neurological responses (Bialosky et al., 2009). Local peripheral tissue responses include improving joint range of motion and reducing stiffness, while centrally-mediated neurological responses include changes in nociception and cortical responses. The following section outlines the literature exploring these physiological changes associated with manual therapy.
Manual therapy and proposed mechanisms

Range of motion and intervertebral spinal joint stiffness

Each joint of the body has a defined, normative range of movement available as it moves from one position to another in different planes of movement. The normal amount of motion available at each joint has an upper and lower limit, which is determined by a number of factors, including age and gender (Soucie et al., 2011). Stiffness of joints can be related to physiological changes associated with pain (Meisingset et al., 2015). Older adults have reduced joint range of motion and stiffness, related to the normal ageing process (Lark, Buckley, Bennett, Jones, & Sargeant, 2003).

Mobilisation involves moving the joint slowly up to the physiological range limit of movement, whereas manipulation moves the joint quickly. This stretching of the joint structures may increase range of motion and reduces stiffness.

Several studies have been undertaken to investigate the therapeutic benefits and effects of joint mobilisation. Single sessions of mobilisation to the cervical or lumbar spine do not lead to appreciable changes in intervertebral movement (McGregor, Wragg, Bull, & Gedroyc, 2005; Powers, Beneck, Kulig, Landel, & Fredericson, 2008) or stiffness (Goodsell, Lee, & Latimer, 2000) during or immediately following the intervention. Snodgrass and colleagues found that intervertebral spinal movement was significantly less stiff compared to de-tuned ultrasound at short term follow-up, but these changes were not apparent immediately after cervical spine mobilisation in neck pain patients, (mean(SD): 4.9(1.8) days) (Snodgrass, Haskins, & Rivett, 2012). This indicates that the mechanism behind these reductions in stiffness and increased range of motion is not likely to be from stretching of the joint structures, but a functional change in the elasticity of the muscles surrounding the intervertebral joint.

Interestingly, asymptomatic participants (those without spinal pain) do not show changes to range of motion following mobilisation or manipulation (Stamos-Papastamos, Petty, & Williams, 2011) whereas, people with neck or low back pain do display increased
intervertebral movement (Chesterton, Payton, & McLaren, 2018; Kim, Lee, & Jeong, 2011; Kulig et al., 2007; Shum, Tsung, & Lee, 2013). In symptomatic neck pain patients, mobilisation applied to symptomatic and hypo-mobile segments, significantly reduced stiffness compared to mobilisation applied to asymptomatic and mobile segments (Tuttle, Barrett, & Laakso, 2008). The force utilised during mobilisation is also a factor in the outcome obtained. Using higher force (90N) compared to lower force (30N) mobilisations provided greater pain relief and less stiffness (Snodgrass, Rivett, Sterling, & Vicenzino, 2014).

Like mobilisation, spinal stiffness may be an important factor in why some patients improve following manipulation. It has been reported that patients with low back pain who responded (had clinically meaningful improvement on low back pain disability) to three sessions of spinal manipulation, displayed improvements in stiffness, compared to those who did not respond to manipulation (Wong, Parent, Dhillon, Prasad, & Kawchuk, 2015). Similarly, Fritz and colleagues have reported that after two sessions of lumbar spine manipulation, participants with improvements in low back pain displayed less lumbar spine stiffness (Fritz et al., 2011). However, in another follow-up study, reduction in chronic low back pain intensity and disability was not associated with reductions in spinal stiffness at either the 2 week or 6 week follow up time points (Xia et al., 2017).

Therefore, it appears that if manipulation and mobilisation reduce spinal stiffness it is where there is hypo-mobility of segments in people with spinal pain. These changes may not be apparent immediately following treatment, and therefore, probably relate to secondary changes of the contractile muscular tissue following manual therapy rather than stretching of capsular tissues. It is likely these sensory changes involve restoration of normal muscle spindle activity which leads to improvement in cervical afferent input to the central nervous system, vestibular and visual systems (Treleaven, 2008).

The mixed results of studies examining stiffness and subjective pain rating improvements suggest this relationship is likely mediated by the peripheral and central
nervous system (Bialosky et al., 2018). In patients with cervicogenic dizziness, these mediators are presumed to be muscle spindles and joint receptors, and the recommended therapeutic approach is restoration of normal proprioception through interventions targeting muscle and joint motion, including manual therapies (Devaraja, 2018).

**Muscle activity**

Changes in muscle activity and strength have been reported following mobilisation of spinal joints. In a randomised, repeated-measures study, Sterling and colleagues (2001) demonstrated that cervical mobilisation performed on participants with mid-to-lower neck pain immediately produced reduced surface electromyography (EMG) activity of the superficial neck flexor muscles during flexion movement, compared to placebo (palpation of C5/C6 without movement of the segments) or control (no contact). Furthermore, women with neck pain demonstrated increased endurance of cervical flexor muscles following six weeks of thoracic mobilisation in combination with exercise training, compared to exercise training alone (Ko, Jeong, & Lee, 2010). In contrast, McClatchie and colleagues reported that muscle strength of the shoulder abductors was not immediately significantly different in strength following cervical spine mobilisation, when compared to receiving a hands-on no mobilisation intervention (McClatchie et al., 2009). Each of these studies measured muscle activity immediately following the intervention, and therefore, may not indicate substantial or long-lasting clinical changes.

Hanrahan and colleagues examined athletes with low back pain, immediately and 24 hours following lumbar spine mobilisation, and reported that they had greater strength in prone spinal extension compared to those randomised to receive no treatment (Hanrahan, Van Lunen, Tamburello, & Walker, 2005). Similarly, Ferreira and colleagues observed an increase in EMG activity of obliquus internus and obliquus externus in abdominal muscles in participants with low back pain during functional arm movements.
following mobilisation, when compared to asymptomatic participants (Ferreira, Ferreira, & Hodges, 2007).

Currie and colleagues measured intra-muscle electromyography and found trends, but no significant differences, between muscular activity during manipulation in people with low back pain versus asymptomatic participants (Currie, Myers, Durso, Enebo, & Davidson, 2016). In young women with chronic neck pain, manipulation with thrust of the upper thoracic spine did not produce significantly different surface EMG activity of sternocleidomastoid muscles, compared to manipulation without thrust (Pires, Packer, Dibai-Filho, & Rodrigues-Bigaton, 2015).

While the preceding studies indicate heterogeneous outcomes in response to manipulation, it is clear that in some instances muscle activity and endurance improved as a result of manual therapy. When present, these changes were evident in people with spinal pain, rather than in asymptomatic control groups.

**Nervous system changes**

Manual therapies are also associated with changes in nervous responses, which may also explain the ability of manual therapies to reduce subjective pain perception in people with spinal pain.

Mobilisation of the cervical spine is associated with reduced thermal sensation, increased pressure pain threshold and lower subjective pain rating (Vicenzino, Collins, Benson, & Wright, 1998; Vicenzino, Collins, & Wright, 1996). In contrast, Sterling and colleagues did not find a significant change in pressure pain threshold, or thermal pain threshold when compared to a sham intervention that consisted of mobilisation set-up without movement (Sterling et al., 2010). They did however, report an increase in spinal cord excitability following mobilisation compared to the set-up without movement. A recent systematic review of 13 RCTs examining the analgesic effects of manual therapy found that local pressure pain threshold increased following the interventions (Voogt et al., 2015).
Spinal manipulation has also been demonstrated to change cerebellar and motor cortex activation. Baarbé and colleagues measured cerebellar-motor cortex activation in people with and without neck pain and found an increase in cerebellar inhibition toward the motor cortex during specific motor tasks in the group with neck pain (Baarbé, Yelder, Haavik, Holmes, & Murphy, 2018). Furthermore, following manipulation of the cervical spine, the neck pain group’s cerebellar inhibition activity reduced to levels seen in the asymptomatic group.

Collectively, these changes to local and central physiological responses indicate that manual therapies produce both subjective and objective changes in pain perception and intervertebral motion in people with spinal pain. While manual therapies directed to the lumbar and cervical spine likely have similar mechanisms of action, there may also be physiological differences in pain perception and intervertebral motion. What is becoming clear is that these changes are not necessarily apparent immediately following treatment, and are more likely to occur in people with spinal pain.

**Clinical trials of manual therapy in older people**

Only one published study has examined cervical spinal manual therapy for neck pain in older people (Maiers et al., 2014). This three-arm RCT of 214 participants compared home exercise to manual therapy with home exercise, and supervised rehabilitation exercise with home exercise. Short term outcomes at 12 weeks favoured manual therapy with home exercise over the two other groups. However, there were no significant differences between the three groups at 26 weeks or 52 weeks. Manual therapy consisted of “spinal manipulation, mobilisation and flexion distraction therapy, with light soft tissue massage” (Maiers et al., 2007). Treatments were individualised for each patient, based on pain provocation and palpation findings, taking into consideration the patient’s age and physical condition.

The literature search conducted for this thesis found no published studies of manual therapy with recorded falls as an outcome measure. However, five clinical studies have
examined whether manual therapy can improve balance in older people. Four of these studies were conducted by Hawk's team at the Cleveland Chiropractic College (Hawk & Cambron, 2009; Hawk, Cambron, & Pfefer, 2009; Hawk et al., 2005; Hawk, Pfefer, Strunk, Ramcharan, & Uhl, 2007), plus one study by Holt and colleagues (Holt, Haavik, Lee, Murphy, & Elley, 2016). These five studies consist of two single group pre- and post-intervention studies (Hawk & Cambron, 2009; Hawk et al., 2005) and three RCTs (Hawk et al., 2009; Hawk et al., 2007; Holt et al., 2016), and all used the Berg Balance Scale as a balance outcome measure. None of these studies had specified inclusion criteria for particular pain or symptomatology. Three studies examined older people with balance impairment defined as the inability to stand on one leg for more than five seconds (One Leg Standing Test).

The first of these studies was a single group of 13 participants who received three weeks of chiropractic spinal manipulation (Hawk et al., 2005). Participants were included if they were aged over 60 years, self-reported dizziness and poor balance (One Leg Standing Test). With such a small sample size and no comparison group, outcomes focused on feasibility and recruitment strategy. The investigators concluded that recruitment was restricted by limited treatment hours and transport options, due to the restricted schedule of the research team.

The next study was an RCT of 11 older adults with balance impairment, who received chiropractic manual therapy or supervised exercise (Hawk et al., 2007). This study did not target potential participants with or without particular health condition, however they had to have balance impairment defined as not being able to achieve more than five seconds on a One Leg Standing Test. Participants were not blinded to group allocation, and two participants dropped out immediately after allocation to the exercise group because they wanted to be in the chiropractic group. Other drop outs included one in the chiropractic group due to hospitalisation from a fall. This left the chiropractic group with five participants and the exercise group with only three. Due to inadequate power,
efficacy could not be assessed, and again outcomes consisted of assessing recruitment methods, compliance and data collection.

This was followed up by another single-group study of 14 older adults aged over 65 years (Hawk & Cambron, 2009). Participants were recruited from a local fitness centre associated with the chiropractic teaching college’s research group. Again, potential participants were not recruited based on particular symptomatology or health condition. They were any interested participants with poor balance (One Leg Standing Test of less than five seconds). Participants were excluded if they were wheelchair-bound, had manual care recently, contraindicated for spinal manipulation, lack of indications for spinal manipulation (such as decreased or increased spinal joint mobility, joint or muscle tenderness). Manual therapy consisted of high velocity, low amplitude thrust manipulation for 3/16 participants and mobilisation, instrument assisted and/or flexion distraction techniques for the remaining 13 participants. As a cohort study, findings were limited to assessing the responsiveness of outcome measures to dictate future studies. They concluded that DHI and the Pain Disability Index were useful measures for dizziness and chronic pain, respectively, in this population. The Berg Balance Scale was not responsive.

In their latest RCT of 34 participants aged over 65 years (Hawk et al., 2009). Participants were again recruited from the local fitness centre (or friends and family of members of the fitness centre) and had to have balance impairment (One Leg Standing Test of less than five seconds). The exclusion criteria were the same as (Hawk & Cambron, 2009) plus central causes of vertigo. Participants were randomised to three groups, chiropractic care for eight weeks (twice per week), chiropractic care for 8 weeks (twice per week) plus maintenance care (ten months (once per month)), or ‘best practice’ guidelines consisting of lifestyle advice via brochures and pamphlets on nutritional advice, exercise advice and hazard prevention. Chiropractic care consisted of manipulation (diversified technique of the spine, hip, knee, ankle and/or foot), soft tissue techniques (massage including trigger
point therapy) and hot packs. While this latest study included a control group, no power analysis was performed and it is questionable if ten participants in a three arm trial are sufficient; particularly in light of their primary aim to ‘collect preliminary information on the effect of a short and longer course of chiropractic care on balance, chronic pain and associated dizziness’. Randomisation also failed, with four participants refusing to participate in the ‘best practice’ group and five participants requesting the ‘best practice’ group. As stated by the authors, this study was limited by small sample size, failure of randomisation and by poor choice of balance outcome measure. The Berg Balance Scale is only responsive in populations with very low balance ability (Bogle Thorbahn & Newton, 1996). Hawk and colleagues (2009) stated that those participants with dizziness had an improvement in dizziness handicap (DHI) scores in the two chiropractic care groups; however, only one participant in the control group reported dizziness, and therefore no comparison could be made between the intervention groups and the control group.

In a recent RCT by a different research group using multiple falls risk outcome measures, Holt and colleagues found small, significant improvements in stepping reaction time and multisensory processing with chiropractic treatment in older people (Holt et al., 2016). Sixty community dwelling older aged 65 years plus were randomised to receive 12 weeks of chiropractic (n=30) or ‘usual care’ (n=30). Usual care did not include any additional intervention being provided to the participants, they were instructed to “continue with any usual health care they required, or wished to engage in”. Outcome measures were sensorimotor tasks (ankle joint position sense, choice stepping reaction time and postural stability), multisensory processing (sound-induced flash illusion), and health-related quality of life (SF36). Similar to studies by Hawk and colleagues, participants were not recruited based on health status or symptomatology. Postural stability was unable to be measured, the aim was to measure participants with eyes closed on a foam surface, and this proved too challenging with 32 (53.3%) participants being unable to complete the task, so stability scores could not be calculated. Choice stepping reaction
time was measured by the time taken to step onto one of four illuminated platforms placed in front and behind the feet. Chiropractic treatment significantly improved reaction time ($p=.01$) and there was a significant between-group difference at 12 weeks ($p=.01$). However, this improvement was only by 0.1 of a second. Multisensory processing was measured with the sound-induced flash illusion, where either one or two light flashes are accompanied by one or two beeps. Participants are asked to identify the number of flashes, without being misled by the number of beeps. Chiropractic treatment improved the number of correct responses by almost 13% ($p=.02$) and there was a significant between-group difference at 12 weeks ($p=.01$). The usual care group barely changed on multisensory processing (0.7% improvement). Ankle joint position sense improved by 0.260 degree, which while significant ($p=0.049$) was small, and not clinically different to the 0.050 degree improvement in the control group. Likewise, the SF-36 physical component score significantly improved by 3.9 points in the chiropractic group ($p=.04$), but there were no significant group differences. There were no significant effects on pass/fail rates on the postural stability task or the SF-36 mental component score.

While these small feasibility studies have significant methodological weaknesses, and therefore cannot provide information to assess the efficacy of chiropractic manual therapy for balance and other sensorimotor function in older people, they do provide useful insights into how to conduct future trials. Effective recruitment strategies consisted of targeted newspaper advertisements, and referral from included participants and local health clinics (Hawk, Rupert, Colonvega, Boyd, & Hall, 2006). The Berg Balance Scale may not be the optimum choice of outcome measure for measuring clinical changes in balance due to a ceiling effect (Bogle Thorbahn & Newton, 1996); these researchers conclude in their 2009 RCT that they are now using the Timed Up and Go Test for future studies (Hawk et al., 2009). Additionally, the balance task chosen should be appropriate for older people, as difficult balance tasks such as standing with eyes closed on foam had high failure rates (Holt et al., 2016). Furthermore, in a RCT of
manual therapy versus exercise, it is important to consider that participants may refuse the group they have been allocated to. A further consideration is that Holt and colleagues compared chiropractic intervention to ‘usual care’, but they did not report what treatment participants in these groups utilised, and what interventions the ‘chiropractic care’ consisted of (Holt et al., 2016). A form of control that can be adequately blinded from participants may be more advantageous than a direct comparison between therapeutic interventions. The use of sham or placebo controls in manual therapy trials would alleviate these biases.

None of these trials targeted particular groups of older people at risk of falling. While in general falls become more debilitating and frequent with ageing, not all older people need interventions to improve balance and sensorimotor function. These trials do not provide sufficient evidence for the usefulness of manual therapy in preventing falls risk in those older people with the most risk of falling.

While these small studies support the feasibility of manual therapy for balance, and reducing falls risk factors, they suffer from several methodological weaknesses and have a high risk of bias. Future studies need to address the following considerations:

- inclusion of control groups;
- participant blinding;
- randomisation of participants;
- clear inclusion criteria targeting older adults with falls-risk health conditions, such as musculoskeletal pain and/or dizziness;
- describe the manual therapeutic interventions that were used;
- use clinically-relevant outcomes.

Until rigorous trials are conducted, the efficacy of manual therapy for the treatment of balance impairments in older persons will remain undetermined. The design of such trials require that the choice of intervention is safe, effective and appropriate for an older age group. Instrument-assisted forms of manipulation may be appropriate tools for an
ageing population that deliver a similar therapeutic effect to other forms of manual therapy.

**Instrument-assisted manipulation and proposed mechanisms**

![Figure 2 Activator II instrument](http://creativecommons.org/licenses/by-sa/3.0)  
Obtained under creative commons (By JohnROT13 (Own work) [CC BY-SA 3.0](http://creativecommons.org/licenses/by-sa/3.0), via Wikimedia Commons). The instrument tip is placed in contact with the skin overlying the joint being manipulated. The user squeezes the handle (top of the picture) which compresses a spring-loaded hammer located inside the shaft of the instrument. Sufficient force on the handle releases the spring, propelling the hammer into the tip (bottom of the picture).

Like manual manipulation, instrument-assisted manipulation produces intervertebral movement (Colloca et al., 2006; Nathan & Keller, 1994). The instrument tip is applied to the skin adjacent to the motion segment the practitioner is manipulating. The instrument can be angled such that the thrust is applied in the direction of joint movement. The amplitude is minimal and the force can be modified, according to the practitioner’s clinical judgement.

There are different types of instrument-assisted manipulation, using various types of technologies. The most common are spring-loaded instruments (Figure 2). In these spring-loaded instruments, a hammer is cocked back in front of a spring. On release of the spring, the hammer hits a tip which imparts the mechanical force onto the overlying
skin of the patient to impart force into the underlying joint tissues. The amount of
loading placed on the spring can be modulated by the practitioner to impart more or less
force.

Instrument-assisted manipulation is commonly used to reduce neck pain in place of
manual therapy (Gemmell & Miller, 2010; Gorrell, Beath, & Engel, 2016; Huggins, Boras,
found that eight clinical trials measuring the effectiveness of instrument-assisted
manipulation for musculoskeletal disorders improved spinal pain (Huggins et al., 2012).
Since that publication, two RCTs targeting neck pain found relief of pain compared to
manipulation and mobilisation (Gemmell & Miller, 2010; Gorrell et al., 2016).
Collectively, all trials suffered from small sample sizes, and a lack of a sham-control
group. Future trials investigating the effectiveness of these instruments need to be
conducted in older age groups with a control/sham group.

**Safety of instrument-assisted manipulation**

Instrument-assisted manipulation makes it possible for practitioners to be specific with
the location, direction, and force of the thrust. The device can be placed over joints that
are in a neutral position, so that structures around the area are not compressed or
stretched. In these ways, instrument-assisted manipulation produces less peak force
compared to manual thrusts and less flexion-extension movement and torque across the
motion segment (Funabashi, Nougarou, Descarreaux, Prasad, & Kawchuk, 2017). In an
older population, it is prudent not to unnecessarily stress or strain surrounding joints
and soft tissues that are less mobile, due to age. Therefore, this instrument was chosen
for the final chapter of this thesis examining the feasibility of to run a large trial to
examine the effectiveness of spinal manipulative therapy for neck pain and non-specific
dizziness in older people. This decision is based on the assumption that instrument-
assisted manipulation is safer for use in older adults (Hawk et al., 2017), however, this
has not been definitively determined to be the case.
Chapter 3 - Neck pain, concerns of falling and physical performance in community dwelling Danish citizens over 75 years of age: A cross-sectional study

Authors: Julie C. Kendall*, Eleanor Boyle2-3, Jan Hartvigsen2-4, Lars G. Hvid2, Michael F. Azari1, Mathias Skjødt2, Paolo Caserotti2-5

1 Discipline of Chiropractic, School of Health and Biomedical Sciences, RMIT University, Melbourne Australia 2 Department of Sports Science and Clinical Biomechanics, University of Southern Denmark 3 Dalla Lana School of Public Health, University of Toronto, Canada 4 Nordic Institute of Chiropractic and Clinical Biomechanics, Odense Denmark 5 National Institutes of Health, National Institute on Aging, Bethesda, USA

Published: Scandinavian Journal of Public Health 2016 44(7), 695-701

*Address correspondence to: Julie Kendall
Abstract

Aims: To determine the associations between neck pain, concerns of falling and physical performance in older people.

Methods: Cross-sectional study of 423 community dwelling Danes aged 75 years and older. Measures consisted of self-reported neck pain, physical performance (Short Physical Performance Battery), self-reported psychological concerns related to falling (Falls Efficacy Scale International), depression (Major Depression Inventory), cognitive function (Mini Mental State Examination), self-reported low back pain and self-reported history of falls. Associations between neck pain and fear of falling were determined using multivariable logistic regression modelling.

Results: Bothersome neck pain that limits daily activities is significantly associated with concerns of falling (unadjusted OR 3.29, 95%CI 1.54-7.03) and impaired physical performance (unadjusted OR 2.26, 95%CI 1.09-4.69). However, these relationships became non-significant after adjusting for confounding. Bothersome neck pain and concerns of falling is confounded by depression, and the relationship between bothersome neck pain and decreased physical performance is confounded by concerns of falling, depression and previous history of falls.

Conclusions: Bothersome neck pain in older people is associated with increased concerns of falling and decreased physical performance that are two known risk factors for falls in older people. However, these relationships are complicated by specific confounders, particularly depression.

Keywords: Aged, Pain, Fear of Falling, Physical Performance
**Introduction**

Musculoskeletal pain and falls are common in older people, and associated with decreased self-rated health and increased health care utilisation (Hartvigsen, Frederiksen, & Christensen, 2006; Shega et al., 2010). There is growing evidence that pain in older people is associated with increased concerns of falling (Leveille et al., 2002; Stubbs et al., 2014c), balance problems (Stubbs et al., 2015b), and increased occurrence of falls (Blyth, Cumming, Mitchell, & Wang, 2007; Leveille et al., 2009; Munch et al., 2015). Concerns of falling, gait speed and balance impairment are strongly associated with future falls (Deandrea et al., 2010; Tiedemann, Shimada, Sherrington, Murray, & Lord, 2008). In particular, the presence of neck pain and low back pain in older people with dizziness has been reported to be associated with multiple falls (Menant et al., 2013).

Neck pain in older people is associated with decreased sensorimotor performance including gait speed, balance, and neck joint position sense, in case-control studies (Poole et al., 2008; Uthaikhup et al., 2012). However, it has not yet been determined if the relationship between neck pain, physical performance and other fall risk factors is also evident in larger population studies, when possible confounders such as depression are taken into account.

The aim of this study was to investigate associations between self-reported neck pain and concerns of falling and physical performance impairment in a sample of community dwelling older Danish people.

**Method**

**Study design**

This cross-sectional study was part of a larger study, the Healthy Ageing Network of Competence (HANC) study (Clinical trial registration NCT02051725, The Regional Scientific Ethical Committees for Southern Denmark approval S-20120149).
**Study population and recruitment**

The study took place in Odense municipality of Denmark. Subjects were recruited through a preventive home visit regulated by the Danish legislation, via an invitation letter (Vass, Avlund, Hendriksen, Philipson, & Riis, 2007). All Danish citizens aged over 75 years are offered a personal interview in their home to evaluate risk factors for disability and loss of independence. Citizens have the right to decline the visit. Between March 2013 and September 2014, the invitation letter contained information to participate in the HANC project.

The primary goal of the HANC study was to optimise the preventive home visit program by incorporating additional objective and self-report assessments to identify older adults at risk of future functional loss and implement a randomised controlled trial to increase functional ability (Hvid et al., 2016).

The home visit consisted of a routine interview designed by the Municipality of Odense to assess the individual’s needs (30-45 minutes); and a short examination consisting of a set of objective assessments and a self-report questionnaire booklet (30-45 minutes). If the citizen agreed to participate in the HANC study a second home visit with additional tests was arranged.

The exclusion criteria for the HANC study were as follows: a Mini Mental State Examination (MMSE) score of 21 or less, amputation or other serious physical impairment, terminal or critical disease (such as cancer, severe heart failure etc.), recent surgery (within the last 6 months), or recent fracture (within the last 3 months). In addition, potential participants were required to wear an accelerometer for a week after the first home visit and agree to the second home visit. Those eligible and interested in joining the HANC study gave informed consent. This recruitment process ensured a representative sample of community dwelling older citizens because participants did not self-select into a study *per se*, but rather a community service (Vass, Avlund, &
Hendriksen, 2007). For this cross-sectional study, HANC participants had to have completed the first and second home visit by November 1, 2014 (Figure 3).

---

**Figure 3 Recruitment and participation**

- Letter sent out to eligible residents (n=15,282)
- Accepted the home visit (n=7334)
  - Not included in HANC study\(^a\)
    - Declined HANC participation (21%)
    - Not eligible\(^b\) (44%)
    - Postponed home visit (7%)
    - Other (16.5%)
  - Assessed for eligibility into cross-sectional study analysis\(^c\) (n=549)
    - Excluded (n=8)
      - Aged less than 75 (n=5)
      - MMSE score <19 (n=1)
      - Incomplete MMSE (n=2)
    - Included (n=423)
      - Excluded after first home visit (n=118)
        - Did not wear accelerometer (n=62)
        - Declined to participate in second home visit (n=34)

\(^a\)According to municipality records. Percentages estimated from audit of clinical records, and rounded to the nearest whole number.

\(^b\)Non-eligibility was at municipality workers discretion. This included, but was not limited to: disease, injury, dementia, and age.

\(^c\)Were enrolled in the HANC study and had completed their second home visit by 1\(^{st}\) November 2014.

MMSE – Mini Mental State Examination
Data collection

During the first home visit, the participants were assessed for physical performance (Short Physical Performance Battery (SPPB)) and cognitive function (MMSE), and were given an accelerometer to wear. During the second home visit, basic anthropometry (height and weight), depression (Major Depression Inventory (MDI)), neck pain, concerns of falling (Falls Efficacy Scale International (FES-I)) and falls history were assessed.

Measures

Neck pain questionnaire
A five-item survey based on a low back pain survey developed by an international consensus of experts in the field was used (Dionne et al., 2008). Neck was substituted for low back in the questionnaire. Participants were considered to have bothersome pain if they answered ‘yes’ to the question “Was the (neck) pain bad enough to limit your normal activities or change your daily route for more than one day?”

Low back pain
Participants were asked to report if they had experienced low back pain within the past 4 weeks (Yes/No).

Falls Efficacy Scale International (FES-I) questionnaire
A 16 item questionnaire rating the concern of falling during various everyday activities. An increased score indicates higher concerns of falling and a cut-off of 23 out of a possible 64 points is used to classify people with increased concerns of falling (Delbaere et al., 2010). FES-I has been shown to have good reliability and validity (Delbaere et al., 2010).

Major Depression Inventory (MDI) questionnaire
A 12 item survey assessing depression. A higher score indicates increased depression.
MDI has been shown to have good reliability and validity (Bech, Rasmussen, Olsen, Noerholm, & Abildgaard, 2001; Olsen, Jensen, Noerholm, Martiny, & Bech, 2003).

**Mini-Mental State Examination (MMSE) questionnaire**

A 30 item questionnaire assessing orientation, calculation and recall (Folstein, Folstein, & McHugh, 1975). A lower score indicates possible cognitive impairment. A cut-off of 21 points was used to exclude participants with low cognitive function (MacKenzie, Copp, Shaw, & Goodwin, 1996). The MMSE is reliable and valid (Folstein et al., 1975).

**History of falls**

Participants were asked to report if they had experienced a fall in the previous 12 months (Yes/No). If yes, they were asked how many falls they had experienced within this time.

**Short Physical Performance Battery (SPPB)**

A battery of three physical performance tests assessing balance, chair rise and self-selected gait speed (Guralnik et al., 1994). Each test is scored out of 0-4, with a total combined score of 0-12 points. A higher score indicates a greater ability in physical performance. Poorer performances on physical activity tasks are associated with an increased risk of falls in older people (Abellan van Kan et al., 2009; Quadri, Tettamanti, Bernasconi, Trento, & Loew, 2005; Tiedemann et al., 2008).

**Analysis**

Univariate analysis was conducted to describe the characteristics of the cohort on the whole and by self-reported neck pain. In addition, the bothersome neck pain group was compared to the non-bothersome neck pain group. Differences in the characteristics by neck pain bothersomeness were calculated using either student’s t test or chi-squared test.

The relationship between neck pain and increased concerns of falling was examined using logistic regression. We further determined if this relationship changed by controlling for potential confounders in the model. A potential confounder was defined...
as a characteristic that could change the beta coefficient of neck pain by more than 10% (Rothman & Greenland, 2008). All identified potential confounders were added to the logistic regression model to calculate the adjusted odds ratios for the associations. This analysis was repeated for the following exposures: bothersome neck pain, neck and/or low back pain and SPPB total score, as the outcome measure. The adjusted models were checked for multicollinearity and the residuals were examined. All statistical analyses were calculated in SPSS for Windows (Version 22, SPSS Inc., Chicago, IL, USA).

This work was supported by a research grant from the Foundation for Chiropractic Research and Postgraduate Education (Denmark). The HANC study is supported by the European funding program INTERREG IVa.

**Results**

Four hundred and twenty three Danes were included in the analysis (Figure 3). Age, sex, cognitive function (MMSE) and physical performance (SPPB) did not differ significantly between excluded participants (n= 126) and those included (n=423) in the analysis.

Demographics of participants can be seen in Table 1 which compares participants reporting neck pain to those without neck pain. Participants with neck pain were found to have significantly higher depression scores, higher FES-I scores and a higher proportion reported low back pain.
Table 1 Description of participants

<table>
<thead>
<tr>
<th>Variable</th>
<th>All Neck Pain</th>
<th>Missing</th>
<th>No Neck Pain</th>
<th>Missing</th>
<th>All</th>
<th>Missing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>$\bar{X} \pm SD$, n (%)</td>
<td>n (%)</td>
<td>$\bar{X} \pm SD$, n (%)</td>
<td>n (%)</td>
<td>$\bar{X} \pm SD$, n (%)</td>
<td>n (%)</td>
</tr>
<tr>
<td>n=118 (27.9)</td>
<td>n=265 (62.6)</td>
<td>n=423 40 (9.5)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female (n)</td>
<td>75 (63.6)</td>
<td>0</td>
<td>154 (58.1)</td>
<td>0</td>
<td>255 (60.3)</td>
<td>0</td>
</tr>
<tr>
<td>Age (years)</td>
<td>81.6 ± 4.3</td>
<td>0</td>
<td>81.9 ± 4.2</td>
<td>0</td>
<td>81.8 ± 4.3</td>
<td>0</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>164.7 ± 7.9</td>
<td>1 (0.8)</td>
<td>164.3 ± 9.3</td>
<td>4 (1.5)</td>
<td>164.3 ± 8.8</td>
<td>16 (3.8)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>71.1 ± 13.0</td>
<td>5 (4.2)</td>
<td>72.7 ± 14.2</td>
<td>7 (2.6)</td>
<td>71.9 ± 13.9</td>
<td>22 (5.2)</td>
</tr>
<tr>
<td>MMSE (score)</td>
<td>28.4 ± 1.8</td>
<td>0</td>
<td>28.4 ± 2.0</td>
<td>0</td>
<td>28.4 ± 1.9</td>
<td>0</td>
</tr>
<tr>
<td>MDI (score)</td>
<td>8.0 ± 8.3**</td>
<td>27 (22.9)</td>
<td>5.4 ± 5.3</td>
<td>39 (14.7)</td>
<td>6.1 ± 6.4</td>
<td>106 (25.1)</td>
</tr>
<tr>
<td>SPPB (score)</td>
<td>9.3 ± 2.7</td>
<td>1 (0.8)</td>
<td>9.5 ± 2.2</td>
<td>0</td>
<td>9.4 ± 2.4</td>
<td>1 (0.2)</td>
</tr>
<tr>
<td>FES-I (score)</td>
<td>23.4 ± 7.9*</td>
<td>7 (5.9)</td>
<td>21.4 ± 6.0</td>
<td>9 (3.4)</td>
<td>22.0 ± 6.6</td>
<td>56 (13.2)</td>
</tr>
<tr>
<td>PrevFall (n)</td>
<td>39 (34.2)</td>
<td>4 (3.4)</td>
<td>71 (28.6)</td>
<td>17 (6.4)</td>
<td>110 (30.4)</td>
<td>61 (14.4)</td>
</tr>
<tr>
<td>Multiple Falls (n)</td>
<td>16 (41.0)</td>
<td>0</td>
<td>31 (44.3)</td>
<td>1 (1.4)</td>
<td>47 (43.1)</td>
<td>1 (0.9)</td>
</tr>
<tr>
<td>Low Back Pain (n)</td>
<td>86 (72.9)***</td>
<td>1 (0.8)</td>
<td>132 (49.8)</td>
<td>0</td>
<td>218 (51.5)</td>
<td>41 (9.7)</td>
</tr>
</tbody>
</table>

$\bar{X}$ – mean; SD - standard deviation; n – number of participants; MMSE – Mini Mental State Examination (/30); MDI – Major Depression Inventory (/50); SPPB – Short Physical Performance Battery total score (/12); FES-I Falls Efficacy Scale International total score (16-64); PrevFall – Number of fallers within the last 12 months; Multiple falls – Number of multiple fallers (2 or more falls) within the last 12 months; Low Back Pain – Presence of low back pain in last 4 weeks; *p<.05, **p<.01, ***p<.001.

Participants with bothersome neck pain compared to those with non-bothersome neck pain had higher depression scores, poorer physical function and higher FES-I scores (Table 2). Bothersome neck pain was significantly more intense and more frequent than non-bothersome neck pain, with 44.1% of people with bothersome neck pain reporting daily neck pain compared to 15.5% of people with neck pain that was not bothersome.
### Table 2 Neck pain

<table>
<thead>
<tr>
<th>Variable</th>
<th>Bothersome Neck Pain</th>
<th>Missing</th>
<th>Not Bothersome Neck Pain</th>
<th>Missing</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>( \bar{X} \pm \text{SD}, n (%) )</td>
<td>n (%)</td>
<td>( \bar{X} \pm \text{SD}, n (%) )</td>
<td>n (%)</td>
</tr>
<tr>
<td>Female (n)</td>
<td>24 (70.6)</td>
<td>0</td>
<td>51 (60.7)</td>
<td>0</td>
</tr>
<tr>
<td>Age (years)</td>
<td>81.5 ± 4.3</td>
<td>0</td>
<td>81.6 ± 4.3</td>
<td>0</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>163.6 ± 7.8</td>
<td>0</td>
<td>165.2 ± 7.9</td>
<td>1 (1.2)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>69.1 ± 11.8</td>
<td>3 (8.8)</td>
<td>71.9 ± 13.4</td>
<td>2 (2.4)</td>
</tr>
<tr>
<td>MMSE (score)</td>
<td>28.2 ± 1.5</td>
<td>0</td>
<td>28.5 ± 1.8</td>
<td>0</td>
</tr>
<tr>
<td>MDI (score)</td>
<td>13.4 ±10.5**</td>
<td>8 (23.5)</td>
<td>5.9 ± 6.0</td>
<td>19 (22.6)</td>
</tr>
<tr>
<td>SPPB (score)</td>
<td>8.3 ± 3.0*</td>
<td>1 (2.9)</td>
<td>9.7 ± 2.4</td>
<td>0</td>
</tr>
<tr>
<td>FES-I (score)</td>
<td>26.6 ± 9.6*</td>
<td>3 (8.8)</td>
<td>22.1 ± 6.8</td>
<td>4 (4.8)</td>
</tr>
<tr>
<td>PrevFall (n)</td>
<td>10 (31.3)</td>
<td>2 (5.9)</td>
<td>29 (35.4)</td>
<td>2 (2.4)</td>
</tr>
<tr>
<td>Multiple Falls (n)</td>
<td>5 (50.0)</td>
<td>0</td>
<td>11 (37.9)</td>
<td>0</td>
</tr>
<tr>
<td>LBP (n)</td>
<td>29 (85.3)</td>
<td>0</td>
<td>57 (68.7)</td>
<td>1 (1.2)</td>
</tr>
<tr>
<td>Intensity (0-10)</td>
<td>5.76 ± 1.67***</td>
<td>0</td>
<td>3.59 ± 1.75</td>
<td>8 (9.5)</td>
</tr>
<tr>
<td>Some days (n)</td>
<td>12 (35.3)**</td>
<td>0</td>
<td>56 (66.7)</td>
<td>0</td>
</tr>
<tr>
<td>Most days (n)</td>
<td>7 (20.6)**</td>
<td>0</td>
<td>15 (17.9)</td>
<td>0</td>
</tr>
<tr>
<td>Every day (n)</td>
<td>15 (44.1)**</td>
<td>0</td>
<td>13 (15.5)</td>
<td>0</td>
</tr>
</tbody>
</table>

\( \bar{X} \) – mean; SD - standard deviation; n – number of participants; MMSE – Mini Mental State Examination (/30); MDI – Major Depression Inventory (/50); SPPB – Short Physical Performance Battery total score (/12); FES-I Falls Efficacy Scale International total score (16-64); PrevFall - Number of fallers within the last 12 months; Multiple falls - Number of multiple fallers (2 or more falls) within the last 12 months; Low Back Pain – Presence of low back pain in last 4 weeks; Neck Pain - Intensity scored 0-10; Neck pain experienced “some days”, “most days” or “everyday” within the last 4 weeks”; *p<0.05, **p<0.01, ***p<.001.

Participants with bothersome neck pain were three times more likely to have increased concerns of falling (OR 3.29, 95%CI (1.54-7.03)). However, this relationship became non-significant after controlling for depression (Table 3). Likewise, participants with bothersome neck pain were twice as likely to have decreased physical performance (OR
2.26, 95%CI (1.09-4.69)) which became non-significant after controlling for concerns of falling, depression and history of a previous fall.

Table 3 Concerns of falling and physical performance

<table>
<thead>
<tr>
<th>Higher Concerns of Falling (FES-I &gt;23)</th>
<th>Univariate</th>
<th>Adjusted</th>
<th>Confounders</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable</td>
<td>n (%)</td>
<td>OR</td>
<td>95% CI</td>
</tr>
<tr>
<td>All Neck Pain (NP)</td>
<td>111 (30.2)</td>
<td>1.41</td>
<td>0.87-2.28</td>
</tr>
<tr>
<td>Bothersome NP</td>
<td>31 (8.4)</td>
<td>3.29**</td>
<td>1.54-7.03</td>
</tr>
<tr>
<td>Low Back Pain &amp; NP</td>
<td>82 (22.4)</td>
<td>1.41</td>
<td>0.82-2.4</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Lower Physical Performance (SPPB ≤8)</th>
<th>Univariate</th>
<th>Adjusted</th>
<th>Confounders</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable</td>
<td>n (%)</td>
<td>OR</td>
<td>95% CI</td>
</tr>
<tr>
<td>All Neck Pain (NP)</td>
<td>117 (30.6)</td>
<td>0.80</td>
<td>0.51-1.28</td>
</tr>
<tr>
<td>Bothersome NP</td>
<td>33 (8.6)</td>
<td>2.26*</td>
<td>1.09-4.69</td>
</tr>
<tr>
<td>Low Back Pain &amp; NP</td>
<td>85 (22.3)</td>
<td>1.18</td>
<td>0.70-1.99</td>
</tr>
</tbody>
</table>

n – number of participants; OR – Odds ratio; 95% CI – 95% confidence interval around the odds ratio; NP – neck pain; MMSE – Mini Mental State Examination; MDI – Major Depression Inventory; SPPB – Short Physical Performance Battery; FES-I Falls Efficacy Scale International; PrevFall – fall within the last 12 months; CI – Confidence interval *p<.05 **p<.01

Discussion

This study is the first population study to show that bothersome pain in the neck is associated with increased concerns of falling (FES-I) and decreased physical performance (SPPB) in older people. This adds to the growing body of knowledge linking pain to concerns of falling and decreased physical performance in this vulnerable segment of the population. For instance, previous reports show that fear of falling is more prevalent in older adults with bothersome pain in general (Patel et al., 2014) and that bothersome pain is significantly associated with both concerns of falling (Stubbs et al., 2014c) and previous history of falls (Blyth et al., 2007). Interestingly, contrary to previous studies (Leveille et al., 2009; Stubbs et al., 2015b), we did not find a significant
association between the addition of low back pain with neck pain and risks factors for falls.

The present report is also the first to examine the link between neck pain and risk factors for falling while controlling for the potential effects of depression. We found that depression confounded both the relationship between neck pain and concerns of falling and physical performance. Because this was a cross-sectional analysis, we were unable to take into account the bidirectional influence between pain and depression (Chou, 2007) and this should be investigated in future longitudinal studies. The relationship between pain, depression and falls is complex, and there is likely not a direct pathway from bodily pain to depression or vice versa in relation to their association with falls risk (Eggermont, Penninx, Jones, & Leveille, 2012).

The strength of this study is that examines neck pain specifically in relation to concerns of falling as well as decreased physical performance in older people. This is important in light of the association between neck pain, balance and motor co-ordination dysfunction (Poole et al., 2008; Uthaikhup et al., 2012), including reduced neck muscle activation during balance correction tasks (Boudreau & Falla, 2014). Furthermore, the recruitment and screening of eligible subjects were widely available to older Danish people and were carried out within the Danish public healthcare network, collected by clinicians independent of the research team. This study also utilised simple screening tools that can be adopted by the public health care service to identify important risk factors for falls, an important consideration in implementing services to maintain older people living in the community in their own homes. However, there are a number of limitations when interpreting the results of this study. Firstly, as a cross-sectional study, the causal relationships or the sequence of events between the variables cannot be elucidated. Secondly, analysis was limited to the data collected by the municipality, these home visits did not collect information on current medications or the presence of dizziness, both known to be relevant to falls (Ekvall Hansson & Magnusson, 2013; Richardson, Bennett,
& Kenny, 2014). Some data were missing because many participants skipped individual questions on the questionnaires leading to the inability to calculate some total scores (Table 1). In addition, 39 participants at the beginning of data collection were not administered the neck pain and FES-I questionnaires. Overall, missing responses were below 15%, with the exception of depression. Data imputation was not used. However, there were no statistically significance differences in age, sex, FES-I score, SPPB score and the presence of neck pain between participants with and without missing data. Due to the recruitment process, analysis of participants who declined participation was not possible. However, due to the pragmatic recruitment through a community service, we consider these Danes to be representative of community dwelling older people, and we have no reason to suspect a systematic bias.

This study adds to the growing body of research highlighting the importance of musculoskeletal pain as a risk for falling in older people. Pain and depression, which are potential targets for treatment in older people, should be included in screening protocols by health care providers and health service workers who aim to identify individuals at risk of falling.

**Conclusions**

Bothersome neck pain in community dwelling older people is associated with increased concerns of falling and decreased physical performance, two known risk factors for falling. However, the relationship between neck pain and concerns of falling is confounded by depression, and the relationship between neck pain and decreased physical performance is confounded by concerns of falling, depression and previous history of falls.

**Conflict of interest**

None declared.
Funding

This work was supported by an international stipend from the Foundation for Chiropractic Research and Postgraduate Education (Denmark) [grant: 14/603]. The HANC study is supported by the European funding program INTERREG Iva [grant: 11/23147]

Author contribution

Data acquisition by LGH, MS and PC; study design and interpretation JCK, JH, LGH, MFA, EB, PC; statistical analysis JCK and EB; drafting of the manuscript JCK, JH and EB. All authors contributed to and approved the final manuscript.
Chapter 4– The effects of non-pharmacological interventions for dizziness in older people: a systematic review

Authors: Julie C. Kendall¹, Jan Hartvigsen², Michael F. Azari¹⁴, Simon D. French³

¹Discipline of Chiropractic, School of Health Sciences, RMIT University, Melbourne Australia. ²Department of Sports Science and Clinical Biomechanics, University of Southern Denmark and Nordic Institute of Chiropractic and Clinical Biomechanics, Odense Denmark. ³School of Rehabilitation Therapy, Queens University, Kingston Canada. ⁴Health Innovations Research Institute, RMIT University, Melbourne Australia

Published: Physical Therapy 2016 96(5),641-649

*Address correspondence to: Simon French

Sources of Support:

MA, JH and JK are supported by a grant from Foundation for Chiropractic Research and Postgraduate Education of Denmark.

SF is funded by a professorship provided by the Canadian Chiropractic Research Foundation
Abstract

Background: Non-pharmacological interventions have been shown to have some effectiveness in adults with dizziness; however, the effectiveness of these interventions in older people is unknown.

Purpose: To determine the effects of conservative non-pharmacological interventions for dizziness in older people.

Data Sources: Databases Cochrane Central Register of Controlled Trials, PubMed, EMBASE, SCOPUS, CINAHL, AMED, Index to Chiropractic Literature, PsychINFO and MANTIS.

Study Selection: Controlled trials with participants over 60 years of age with dizziness. Dizziness from a specific diagnosis such as Meniere’s disease and benign positional paroxysmal vertigo were not included. Outcome measures from included studies included self-reported dizziness and postural balance.

Data Extraction: At least two investigators independently extracted data on participants, interventions, comparison group, outcome measures and results. Methodological quality of included studies was assessed with the Cochrane Handbook 12-item risk of bias, and Cochrane Back Group 5-item clinical relevance assessment.

Data Synthesis: Seven articles consisting of seven controlled trials were included. All studies utilised some form of exercise as the main intervention including vestibular rehabilitation exercises, postural balance exercises, and Tai-Chi exercise. Studies had a high risk of bias with a lack of adequate randomization and allocation concealment, reporting on co-interventions, reporting on reasons for drop-outs, and reporting on participant compliance.

Limitations: Heterogeneity between the included studies on interventions and outcome measures prohibited meta-analysis. Only two studies reported a significant difference between the intervention and comparison groups on self-reported dizziness.
**Conclusion:** There is insufficient evidence to determine the effectiveness of non-pharmacological treatments for dizziness in older people. Current evidence suffers from high risk of bias and future well-designed trials are needed with adequate blinding, randomization and compliance.

**Keywords:** systematic review, dizziness, aged
**Introduction**

Dizziness is frequently experienced by older people with an estimated 32-58% of women and 22-30% of men over 65 years of age reporting dizziness (Colledge et al., 1994; Gassmann & Rupprecht, 2009; Jonsson, Sixt, Landahl, & Rosenhall, 2004). Importantly this prevalence increases with age (Colledge et al., 1994; Jonsson et al., 2004). The consequences of dizziness are not only personal distress but an economic burden on the health care system; for instance the cost of emergency department visits for dizziness in the United States has been estimated to be US$3.9 million (Saber Tehrani et al., 2013). One of the most concerning consequences of dizziness in older people is the association with an increased risk of falls (Deandrea et al., 2010). Falls are associated with decreased independence, disability, morbidity and mortality (Campbell et al., 1990; Cripps & Carman, 2001). Falls in older people contribute to a significant personal and economic burden, and with the ageing population increasing the direct cost of falls in Australia is expected to rise to AUD$1375 million per annum by 2051 (Moller, 2003).

Dizziness in older people may be empirically classified in six categories: frailty; psychological; cardiovascular; presyncope; non-specific disorders; and ear, nose and throat disorder (Dros et al., 2011). Older people with dizziness are under-referred for specialist consultation and lack access to appropriate interventions (Bird, Beynon, Prevost, & Baguley, 1998). Furthermore, dizziness in older people is often multifactorial (Gassmann & Rupprecht, 2009; Maarsingh et al., 2010) and shown to be associated with anxiety (Menant et al., 2013), spinal pain (Menant et al., 2013), and increased medications (Gassmann & Rupprecht, 2009; Maarsingh et al., 2010; Menant et al., 2013). The inappropriate prescription of some medications for dizziness has been questioned (Maarsingh et al., 2012) and polypharmacy is common, with 33% of older people with dizziness using 5 or more medications and 37% using three or more fall-risk-increasing medications (Maarsingh et al., 2010). The effectiveness of non-pharmacological therapies, alone or in combination for dizziness, particularly in older
people who may be at risk of polypharmacy is needed. Non-pharmacological interventions reportedly used for dizziness in older people include exercises (including vestibular rehabilitation therapy) (Hall, Heusel-Gillig, Tusa, & Herdman, 2010; Johansson, Akerlund, Larsen, & Andersson, 2001; Jung, Kim, Chung, Woo, & Rhee, 2009; Maciaszek & Osinski, 2012; Moreira Bittar, Simoceli, Bovino Pedalini, & Bottino, 2007), cognitive behaviour therapy (Andersson, Asmundson, Denev, Nilsson, & Larsen, 2006; Holmberg, Karlberg, Harlacher, & Magnusson, 2007; Johansson et al., 2001) and manual therapy (Hawk & Cambron, 2009; Hawk et al., 2009).

The effectiveness or optimal combinations of therapies, particularly non-pharmacological therapies in older people have not been determined and, to our knowledge, a systematic literature review of non-pharmacological therapies for dizziness in older people has not been done. This review seeks to address this need, and provide an overview of controlled trials carried out to date, to determine the effects of non-pharmacological interventions for dizziness in older people.

**Objective**

To determine the effects of conservative non-pharmacological treatments for dizziness in older people.

**Methods**

**Data sources and searches**

**Electronic databases**

The following electronic databases were searched, with assistance from a Research Librarian, from inception to May 2014: Cochrane Central Register of Controlled Trials, PubMed, EMBASE, SCOPUS, CINAHL, AMED, Index to Chiropractic Literature, PsychINFO and MANTIS. Reference lists of included papers, and relevant systematic reviews retrieved in the search, were screened for additional relevant papers. Search
terms related to clinical trials, older age, dizziness, and various non-pharmacological therapies were linked with Boolean operators. Non-pharmacological therapies search terms included (but were not limited to) “vestibular rehabilitation exercises”, “acupuncture”, “chiropractic”, “physiotherapy”, “osteopathy”, “cognitive behaviour therapy”, and “massage” (for a full list of search terms see appendix p166). Search terms were modified for each database, with appropriate subject headings used for each database searched.

**Study selection**

Two authors (JK, and MA or SF) independently screened all titles and abstracts retrieved via the electronic database search and studies that did not meet the inclusion criteria were discarded. The full texts of the remaining articles were obtained and two review authors (JK, and JH or MA) independently applied the inclusion criteria to determine included studies. Discrepancies between review authors were resolved by consultation and consensus between authors.

**Study design**

Studies included in this review were controlled trials (including randomised, quasi-randomised and non-randomised trials). Retrospective study designs, cohort studies, case reports, case series, commentaries, letters to the editor and expert opinions were excluded. Non-English language articles that were not able to be assessed were excluded.

**Participants**

Studies with participants over 60 years of age with dizziness were included, this included participants with presbyastasis, non-specific dizziness, cervicogenic dizziness with associated osteoarthritis and dizziness of unspecified origin. Studies were excluded that recruited participants with dizziness from specific diagnosed causes, including conditions of the ear, nose, throat, central nervous system, cardiovascular, migraine associated vertigo, benign positional paroxysmal vertigo, Meniere’s disease, peripheral neuropathy, and infection.
**Types of interventions**

Studies utilizing any non-pharmacological interventions including, but not restricted to: exercises; manual therapy (massage, soft tissue therapy, manipulation, traction); cognitive behavioural therapy (CBT); and acupuncture. Studies utilizing herbal formulations and homeopathic remedies were excluded as they were considered to be pharmacological in nature. Comparison groups consisting of placebo, sham therapy, no treatment (wait-list control), and any other type of active intervention were included.

**Outcome measures**

The primary outcome measure was any self-reported measure of dizziness (e.g. DHI, Visual Analogue Scale (VAS), Numeral Rating Scale (NRS), subjective improvement, daily activities, and global perceived effect). We also included objective measures such as balance (e.g. Berg Balance scale, Activities-specific balance confidence; force plate centre of pressure analysis), number of falls, quality of life (e.g. SF-36), and other outcomes reported in the included studies.

**Data extraction**

Two authors (JK and JH, SF or MA) independently extracted data from the included articles. Data extracted included characteristics (population, number of participants, age, gender) interventions (intervention group and control group), and outcomes (primary and secondary outcomes related to dizziness, balance, falls, quality of life). Discrepancies between authors in data extraction were resolved by consultation and consensus between authors.

**Quality assessment**

Two review authors (JK and JH, SF or MA) independently assessed each article for risk of bias according to the 12-item criteria described in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins & Green, 2011). Any discrepancies
between authors on the risk of bias assessment was discussed and resolved through consensus.

The clinical relevance of each publication was also assessed by a 5 item clinical relevance assessment from the Cochrane Back Group (Furlan, Pennick, Bombardier, & van Tulder, 2009). Each item was judged as ‘yes’ fulfilling the requirement, ‘no’ or ‘don’t know’. These criteria were judged independently by JK and one other reviewer (JH, SF or MA). The clinical relevance items included the following:

- Are participants described in detail so that you can decide whether they are comparable with patients that you see in your practice?
- Are the interventions and treatment settings described well enough that you can provide the same for your patients?
- Were all clinically relevant outcomes measured and reported?
- Is the size of the effect clinically important?
- Are the likely treatment benefits worth the potential harms?

**Data synthesis and analysis**

Although a meta-analysis was planned, included studies were too heterogeneous in their interventions and outcome measures for meta-analysis; therefore, a descriptive, narrative synthesis of results and quality of the included studies is presented.

**Results**

A total of seven studies met the inclusion criteria and were included (Hall et al., 2010; Hansson, Månsson, Ringsberg, & Håkansson, 2008; Kammerlind, Hakansson, & Skogsberg, 2001; Kao et al., 2014; Maciaszek & Osinski, 2012; Moreira Bittar et al., 2007; Prasansuk, Siriyananda, Nakorn, Atipas, & Chongvisal, 2004) (Figure 4). There were 1,966 electronic publication records identified through database searching. After 530 duplicate references were removed, the remaining 1,436 records were screened with 66
records identified for full text analysis; 11 of these full text publications were unable to be translated from non-English languages (five Chinese, one Turkish, two German, one Italian, and two Polish) and were therefore excluded. Of the remaining 55 full text articles, 47 did not meet the inclusion criteria and were excluded (see appendix p169). Screening of reference lists did not identify additional relevant articles. Due to the low number of included studies and their general high risk of bias, this analysis focuses on describing the available evidence of various therapeutic modalities, rather than assessing the effectiveness or comparing the effectiveness of modalities.

Of the included studies, all contained some form of exercises as the main intervention: vestibular rehabilitation exercises (Hall et al., 2010; Hansson et al., 2008; Kao et al., 2014; Moreira Bittar et al., 2007); balance exercises (Kammerlind et al., 2001; Prasansuk et al., 2004) and tai chi exercise (Maciaszek & Osinski, 2012) (see Table 4 for the characteristics of included studies). Study design of the included studies consisted of: randomised controlled trials (Hall et al., 2010; Kammerlind et al., 2001; Maciaszek & Osinski, 2012); aged-matched controlled trials with (Hansson et al., 2008; Moreira Bittar et al., 2007), and without dizziness (Kao et al., 2014); and a non-randomised controlled trial (Prasansuk et al., 2004).
Figure 4 Identification of included studies
### Table 4 Characteristics of included studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Participants</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Outcome Measures</th>
<th>Results</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moreira Bittar (2007)</td>
<td>Participants 65-95 years old with dizziness not of vestibular origin.</td>
<td>Vestibular rehabilitation therapy (n=52). Individual adaptation of the: Cawthorne-Cooksey basic protocols; vestibular ocular reflex; and Norre exercises.</td>
<td>Older people in the general ward of the hospital (not necessarily treated for systemic diseases) (n=44).</td>
<td>Total number of participants who obtained complete improvement (remission), between 50-90% improvement (improvement) or less than 50% improvement (no improvement).</td>
<td>Significantly more participants in the active group had “improvement” compared to the control group (p&lt;0.05). There was no significant difference between the number of participants categorized as in remission or not improved.</td>
<td>Study design compared groups of participants who had concomitant systematic conditions that may have been contributing to dizziness. The inclusion and exclusion criterion was not defined. The only outcome measure reported was subjective percentage of improvement.</td>
</tr>
<tr>
<td>Hall (2010)</td>
<td>Older people of at least 60 years of age with documented balance or mobility problems, and normal vestibular function. Dizziness was defined as symptoms of unsteadiness, spinning, a sense of movement or light-headedness. Participants were recruited from an outpatient physical therapy centre.</td>
<td>Gaze stability exercises (n=20). Exercises required the individual to fixate on a visual target during either horizontal or vertical head movements; and performing eye-head movements between targets with the goal of seeing clearly during those tasks. Frequency: 3x per day, total time did not exceed 30 mins. Home exercise program consisting of balance and walking exercises.</td>
<td>Randomly assigned to placebo eye exercises with the head stationary (n=19). Saccadic eye movements with and without targets against a white wall. Frequency: 3x per day until discharge from outpatient centre, total time did not exceed 30 mins. Home exercise program consisting of balance and walking exercises.</td>
<td>Self-reported difference in severity of dizziness before and after 1 minute of head turns (VAS)</td>
<td>There was a significant difference between groups on the DGI (p=.026), All other outcomes measures were non-significant between groups.</td>
<td>Randomization procedure was not defined.</td>
</tr>
<tr>
<td>Hansson (2008)</td>
<td>Multisensory dizziness in older people over 65 years. Participants were recruited from those referred to a physiotherapy centre in a major city.</td>
<td>Group vestibular rehabilitation program at a physiotherapy centre (n=31). Standing on foam turning the head from side to side. Walking on a slope and turning the head from side to side. Standing on a trampoline, slightly flexing the knees and turning the head from side to side. Standing on a sport mat, walking on the spot and turning the head from side to side. Sitting on a Bobath ball, feet on foam and bouncing slightly while turning the head from side to side. Frequency: 50</td>
<td>Aged-matched dizziness suffering participants, recruited from medical centres in the community. No treatment (n=27)</td>
<td>Dizziness Handicap Inventory (DHI). Balance was assessed using the time able to stand (up to 30 sec) in: tandem stance with eyes open and closed; Standing one leg eyes open (SOLEO); Standing one leg eyes closed (SOLEC). The ability to walk over 5 meters heel-to-toe or in a figure of eight.</td>
<td>No significant difference between groups on DHI. Significant group differences on SOLEC (p=.038) and walking heel to toe (p=.044). All other balance measures were non-significant.</td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Participants</td>
<td>Intervention</td>
<td>Comparison</td>
<td>Outcome Measures</td>
<td>Results</td>
<td>Comments</td>
</tr>
<tr>
<td>-------------</td>
<td>------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Kammerlind</td>
<td>Older people aged over 65 with non-peripheral vertigo and/or unsteadiness. Recruited from an ENT department at a university hospital.</td>
<td>minutes 2x week over 9 weeks</td>
<td>Randomised into no treatment, &quot;were supposed to live as usual&quot; (n=12).</td>
<td>Self-reported vertigo/unsteadiness (VAS).</td>
<td>Dizziness as measured by VAS significantly improved in the exercise group compared to the control group (p=.046). The ability to stand on one leg with eyes open was significantly longer in the intervention group compared to the control group (p=.036), however all other balance outcome measures were non-significant. There were significant between group differences on 3 out of 6 of the SOT components.</td>
<td></td>
</tr>
<tr>
<td>Study</td>
<td>Participants</td>
<td>Intervention</td>
<td>Comparison</td>
<td>Outcome Measures</td>
<td>Results</td>
<td>Comments</td>
</tr>
<tr>
<td>-------</td>
<td>--------------</td>
<td>--------------</td>
<td>------------</td>
<td>-----------------</td>
<td>---------</td>
<td>----------</td>
</tr>
<tr>
<td>Kao (2014)</td>
<td>Older people with chief complaints of dizziness for more than 1 year. Recruited from physical medicine and rehabilitation department of a veteran’s hospital.</td>
<td>Vestibular rehabilitation exercises and strength and balance training (n=15). Consisting of: reading targets from 2m while performing horizontal head movements during sitting and standing on soft and hard surfaces; leg strengthening in a chair; and standing on one leg. Frequency: 3x week for 30-40 minutes over 6 weeks.</td>
<td>Aged-matched participants without a history of dizziness. No treatment (n=15)</td>
<td>Self-report dizziness (VAS), DHI, Tinetti Fall Risk Performance Scale (POMA). Various blood level inflammation and oxidative stress markers (mRNA, PCR, immunoblotting, SIRT1, NAD+/NADH ratio, antioxidant enzyme activity, hydrogen peroxide, malondialdehyde)</td>
<td>Blood expression and activity levels of SIRT1, an important modulator of inflammation, were different between dizzy and non-dizzy subjects. After exercise training, these values approximated those seen in the control group.</td>
<td>There was no follow-up for the control group. Baseline data from control and intervention groups was compared to post intervention results.</td>
</tr>
<tr>
<td>Study</td>
<td>Participants</td>
<td>Intervention</td>
<td>Comparison</td>
<td>Outcome Measures</td>
<td>Results</td>
<td>Comments</td>
</tr>
<tr>
<td>------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>Maciaszek (2012)</td>
<td>Men aged 60-80 years with self-reported dizziness within the previous 12 months. Relatively sedentary lifestyle, not having done sport or exercise in the last 5 years. Recruited from direct mailing and community information.</td>
<td>Tai Chi exercises (n=20). Frequency: 2x week, 45 minutes over 18 weeks.</td>
<td>Randomised into a no treatment group (n=20)</td>
<td>Centre of pressure (COP) measured on a computer posturographic system during the “8 foot up and go test” and limits of stability (LOS) (forward, back, left, and right lean, and area of sway).</td>
<td>Significant difference between groups on 3 out of the 6 COP balance parameters (8 foot up and go, backward lean, and max sway area).</td>
<td>Randomization procedure not defined.</td>
</tr>
<tr>
<td>Study</td>
<td>Participants</td>
<td>Intervention</td>
<td>Comparison</td>
<td>Outcome Measures</td>
<td>Results</td>
<td>Comments</td>
</tr>
<tr>
<td>--------</td>
<td>------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------------------------</td>
<td>-----------------------------------------------------------</td>
<td>---------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Pransansuk (2004)</td>
<td>Older people with current symptoms of disequilibrium, unsteadiness or vertigo. Recruited from communities adjacent to a local hospital.</td>
<td>Head-neck balance exercises based on the Cawthorne-Cooksey protocol (n=110).</td>
<td>Allocated into Multivitamin supplementation (n=105).</td>
<td>Subjective magnitude numerical scale (average severity of symptoms of dizziness) (0-without symptoms 10-maximum severity of symptoms).</td>
<td>Remission of symptoms was not significantly different between the two groups. At week 8 significantly less participants in the exercises group had abnormal posturography, compared to the control group (p=0.03). All other outcomes were non-significant between groups.</td>
<td>Every second participant was allocated to intervention group. *Intervention between active and comparison groups was identical after 8 weeks. Results presented in this table are between groups at the 8 week time point. (All analysis at 20 week time point was non-significant)</td>
</tr>
</tbody>
</table>

Abbreviations: COP – centre of pressure; DGI – Dynamic Gait Index; DHI – Dizziness Handicap Inventory; DVA – dynamic visual acuity; LOS – limits of stability; POMA - Tinetti Fall Risk Performance Scale; SOLEC - standing one leg eyes closed; SOLEO – standing one leg eyes open; SOT – sensory organization test; VAS – visual analogue scale.
The most common outcome measures were self-reported dizziness and balance, with dizziness measured in six out of seven studies (Hall et al., 2010; Hansson et al., 2008; Kammerlind et al., 2001; Kao et al., 2014; Moreira Bittar et al., 2007; Prasansuk et al., 2004), and balance in six out of seven (Hall et al., 2010; Hansson et al., 2008; Kammerlind et al., 2001; Kao et al., 2014; Maciaszek & Osinski, 2012; Prasansuk et al., 2004). Other outcome measures included: gait speed and/or gait performance (Hall et al., 2010; Hansson et al., 2008); blood inflammatory markers (Kao et al., 2014); and vestibular and cerebral tests (audiometry, acoustic impedance, intra-cranial Doppler) (Prasansuk et al., 2004).

Only two studies reported a significant difference between the intervention and comparison groups on self-reported dizziness (Kammerlind et al., 2001; Moreira Bittar et al., 2007). Four studies found significant differences between intervention and control groups on balance performance, however each study that measured balance used multiple balance outcome measures and no single study reported all balance parameters as statistically significantly different between the intervention and control groups (Hansson et al., 2008; Kammerlind et al., 2001; Kao et al., 2014; Maciaszek & Osinski, 2012). Generally the sample sizes were small, with six out seven studies having groups of between 12-52 participants (Hall et al., 2010; Hansson et al., 2008; Kammerlind et al., 2001; Kao et al., 2014; Maciaszek & Osinski, 2012; Moreira Bittar et al., 2007) thus a lack of statistical power is likely to have contributed to the observed non-statistically significant differences.

There was high risk of bias with all included studies including a lack of adequate randomization and allocation concealment (Hall et al., 2010; Hansson et al., 2008; Kammerlind et al., 2001; Kao et al., 2014; Maciaszek & Osinski, 2012; Moreira Bittar et al., 2007; Prasansuk et al., 2004), lack of reporting on co-interventions (Hall et al., 2010; Hansson et al., 2008; Kammerlind et al., 2001; Kao et al., 2014; Maciaszek & Osinski, 2012; Moreira Bittar et al., 2007; Prasansuk et al., 2004), lack of reporting on reasons for drop-outs (Hansson et al., 2008; Kao et al., 2014; Maciaszek & Osinski, 2012; Moreira Bittar et al., 2007; Prasansuk et al., 2004), selective reporting of results (Moreira Bittar et al., 2007), and
lack of reporting on participant compliance (Hall et al., 2010; Hansson et al., 2008; Kao et al., 2014; Maciaszek & Osinski, 2012; Moreira Bittar et al., 2007; Prasansuk et al., 2004) (Table 5). In addition, studies lacked adequate reporting to allow informed conclusions on the clinical relevance of the interventions for the conditions treated (Table 6). Finally, participants were not clearly described, and all but one study failed to give adequate information about the clinical setting utilised (Hansson et al., 2008).

Table 5 Risk of bias assessment of the included studies
Table 6 Clinical relevance assessment

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Are participants described in detail so that you can decide whether they are comparable with patients that you see in your practice?</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Are the interventions and treatment settings described well enough that you can provide the same for your patients?</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Were all clinically relevant outcomes measured and reported?</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Is the size of the effect clinically important?</td>
<td>Don’t Know</td>
<td>No</td>
<td>No</td>
<td>Don’t Know</td>
<td>Don’t Know</td>
<td>Don’t Know</td>
<td>No</td>
</tr>
<tr>
<td>Are the likely treatment benefits worth the potential harms?</td>
<td>Don’t Know</td>
<td>Don’t Know</td>
<td>Don’t Know</td>
<td>Don’t Know</td>
<td>Don’t Know</td>
<td>Don’t Know</td>
<td>Don’t Know</td>
</tr>
</tbody>
</table>
Discussion

The body of literature addressing the effectiveness of non-pharmacological therapies for dizziness in older people suffers from serious methodological shortcomings, a high risk of bias, and inadequate reporting. Therefore, at present, no conclusions can be made regarding the effectiveness of any of these therapies.

The strength of this study is that, to our knowledge, this is the first systematic review to be conducted to evaluate non-pharmacological therapies for dizziness in older people. However, this review is limited by the general lack of literature, particularly high quality literature in this area; consequently we are unable to make judgments about the effectiveness, optimal dose or combination of non-pharmacological therapies for dizziness in this population. The possible range of therapies that fall under the broad term ‘non-pharmacological’ is difficult to define. It is possible that not all relevant search terms were used, and there may be publications that were missed. Additionally, due to lack of resources, translations of non-English language publications were unable to be included for analysis.

Interestingly, no study met our inclusion criteria utilizing cognitive behavioural therapy or manual therapy. A systematic review of psychotherapy for dizziness (Schmid, Henningsen, Dieterich, Sattel, & Lahmann, 2011) concluded that while there had only been a small number of studies, cognitive behavioural therapy may be effective for patients with dizziness, however the three studies included did not meet our inclusion criteria due to the age of participants (Andersson et al., 2006; Holmberg et al., 2007), and specific dizziness diagnosis (Johansson et al., 2001). Similarly, two systematic reviews in younger adult populations of manual therapy for dizziness associated with neck pain found that while there was a general lack of high quality publications, there is limited to moderate support for manual therapy (Lystad et al., 2011; Reid & Rivett, 2005; Yaseen et al., 2018).
This review highlights the paucity of quality research addressing non-pharmacological therapies for dizziness in older people. Future research of high methodological quality is needed across a range of therapies to address dizziness in older people. Furthermore, studies assessing therapies alone and in combination are needed to define optimum treatment strategies. In addition studies utilizing long-term follow-up for these therapies are needed to assess long-term effectiveness.

Acknowledgements

We would like to thank Majbritt Johansen, Research Librarian from The University of Southern Denmark for her assistance with the electronic database searching.

Conflict of Interest: No conflicts of interest

Author Contribution: All authors were involved in designing the study. JK performed the electronic database searching with assistance from Majbritt Johansen. JK performed all screening of title, abstracts and (where appropriate) full text with the assistance of one of the other authors (SF, JH or MA). Risk of bias and clinical relevance was performed by JK, and one of the other three authors (SF, JH or MA). All authors contributed to analysis and interpretation of data. The manuscript was drafted by JK and all authors (JK, SF, JH and MA) were involved in revision, and approval of the final version.

Sources of Funding: Sources of Funding: MA, JH and JK are supported by a grant from Foundation for Chiropractic Research and Postgraduate Education of Denmark. SF is funded by a professorship provided by the Canadian Chiropractic Research Foundation. No funding program was involved in the design, execution, analysis or interpretation of this research study.
Chapter 5 – Impact of musculoskeletal pain on balance and concerns of falling in mobility-limited, community-dwelling Danes over 75 years of age: a cross-sectional study.

Authors: Julie C. Kendall*, Lars G. Hvid, Jan Hartvigsen, Azharuddin Fazalbhoy, Michael F. Azari, Mathias Skjødt, Stephen R. Robinson, Paolo Caserotti

1School of Health and Biomedical Sciences, RMIT University, Melbourne, Australia.
2Section for Sport Science, Department of Public Health, Aarhus University, Aarhus, Denmark.
3Department of Sports Science and Clinical Biomechanics, University of Southern Denmark, Odense, Denmark.
4Nordic Institute of Chiropractic and Clinical Biomechanics, Odense, Denmark.

Published: Aging Clinical and Experimental Research 2017

*Address correspondence to:

Julie Kendall
School of Health and Biomedical Sciences RMIT University
PO Box 71 Bundoora VIC 3083 Australia
julie.kendall@rmit.edu.au
Funding: This work was supported by an international stipend from the Foundation for Chiropractic Research and Postgraduate Education (Denmark) (grant number 14/603). The HANC study is supported by the European funding program INTERREG Iva (grant number 11/23147). Neither funding source had any involvement in: study design; in the collection, analysis and interpretation of data; in the writing of the report; or in the decision to submit the article for publication.
Abstract

**Background:** In older adults, musculoskeletal pain is associated with increased concerns of falling, reduced balance and increased occurrence of falls. In younger adults, the intensity of neck pain and low back pain are associated with increased postural sway. It is not known if pain further impairs balance and concerns of falling in mobility-limited older adults, and if so, whether this is associated with different intensities of pain.

**Objective:** This study examined whether mobility-limited older adults with mild or intense neck pain and/or low back pain have significantly increased postural sway as measured by centre of pressure (COP) changes and concerns of falling compared to those without pain.

**Methods:** 48 older adults with a gait speed of <0.9m/s from Odense, Denmark were recruited through the public health service. Self-reported neck pain, low back pain, and concerns of falling were recorded on questionnaires. Sway range, velocity and area were recorded on a force plate in a comfortable standing stance. Pain intensity was rated on an 11 point numerical rating scale (0-10). Participants were sub-grouped into mild (0-4) and intense (>5) neck pain or low back pain.

**Results:** Intense neck pain was associated with increased anterior-posterior sway range and area of sway. Intense low back pain was associated with increased concerns of falling.

**Conclusion:** Intense neck pain in mobility-limited older adults is associated with significant changes in postural balance, and intense low back pain is associated with significantly higher concerns of falling.
Introduction

Falls are one of the leading health concerns facing older adults, affecting their capacity to engage in activities of daily living, loss of independence, and the risk of sustaining moderate-to-severe injury. Several factors have been identified that lead to an increased risk of falls in this age group, including reduced gait speed (Shimada et al., 2009). One of the determinants of gait speed is good postural control, and it has been observed that musculoskeletal pain is associated with reduced balance, increased concerns of falling, and increased occurrence of falls in older adults (Leveille et al., 2009; Stubbs et al., 2014a; Stubbs et al., 2015b).

Previous studies have demonstrated that older adults with a history of falls displayed an increased range and velocity of sway when their balance was tested in a static standing position on a force plate (Piirtola & Era, 2006). It has been hypothesised that deteriorating anterior to posterior (AP) postural control occurs as a natural consequence of ageing, particularly of the lower limb muscles tibialis anterior and biceps femoris, which demonstrate increased activity in static standing when compared to young healthy controls (Laughton et al., 2003). The resulting flexed posture and increase in rigidity may be an adaptation that facilitates the forward displacement of the centre of gravity, to reduce the likelihood of falling (Laughton et al., 2003). A retrospective study, in older adults, conducted to analyse balance control parameters in fallers and non-fallers suggested that fallers had increased medial-lateral (ML) sway rather than AP sway (Melzer, Kurz, & Oddsson, 2010). Despite these preliminary observations, the relationship between increased sway and falls risk in older adults remains to be fully investigated.

The speed of postural sway is influenced by a range of factors that are likely to be linked to the risk of falls. For instance, it has been demonstrated in older adults that a concern of falling, indicated by high Falls Efficacy Scale International Questionnaire (FES-I) scores, is associated with significant reductions in both AP and ML velocity (del-Rio-
Valeiras et al., 2016). In contrast, in studies on younger adults, neck pain and low back pain increase the extent of sway in the AP direction more so than the ML direction, and high intensity neck pain increases the velocity of both AP and ML sway (Ruhe, Fejer, & Walker, 2011b, 2013). Yet, these studies on balance and musculoskeletal pain have been conducted in younger adults. There is a need to determine if mobility-limited older adults with musculoskeletal pain exhibit significant increases in sway and poor balance.

This retrospective cross-sectional study examined neck pain, low back pain, postural stability, and concerns of falling in a group of mobility-limited older adults (low gait speed). Postural stability was assessed in terms of both the range and velocity of AP sway and ML sway.

The aims of this study were to: i) examine whether mobility-limited older adults with mild or intense neck pain and/or low back pain have significantly increased COP sway compared to those without pain; and ii) examine whether concerns of falling are associated with increases in COP sway in this population.

Methods

Older adults were recruited from Odense, Denmark, through a preventative home visit program from the municipality. This program includes interviews, with cognitive and physical assessments, to evaluate risk factors for disability and loss of independence. Participants included in this analysis were those who underwent COP analysis recruited to a RCT aimed at increasing functional ability (Hvid et al., 2016). These data were baseline data before any intervention was delivered. This trial was part of the Healthy Ageing Network of Competence (HANC) study (Clinical trial registration NCT02051725, The Regional Scientific Ethical Committees for Southern Denmark approval S-20120149). To be included in the HANC trial, participants had to be ≥75 years of age, have a self-paced gait speed of <0.9m/s, and a mini-mental state examination score of >21/30 (MacKenzie et al., 1996). The cut point for MMSE of 21/30 was chosen to take
into account those with low educational levels (Kahle-Wroblewski, Corrada, Li, & Kawas, 2007). Additionally, participants underwent a medical screening including a general medical history and blood pressure assessment. They were excluded if they had an amputated limb or other serious physical impairment, terminal or critical disease (such as cancer, severe heart failure, etc.), recent surgery (within the last six months) or a recent bone fracture (within the last three months). A total of 65 participants were recruited into the trial. Force plate data for 15 participants was not recorded properly, of those remaining 50; two participants did not respond to the neck pain and low back pain questionnaires, leaving data from 48 participants included in this analysis. Where there was additional missing data, these data were excluded pairwise from analyses.

Self-reported neck pain and low back pain within the previous four weeks was recorded via two questionnaires based on a low back pain questionnaire developed by an international consensus of experts in the field of low back pain (Dionne et al., 2008). In the first questionnaire, participants were asked whether they had experienced low back pain within the previous 4 weeks, and if so, to rate the intensity of pain on a numerical rating scale (NRS) from 0-10 (0 = no pain, 10 = severe pain). The second questionnaire was identical, except that it asked about the presence and intensity of neck pain.

Concerns of falling were reported on the Falls Efficacy Scale Questionnaire (FES-I), a 16-item questionnaire that measures the concerns of falling whilst performing daily routines and activities. FES-I is a valid and reliable measure of concerns of falling, and the following cut-off points were used to denote low (<20), medium (20-27) and high (>27) concerns of falling (Delbaere et al., 2010).

Participants were instructed to remove their shoes before stepping onto the force plate. Balance was measured on a force plate (Kistler, 9281 B) in comfortable standing stance with the participants' heels separated by 13.5 cm. Participants were given time to step onto the force plate, find the correct foot position and compose themselves prior to testing. Participants kept their eyes open, gazing straight ahead and were asked to stay as
still as possible during both trials, carried out in quiet laboratory. Thirty seconds of continuous recording from the force plate was used for analysis. Two trials were recorded and the second trial was used for analysis. COP postural sway was analysed in three parameters: area of sway, range and velocity. Range and velocity were calculated in the AP and ML directions. Range was the difference between the maximum points of sway in each direction (mm). Velocity was the distance travelled divided by the recording time in (mm/s). Area was calculated using the area of an ellipse covering 90% of data points (mm²) (Doyle, Hsiao-Wecksl, Ragan, & Rosengren, 2007). Participants reporting neck pain or low back pain were categorised into intense (≥5/10) or mild (1-4/10) pain according to their numerical pain rating score.

Once the numerical data were extracted from the recordings, further data analysis was conducted in IBM SPSS (version 22). Normality of the data was determined by examination of histograms, Q-Q plots and Shapiro-Wilk tests of normality. Non-parametric tests were used where data were not normally distributed.

Demographic differences between groups of participants with no pain compared to participants with neck pain were analysed using t-tests for continuous variables (height) and chi-squared tests for dichotomous variables (gender). Weight was not normally distributed and a Mann-Whitney U test was conducted instead of t-test. Similarly, differences between groups of participants with and without low back pain were compared for continuous, dichotomous and non-normally distributed data as above.

Data for all COP parameters and FES-I scores were not normally distributed. Differences on each COP parameter between groups of participants without pain, with mild neck pain and intense neck pain were examined using Kruskal-Wallis tests. Where these tests indicated a significant difference between groups pairwise post-hoc tests were conducted and adjusted with a Bonferroni correction (Dunn-Bonferroni test). To examine differences between no pain, mild low back pain and intense low back pain, Kruskal-Wallis and post hoc tests were conducted likewise. Similarly, differences on FES-I scores
were examined using Kruskal-Wallis and post-hoc tests between intensities of both neck pain and low back pain using the same methods as with COP parameters. Significance was set at p=0.05. Data was plotted in GraphPad Prism 7.02 with Tukey box & whisker plots.

**Results**

Musculoskeletal pain was common, with 24 (48%) reporting low back pain and 14 (28%) reporting neck pain (Table 7). Of these participants, 9 (18%) reported both neck pain and low back pain. A total of 19 (38%) participants reported not having experienced neck pain or low back pain within the previous four weeks. Of the 48 participants, 46 responded to the FES-I questionnaire. Most of the participants reported concerns of falling, with 24 (52%) respondents scoring between 20-27 (medium concern of falling), 6 (13%) scoring 28 or more points (high), and 16 (35%) scoring 19 or less (low).

When comparing participants with or without neck pain and/or low back pain, there were no significant differences between groups with respect to gender, height, weight, FES-I score or any COP parameter. However, participants with neck pain were significantly older than participants (84.21+/-4.93,SD) without neck pain (81.11+/-4.38,SD) (t-test p=0.033) (Table 7). The maximum pain intensity rating for either neck pain or low back pain was 8/10, indicating a high-intensity of musculoskeletal pain.

Examination of the results from groups with no pain, mild neck pain, and intense neck pain elucidated several differences (Figure 5). COP sway area was significantly different between no pain, mild pain, and intense neck pain (p=0.02) (Figure 5, Panel a). Post-hoc analysis identified that this difference was primarily due to the difference between the mild and intense pain groups (p=0.02). Similarly, AP sway range was different between pain intensities (p=0.006). Again, the post-hoc analysis identified a significant difference between the mild and intense neck pain groups (p=0.006). There were no significant
differences between the neck pain intensity groups on sway velocity (both AP and ML),
ML sway range, or FES-I scores (Figure 5 panels b, d, e and f).
### Table 7 Group characteristics

<table>
<thead>
<tr>
<th></th>
<th>All</th>
<th>Neck pain</th>
<th>Low back pain</th>
<th>No neck pain or low back pain</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=48</td>
<td>n=14</td>
<td>n=24</td>
<td>n=19</td>
</tr>
<tr>
<td>μ/(n)</td>
<td>SD/%</td>
<td>μ/(n)</td>
<td>SD/%</td>
<td>μ/(n)</td>
</tr>
<tr>
<td>Age</td>
<td>82.06 4.53</td>
<td>84.21* 4.93</td>
<td>82.42 4.662</td>
<td>81.11 4.38</td>
</tr>
<tr>
<td>Male</td>
<td>16 33%</td>
<td>2 16%</td>
<td>7 29.2%</td>
<td>8 42.1%</td>
</tr>
<tr>
<td>Height (mm)</td>
<td>164.2 8.65</td>
<td>162.21 7.19</td>
<td>163.70 8.42</td>
<td>164.29 9.42</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>74.73 14.87</td>
<td>71.23 8.94</td>
<td>78.36 15.29</td>
<td>71.32 14.56</td>
</tr>
<tr>
<td>NP intensity (0-10)</td>
<td>5.14 1.99</td>
<td>5.14 1.99</td>
<td>1.83 2.70</td>
<td>-</td>
</tr>
<tr>
<td>LBP intensity (0-10)</td>
<td>4.83 1.77</td>
<td>3.43 3.08</td>
<td>4.83 1.77</td>
<td>-</td>
</tr>
<tr>
<td>FES-I (16-64)</td>
<td>22.11 5.75</td>
<td>24.15 7.37</td>
<td>23.83 7.00</td>
<td>20.44 3.37</td>
</tr>
<tr>
<td>COP area (mm²)</td>
<td>441.06 477.96</td>
<td>478.14 587.31</td>
<td>412.38 297.02</td>
<td>416.42 526.77</td>
</tr>
<tr>
<td>COP AP range (mm)</td>
<td>32.25 13.17</td>
<td>35.21 17.31</td>
<td>33.08 12.25</td>
<td>29.37 12.94</td>
</tr>
<tr>
<td>COP ML range (mm)</td>
<td>17.67 11.91</td>
<td>17.93 16.94</td>
<td>17.58 9.11</td>
<td>16.37 9.71</td>
</tr>
<tr>
<td>COP AP velocity (mm/s)</td>
<td>16.85 9.42</td>
<td>16.07 9.22</td>
<td>18.71 10.87</td>
<td>14.79 7.21</td>
</tr>
<tr>
<td>COP ML velocity (mm/s)</td>
<td>7.13 5.25</td>
<td>7.21 6.55</td>
<td>7.42 5.26</td>
<td>6.37 2.99</td>
</tr>
</tbody>
</table>

μ - mean; SD – standard deviation; NP – neck pain; LBP – low back pain; FES-I – falls efficacy scale international; COP – centre of pressure; AP – anterior to posterior; ML – medial to lateral; * indicates significant difference between no neck/back pain and neck pain.

Participants with no low back pain, mild back pain or intense low back pain did not show any significant differences on any COP parameter (Figure 6 panels a, c, d, e and f).

Participants with intense low back pain had significantly higher FES-I scores (mean 26.77, 95%CI 21.87-31.67) compared to those with no neck pain or low-intensity back pain (mean 20.44 95%CI 18.77-22.12) (p=0.046) (Figure 6, panel b). When comparing participants with high concerns of falling to participants with low concerns of falling, there was a general trend for the former group of participants to have increased range, velocity and area of sway (Table 8). However, none of these trends reached statistical significance.
Figure 5 Neck pain and instability

Median COP sway and concerns of falling in groups without neck or low back pain, mild neck pain and intense neck pain. Boxes extend to 25th and 75th percentiles. Whiskers are data points equal to or less than the sum of 75th percentile and 1.5IQR (equal to or greater than 25th percentile for lower whiskers). Individual data points are values outside of these ranges. Overall group effects: *p<0.05 **p<0.01. Post-hoc specific group effects: *p<0.05 **p<0.01
Figure 6 Low back pain and instability

Median COP sway and concerns of falling in groups without neck or low back pain, mild low back pain and intense low back pain. Boxes extend to 25th and 75th percentiles. Whiskers are data points equal to or less than the sum of 75th percentile and 1.5IQR (equal to or greater than 25th percentile for lower whiskers). Individual data points are values outside of these ranges. Overall group effects: *p<0.05 **p<0.01. Post-hoc specific group effects: *p<0.05 **p<0.01
Table 8 Concerns of falling and COP parameters

<table>
<thead>
<tr>
<th>COP parameter</th>
<th>Low concerns of falling (FES-I score &lt;20)</th>
<th>Medium concerns of falling (FES-I score 20-27)</th>
<th>High concerns of falling (FES-I score &gt;27)</th>
<th>Kruskal-Wallis test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Area (mm²)</td>
<td>308.75 (151.01-466.49)</td>
<td>373.88 (256.19-491.56)</td>
<td>434.33 (258.07-610.60)</td>
<td>p=0.21</td>
</tr>
<tr>
<td>AP range (mm)</td>
<td>28.44 (23.68-33.20)</td>
<td>31.09 (25.70-36.47)</td>
<td>36.00 (24.33-47.67)</td>
<td>p=0.361</td>
</tr>
<tr>
<td>ML range (mm)</td>
<td>14.44 (9.92-18.95)</td>
<td>15.63 (12.49-18.76)</td>
<td>20.33 (13.91-26.76)</td>
<td>p=0.121</td>
</tr>
<tr>
<td>AP velocity (mm/s)</td>
<td>15.19 (9.47-20.90)</td>
<td>15.59 (12.52-18.65)</td>
<td>22.50 (10.43-34.57)</td>
<td>p=0.14</td>
</tr>
<tr>
<td>ML velocity (mm/s)</td>
<td>6.38 (3.14-9.61)</td>
<td>6.08 (5.02-7.14)</td>
<td>8.67 (4.93-12.40)</td>
<td>p=0.114</td>
</tr>
</tbody>
</table>

Values are displayed as mean (95% confidence interval)

COP – centre of pressure; FES-I – falls efficacy scale international; AP – anterior to posterior; ML – medial to lateral

Discussion

This study examined mobility-limited older adults with slow gait speed (<0.9m/s), and explored the relationships between back and neck pain, postural stability and concerns of falling. Participants with higher intensity of neck pain were found to have a significantly increased range of AP sway and area of sway, and those with higher intensity of low back pain had significantly increased concerns of falling.

In experimental pain studies, significant changes in postural stability have been observed with strong pain intensity induced by noxious electrical stimulation of the skin overlying the upper trapezius muscle (Vuillerme & Pinsault, 2009), and not with mild pain intensity induced by bolus injections into the upper trapezius muscle belly (Madeleine, Prietzel, Svarrer, & Arendt-Nielsen, 2004). Results of the current study show that in mobility-limited older adults postural sway is only increased with high intensity of neck pain. This is also consistent with findings in younger adults with neck pain (Ruhe et al., 2013) where a linear relationship has been reported between neck pain intensity and increased postural sway. Indeed, these findings indicate that there may be a tendency for mild neck pain to increase COP sway; however, this was not the case with mild low back
pain. This result is in contrast to a previous study in younger adults, which did observe a relationship between increasing COP sway and increasing intensities of low back pain (Ruhe et al., 2011b).

Neck pain has been shown to alter the muscle recruitment pattern in the neck during balance correction tasks (Boudreau & Falla, 2014), and this may contribute to the reduced balance and motor coordination in older adults with poor mobility and neck pain, above and beyond expected deterioration due to the ageing process (Uthaikhup et al., 2012). The high density of proprioceptors in the neck, particularly the upper neck (Liu et al., 2003), may explain why high intensity neck pain was significantly associated with increased sway, and not low back pain.

Whilst there was no statistically significant difference in COP parameters when comparing participants with high, medium, or low concerns of falling, the trend observed may suggest that COP parameters tend to be higher in those with high concerns of falling. Medium concerns of falling was similar, or slightly higher compared to those with low concern.

One of the strengths in the current study was that the participants are representative of the mobility-limited older population of Denmark, due to the recruitment process within the public healthcare system. This study is of clinical relevance, since all of the participants were over the age of 75 years and had reduced gait speed, placing them at high risk of experiencing a fall in the future (Shimada et al., 2009). The present results suggest that a subgroup of this sample population, those with intense neck or back pain, may have an increased risk of having a fall, and hence it might be prudent to target interventions alleviating this pain. However, the study sample was relatively small; consequently it was not possible to conduct detailed subgroup analyses of the effects of age and gender on neck pain and low back pain. The group with neck pain was significantly older than the group without neck pain. So it is possible that a proportion of the difference observed in sway between the groups may be attributable to age.
Furthermore, the sample size was too small to subgroup participants into neck pain only or low back pain only groups. Also, the study did not consider additional factors that affect balance such as, cognitive function (Deschamps, Beauchet, Annweiler, Cornu, & Mignardot, 2014), current medications (Richardson et al., 2014), and the presence of dizziness (Ekvall Hansson & Magnusson, 2013). Increased medication use is associated with mobility impairment and spinal pain in older people (Karttunen et al., 2012). It is therefore, possible that people in this study with pain, particularly intense pain, may be taking more medications and this may have produced their poor performance on COP. Likewise, dizziness is associated with spinal pain (Menant et al., 2013) and could have similarly impacted the results. As a fairly small sample from Odense, Denmark, the findings in this study will need to be confirmed with larger numbers of participants and drawn from other populations.

**Conclusion**

This study demonstrated that mobility-limited older adults with intense neck pain have significantly poorer postural balance when compared to frail older adults without neck pain. Also, intense low back pain is associated with significantly higher concerns of falling. While these findings support the view that intense neck or back pain contribute to an increased risk of falls, consistent with data observed in younger adults, the current study and cross-sectional design did not permit a prospective examination of the participants’ subsequent falls history. Future studies may examine whether high intensity neck or back pain are predictive of future falls risk in older frail individuals.

**Compliance with ethical standards**

**Conflict of interest**

All authors declare they do not have any conflict of interest.
Statement of human and animal rights

This trial was part of the Healthy Ageing Network of Competence (HANC) study (Clinical trial registration NCT02051725) and obtained ethics approval from the Regional Scientific Ethical Committees for Southern Denmark (approval S-20120149).

Informed consent

All participants gave informed consent as part of the HANC study.
Chapter 6 - Chiropractic treatment including instrument-assisted manipulation for non-specific dizziness and neck pain in community-dwelling older people: a feasibility randomised sham-controlled trial

Authors: Julie C. Kendall¹, Simon D. French²⁻³, Jan Hartvigsen⁴⁻⁵, & Michael F. Azari⁶

¹School of Health and Biomedical Sciences, RMIT University, Melbourne, Australia
²School of Rehabilitation Therapy, Queens University, Kingston, Canada. ³Department of Chiropractic, Macquarie University, Sydney, Australia. ⁴Department of Sports Science and Clinical Biomechanics, University of Southern Denmark. ⁵Nordic Institute of Chiropractic and Clinical Biomechanics, Odense, Denmark

Published: Chiropractic & Manual Therapies 2018 26(1),14

*Address correspondence to: Dr Michael Azari
Abstract

**Background:** Dizziness in older people is a risk factor for falls. Neck pain is associated with dizziness and responds favourably to neck manipulation. However, it is unknown if chiropractic intervention including instrument-assisted manipulation of the neck in older people with neck pain can also improve dizziness.

**Methods:** This parallel two-arm pilot trial was conducted in Melbourne, Australia over nine months (October 2015 to June 2016). Participants aged 65-85 years, with self-reported chronic neck pain and dizziness, were recruited from the general public through advertisements in local community newspapers and via Facebook. Participants were randomised using a permuted block method to one of two groups: 1) Activator II™-instrument-assisted cervical and thoracic spine manipulation plus a combination of: light massage; mobilisation; range of motion exercises; and home advice about the application of heat, or 2) Sham-Activator II™-instrument-assisted manipulation (set to zero impulse) plus gentle touch of cervical and thoracic spinal regions. Participants were blinded to group allocation. The interventions were delivered weekly for four weeks. Assessments were conducted one week pre- and post-intervention. Clinical outcomes were assessed blindly and included: dizziness (DHI); neck pain (NDI); self-reported concerns of falling; mood; physical function; and treatment satisfaction. Feasibility outcomes included recruitment rates, compliance with intervention and outcome assessment, study location, success of blinding, costs and harms.

**Results:** Out of 162 enquiries, 24 participants were screened as eligible and randomised to either the chiropractic (n=13) or sham (n=11) intervention group. Compliance was satisfactory with only two participants lost to follow up; thus, post-intervention data for 12 chiropractic intervention and 10 sham intervention participants were analysed. Blinding was similar between groups. Mild harms of increased spinal pain or headaches were reported by 6 participants. Costs amounted to AUD$2,635 per participant. The data showed a trend favouring the chiropractic group in terms of clinically-significant
improvements in both NDI and DHI scores. Sample sizes of n=150 or n=222 for dizziness or neck pain disability as the primary outcome measure, respectively, would be needed for a fully powered trial.

**Conclusions:** Recruitment of participants in this setting was difficult and expensive. However, a larger trial may be feasible at a specialised dizziness clinic within a rehabilitation setting. Compliance was acceptable and the outcome measures used were well accepted and responsive.

Trial Registration: Australian New Zealand Clinical Trials Registry (ANZCTR)
ACTRN12613000653763 Registered 13 June 2013

Trial funding: Foundation for Chiropractic Research and Postgraduate Education (Denmark)

Keywords:
Neck Pain, Dizziness, Elderly, Chiropractic, Randomised Controlled Trial


**Background**

Dizziness and musculoskeletal pain are common in older people (Colledge et al., 1994; Hartvigsen, Christensen, & Frederiksen, 2004; Hartvigsen et al., 2006; Jonsson et al., 2004) and are associated with postural instability (Poole et al., 2008), fear of falling (Leveille et al., 2002; Perez-Jara et al., 2009; Perez-Jara et al., 2012), and increased incidence of falls (Deandrea et al., 2010; Gassmann & Rupprecht, 2009; Leveille et al., 2009; Pluijm et al., 2006). Among Australian adults, 36% of people aged over 50 years report the presence of dizziness within the last month (Gopinath et al., 2009). Similarly, the prevalence of neck pain in Australian older adults has been estimated at 36% and 41% for men and women respectively (March et al., 1998), and in older adults, 5% of men and 8% of women report that neck pain interferes with their physical activity (Hartvigsen et al., 2006).

Dizziness is a known risk factor for falls in community-dwelling older people (Deandrea et al., 2010), and dizziness is not optimally managed at present. One in three older people with dizziness are prescribed medications that are known to increase the risk of falling including: anti-hypertensives; anxiolytics and antidepressants; nitrates; analgesics; and anti-vertigo medications (Maarsingh et al., 2010). Anti-vertigo medications in particular, are commonly prescribed for non-vestibular causes of dizziness (Maarsingh et al., 2012). Therefore, there is a need to develop and validate non-pharmacological treatment strategies for dizziness in this population, which in turn may reduce the need for prescription of pharmacological agents with their attendant potential side-effects (Maarsingh et al., 2010; van Vugt, van der Horst, Payne, & Maarsingh, 2017).

Neck pain may increase the risk of falls in older people. Sensory information from various structures including the vestibular apparatus in the inner ear, the eyes, and the proprioceptive receptors in muscles and joints, particularly of the neck, is integrated by the brain for position sense, balance and motor control (Kristjansson & Treleaven, 2009). In some individuals, neck pain is linked with dizziness, in a syndrome termed
‘cervicogenic dizziness’ or ‘cervical dizziness’ (Boyd-Clark et al., 2002; Liu et al., 2003; Yacovino, 2012). There are reports in neck pain patients of a correlation between cervical joint stiffness and hypertonicity of the upper cervical musculature and the presence of dizziness (Malmstrom, Karlberg, Melander, Magnusson, & Moritz, 2007; Matsui, Ii, Hojo, & Sano, 2012; Yahia et al., 2009). There are many different causes of dizziness in older people, including vestibular, cardiovascular, and psychological (Dros et al., 2011). In addition, since cervicogenic dizziness is a diagnosis of exclusion, its exact incidence and prevalence remain unknown and a definitive diagnosis of cervicogenic dizziness is not possible in primary care settings. Therefore, this study recruited older people who reported both chronic non-specific dizziness and chronic neck pain to optimise the relevance of the study findings for primary care settings.

Spinal manipulative therapy (SMT) is widely used by chiropractors, osteopaths and physiotherapists, for musculoskeletal conditions, including neck pain (Hurwitz, 2012). SMT has been shown to reduce neck pain in adults in general (Gross et al., 2010) and in older people specifically (Maiers et al., 2014). Furthermore, there have been small studies reporting positive effects of manual therapy in improving dizziness and musculoskeletal pain in older people (Hawk & Cambron, 2009; Hawk et al., 2009; Hawk et al., 2005). In fact, there is evidence that dizziness specifically associated with neck pain in adults may be attenuated with manual therapy, including SMT (Lystad et al., 2011; Reid & Rivett, 2005). However, previous studies have several important limitations including: lack of specific examination of neck pain (Hawk & Cambron, 2009; Hawk et al., 2009; Hawk et al., 2005); lack of a control group (Hawk & Cambron, 2009; Hawk et al., 2005; Strunk & Hawk, 2009); use of a ‘no treatment’ control group (Hawk et al., 2009), issues with appropriate outcome measures (Holt et al., 2016) and small sample sizes. SMT can be performed manually or assisted through an instrument. There is some evidence suggesting that low-force Activator™-instrument-assisted manipulation may produce effects on musculoskeletal pain that are comparable to those of manual SMT (Huggins et al., 2012). Even though reported significant harms following neck SMT in older people
are rare (Cassidy et al., 2008), due to increased risk of osteoporosis in this population, low-force SMT techniques are recommended by recent chiropractic guidelines (Hawk et al., 2017).

A feasibility or pilot study is generally recommended before a Phase III clinical trial (Craig et al., 2008). Feasibility studies can determine the efficiency of recruitment strategies, adequacy of randomisation and blinding, appropriateness of outcome measures, and acceptability of compliance levels, as well as give some indication of the frequency and nature of harms. In this way, it is possible to ensure that the full-scale trial makes efficient use of resources, and is sufficiently powered to provide meaningful results (Thabane et al., 2010).

We conducted a feasibility RCT of a chiropractic intervention including instrument-assisted SMT in older people with chronic dizziness and concomitant chronic neck pain. The primary objective of this trial was to test the feasibility of a fully-powered RCT, based on recruitment rates, compliance with intervention and outcome assessment, study location, success of blinding, costs and harms. The secondary objective of this trial was to calculate, based on observed group differences, sample sizes for fully-powered RCTs using the DHI or neck disability index (NDI) as the primary outcome measures.

**Methods**

**Study design**

We conducted a parallel two-arm, randomised, sham-controlled feasibility trial. Participants were allocated to either a chiropractic intervention or sham intervention using to a block randomisation procedure.

**Ethics and trial registration**

The human ethics clearance was obtained from RMIT University's human research ethics committee (HREC) (Approval number 29/13 – see appendix p177). The trial was
registered in the Australian New Zealand Clinical Trials Registry (ANZCTR)
(Registration number: ACTRN12613000653763).

Participants

Recruitment

Participants were recruited from the northern Melbourne metropolitan region via notices in ‘The Leader’ local newspapers (covering Diamond Valley, Hume, Whittlesea, and Moreland municipal areas), flyers at local community centres surrounding the research location (see appendix p178), flyers at RMIT university departments, and targeted online Facebook advertisements. Potential participants who responded to these recruitment methods were interviewed over the telephone to determine eligibility for study enrolment. If eligibility could not be determined via telephone alone, potential participants were invited to the university campus for further examination by a research assistant, who was a registered chiropractor (see appendix 184). All participants gave written informed consent (see appendix p179), and were sent a follow up letter at the conclusion of the trial (see appendix p197).

Inclusion criteria

Participants included in the study were men and women aged between 65 and 85 years. Participants had to report having neck pain with concomitant dizziness (described as dizziness or unsteadiness), at least of three months duration for each. Pain and dizziness could be constant or intermittent within the previous three months.

Exclusion criteria

Participants were excluded if they self-reported: diagnosed vestibular pathology such as Meniere’s disease or benign paroxysmal positional vertigo; a history of cerebrovascular accident or myocardial infarct; psychiatric disease; active inflammatory spondyloarthopathies (e.g. rheumatoid arthritis, psoriatic arthritis, ankylosing
spondylitis); recent spinal trauma; osteomyelitis; spinal tumours; acute myelopathy; and if they had received neck any SMT or neck massage during the previous three months. Participants were excluded if they showed signs of cognitive impairment as demonstrated by a Montreal Cognitive Assessment (MoCA) score of 20 or less (Trzepacz, Hochstetler, Wang, Walker, & Saykin, 2015).

**Interventions**

All interventions, including the sham intervention, were delivered by either one of two registered practicing chiropractors (depending on availability) who each had at least 20 years of clinical experience. Four intervention sessions were given over four weeks, and the duration of each session was kept to 15 minutes in both groups.

**Chiropractic intervention**

Chiropractic care included: Activator II™ instrument-assisted manipulation plus one or more of the following: joint mobilisation; massage; range of motion neck exercises; or advice to apply heat at home. Interventions were directed to cervical and thoracic joints that displayed local tenderness and/or areas of joint stiffness in accordance with common chiropractic practice (Triano et al., 2013). The chiropractor administered the instrument-delivered thrust following pre-tensioning of hypo-mobile cervical joints in lateral flexion without extending or rotating the neck (Mitchell et al., 2004). Instrument-assisted manipulations to the thoracic spine were delivered in the prone position. Manipulation with or without mobilisation was supplemented with massage to hypertonic muscles of the cervical and thoracic spine, as determined by the clinical judgment of the practitioner, as well as advice on local application of heat at home. Massage consisted of a combination of effleurage, and ischaemic compression techniques. The intervention approach was designed to reflect actual contemporary Australian chiropractic care (unpublished data) and recent chiropractic practice guidelines (Hawk et al., 2017).

**Sham intervention**
Activator II™ instrument impulses (set at zero) and gentle placement of the practitioner's hands on the cervical and thoracic spine regions. This was a modification of a published sham procedure (Walker et al., 2011). No massage, mobilisation, or home advice was given to the participants in the sham group.

**Outcome measures**

*Feasibility outcome measures*

Feasibility of running a larger trial was determined based on recruitment rates, compliance with intervention and outcome assessment, reviewing the study location, blinding, costs and reporting of harms.

**Recruitment rate:** The recruitment rate was determined by comparing the number of enquiries from each advertising method with the number of participants who were enrolled from each of those methods. Additionally, the inclusion and exclusion criteria were reviewed by examining the frequency and the reasons for exclusion during screening.

**Compliance:** Participants’ compliance with the outcome assessment was examined by noting the time taken to complete the baseline questionnaires and assessments, and reviewing if any outcome measures were consistently filled out incorrectly or were incomplete. Compliance with the intervention schedule was examined by measuring drop-out rates and reasons for drop-outs.

**Study location:** We determined if participants dropped out, or had difficulty finding the clinical trial centre, due to its location on the Bundoora campus of RMIT University.

**Blinding and treatment satisfaction:** At the conclusion of the follow-up outcome measure assessment, participants indicated which intervention group they believed they were in (sham or chiropractic) to determine the integrity of allocation. All participants were also asked to rate their satisfaction with treatment on a five-point scale (from 1: I feel much worse to 5: I feel much better).
**Costs:** The feasibility of conducting a larger, fully-powered study was assessed on the basis of the costs of: advertising, equipment, and hiring the chiropractors and research assistants to recruit and screen potential participants and administer the interventions.

**Harms:** Harms were defined as adverse consequences of the intervention reported by participants. In accordance with the World Health Organisation’s [45] *Conceptual Framework for the International Classification for Patient Safety*, the degree of harm was classified as: none (no symptoms detected and no treatment required), mild (minimal or intermediate short term harm caused, and minimal or no intervention required), moderate (permanent or long-term harm caused, or intervention required), severe (major permanent or long-term harm caused, or major surgical/medical or life-saving intervention required) or death (death caused or brought forward). Harms and other reactions to interventions were documented by the treating chiropractor at each intervention session.

**Clinical outcomes**

Clinical outcomes were assessed at the baseline visit (one week pre-intervention) and follow-up visit (one week post-intervention). Dizziness, pain, quality of life, mood, and concerns of falling were assessed with self-reported questionnaires (see appendix p186). The physical function and mobility assessments were performed one after the other, and participants were able to take breaks in between if they became tired. During all physical function tasks, the investigator stood close by to assist/steady the participant as required. These outcome measures were chosen to explore potential clinical measures that may show improvement of pain and dizziness to be utilised in a larger trial as primary (neck pain or dizziness) or secondary (quality of life, mood and physical function) outcomes.

**Sample size**

As a feasibility study, this trial did not have an *a priori* calculated sample size. We aimed for a sample size of 40 to generate sufficient information to address the feasibility objectives, particularly the recruitment rate.
**Randomisation**

Participants were randomly assigned after the baseline appointment using a permuted block randomisation protocol. The randomisation schedule was conducted by an independent statistician before recruitment using a computer generated random list of numbers. This list was used to assign random blocks of four or six participants at a time. Group allocations were concealed by placing them in opaque consecutively numbered sealed envelopes, which were opened, in order, by the treating chiropractor before the first intervention session.

**Blinding**

Participants were blinded to group allocation. The researcher performing the outcome assessments was also blinded to group allocation. The chiropractors involved in performing the interventions were blinded to the results of the outcome assessments at pre- and post-intervention.

**Analysis**

**Feasibility determination**

A fully powered RCT using this protocol would be determined *a priori* to not be feasible in our setting if:

- At least 40 participants could not be recruited within the three-month trial period.
- More than 20% of all participants could not participate for the following reasons:
  - Primarily identifying travelling to the study location as inconvenient;
  - Being unable able to complete all outcome measure assessments, or unable to complete them within the allocated two hours;
  - Becoming lost trying to find the study location.
- More than 15% of participants in either group dropped out.
• More than 70% (20% greater than chance) of participants in either group correctly identified their allocation at post-intervention follow-up, or blinding was significantly different between groups.

• The average cost of recruitment and intervention per participant was more than $1,500.

• There were any reported severe harms.

A fully-powered RCT was determined to be feasible with modifications if any of the above criteria were not satisfied but could be modified in such a way as to preserve the integrity of the study.

**Statistical analysis**

To address the primary objective of the trial, descriptive statistics were calculated and reported for all feasibility and clinical outcome measures. Pre- and post- intervention self-reported and test outcomes were calculated for each group with means and standard deviations. A chi-squared test was performed to determine if blinding was similar between groups, using IBM SPSS software (version 22). To address the secondary objective of the trial, two sample size calculations for possible larger, fully-powered trials were conducted at the conclusion of this trial with NDI or DHI as the primary outcome measure. Sample size was calculated in G*Power (version 3.1.9.2) to estimate an *a priori* two-tailed independent two-group mean difference using the effect size (Cohen’s *d*) estimated from the NDI and DHI data based on means and standard deviations of post-intervention scores for each group. Sample size was estimated for a power set to 80%, and significance level of 0.05. Since this was a feasibility study, we did not perform any statistical analysis to determine effectiveness of the chiropractic intervention.
Results

Recruitment

A total of 24 participants were recruited from 162 telephone enquiries (Figure 7). The recruitment period ran over nine months, from October 2015 to June 2016; six months over the planned three-month period. Most commonly, screened participants were excluded due to the presence of self-reported diagnosed vestibular and spinal pathologies (n=27 [20%]), neck pain without symptoms of dizziness (n=19 [14%]), history of cardiovascular incidents (n=18 [13%]), recent manual therapy (n=14 [10%]) and not being able to travel to the research site (n=16 [12%]). Ten participants (7%), who otherwise could have participated, were excluded due to low performance on the MoCA cognitive function assessment.
Figure 7 Flow of participants through the trial
Using Facebook as a recruitment method for older Australians was surprisingly successful, with 38 (23%) enquiries; however, it captured many potential participants who were unable to travel to the trial location. The trial was stopped before the target 40 participants was reached due to time and budget constraints.

**Compliance**

Clinical outcome measurements took between 60 and 90 minutes to complete for most participants, and all participants took less than the 2 hours that was allocated. Participants were offered a break if they became tired, but this proved to be unnecessary in all cases. Questionnaires were checked by the investigator who pointed out several questions that were often missed and asked the participant to complete them.

After enrolment in the trial, participant compliance with the four interventions were deemed acceptable, with only two drop-outs. One drop-out from the sham group had a spontaneous aggravation of a lower back complaint unrelated to intervention and another participant in the chiropractic intervention group did not start the intervention due to inability in making the travel commitment.

**Location**

Travel to the outer-suburban university location was a barrier for 16 (12%) potential participants. Additionally, one drop-out was due to difficulties with travel. Participants often became lost on their initial visit to the campus. While temporary parking permits were provided, the participants had to pick these up from the security station. This was sometimes confusing for them.

**Blinding and overall improvement**

Blinding was similar between groups, with 5 (50%) participants in the sham group and 8 (67%) participants in the chiropractic group correctly identifying which intervention they received [chi-squared=.627, p=0.361 (minimum expected count 4.09)]. Both the chiropractic group and the sham group were equally satisfied with the care they received.
[mean (SD): chiropractic 3.58 (1.0); sham 3.6 (0.7)], indicating that the sham protocol provided sufficient patient satisfaction.

**Costs**

Advertising costs totalled AUD$43,679. Minor equipment costs were AUD$395. Two registered chiropractors were employed part-time as research assistants to set up the procedures, screen participants and quantify outcome measures; the cost for this was AUD$3,033. In addition to one of the investigators (MFA), another experienced registered chiropractor was employed to be available to provide the weekly interventions at a cost of AUD$10,866. Therefore, total costs amounted to AUD$57,973. This translated to AUD$2,635 per participant. The costs (per participant) of recruitment and intervention were AUD$2,141 and AUD$494 respectively. These costs excluded the salary of the senior author (MFA) and the PhD scholarship of the first author (JCK).

**Harms**

Six (27%) participants reported harms. All harms were mild, including increased neck pain (chiropractic n=2, sham n=1), headache (chiropractic n=1, sham n=1) and mid-back pain (chiropractic n=1).

**Clinical outcomes**

Many clinical outcome measures were used in this study (Table 9). Participants had moderate intensity of dizziness at baseline [mean (SD)] in both the chiropractic group and the sham group (Table 10). DHI scores were also similar at baseline and improved in both groups post-intervention [chiropractic 28.33 (14.37) to 40.77 (12.48); sham 44.00 (16.97) to 36.40 (20.11)]. Similarly, NDI scores were reduced post-intervention [chiropractic 24.94 (12.87) to 19.07 (12.50); sham 24.18 (8.22) to 22.8 (6.2)]. Fifty eight percent of the chiropractic group showed a clinically-significant improvement (of at least 19%) in NDI scores compared to 30% of the sham group (Table 11). The DHI scores improved by the clinically significant amount (of at least 18%) in 67% of the chiropractic
group compared to 50% of the sham group. Mood was generally low, with participants commonly reporting symptoms of depression, anxiety and stress on the Depression Anxiety Stress Scale (DASS). Concerns of falling were high in both groups at baseline [chiropractic 26.00 (5.61); sham 29.00 (5.71)], and reduced slightly in both groups [chiropractic 24.42 (5.21); sham 26.7 (6.29)]. All participants were able to complete the physical functional tasks.
<table>
<thead>
<tr>
<th>Clinical outcome</th>
<th>Outcome measure</th>
<th>Description</th>
<th>Scoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dizziness</td>
<td>Numerical rating scale (NRS11)</td>
<td>Participants were asked to rate their dizziness experiences ‘today’ with 0 indicating no dizziness and 10 very severe dizziness.</td>
<td>0-10</td>
</tr>
<tr>
<td></td>
<td>Dizziness Handicap Inventory (DHI)</td>
<td>DHI is a comprehensively validated measure of disability due to dizziness from a range of causes (Jacobson &amp; Newman, 1990), and has demonstrated responsiveness to chiropractic interventions in older people (Hawk &amp; Cambron, 2009).</td>
<td>0-100</td>
</tr>
<tr>
<td>Neck pain</td>
<td>NRS11</td>
<td>Participants were asked to rate their neck pain experience ‘today’ from 0 (no pain) to 10(very severe pain).</td>
<td>0-10</td>
</tr>
<tr>
<td>Neck pain</td>
<td>Neck disability index (NDI)</td>
<td>NDI is a 10 item questionnaire reporting pain and difficulties with everyday activities (Vernon &amp; Mior, 1991).</td>
<td>0-100</td>
</tr>
<tr>
<td>Quality of life</td>
<td>SF12</td>
<td>SF12 is a 12-point questionnaire that gives two combined scores: a physical component score (PCS) and a mental component score (MCS).</td>
<td>PCS: 0-50, MCS: 0-50</td>
</tr>
<tr>
<td>Mood</td>
<td>Depression Anxiety Stress Scale (DASS21)</td>
<td>DASS contains 21 questions that report depression, anxiety and stress symptoms within the past week. Each component is scored separately. Interpretation is as follows: depression normal 0-4, moderate 5-8, severe 9–12 extremely severe 13-21; anxiety normal 0-3, moderate 4-6, severe 7-9, and extremely severe 10-21; stress normal 0-6, moderate 7-11, severe 12-16, and extremely severe 17-21 (Wood, Nicholas, Blyth, Asghari, &amp; Gibson, 2010).</td>
<td>Depression 0-21, Anxiety 0-21, Stress 0-21</td>
</tr>
<tr>
<td>Concerns of falling</td>
<td>Falls Efficacy Scale International (FES-I)</td>
<td>FES-I is a 16 item questionnaire measuring the level of concern of falling undertaking activities and routines (Yardley et al., 2005).</td>
<td>16-64</td>
</tr>
<tr>
<td>Cognitive function</td>
<td>Montreal Cognitive Assessment (MoCA)</td>
<td>MoCA is a 10-minute screening assessment for cognitive impairment. The domains are: attention and concentration, executive functions, memory, language, visuo-constructional skills, conceptual thinking, calculations, and orientation.</td>
<td>0-30</td>
</tr>
<tr>
<td>Clinical outcome</td>
<td>Outcome measure</td>
<td>Description</td>
<td>Scoring</td>
</tr>
<tr>
<td>------------------</td>
<td>-----------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>--------------------------</td>
</tr>
<tr>
<td>Physical function, mobility and balance</td>
<td>Step test</td>
<td>The number of times a person can repeatedly step one foot up and down on and off a standard 7.5cm height step in 15 seconds (Hill, Bernhardt, McGann, Maltese, &amp; Berkovits, 1996). Both feet were tested and a combined score was used.</td>
<td>Number of steps.</td>
</tr>
<tr>
<td></td>
<td>Timed Up and Go (TUG)</td>
<td>A measure of the time taken to stand up from a standard height armchair, walk a distance of three metres, turn, return and sit back down in the chair (Podsiadlo &amp; Richardson, 1991).</td>
<td>The time taken in seconds.</td>
</tr>
<tr>
<td></td>
<td>Functional reach</td>
<td>The distance an individual can reach forward with their dominant arm extended at horizontal, while standing. This is scored with the difference between starting reach and furthest reach in centimetres (Duncan, Weiner, Chandler, &amp; Studenski, 1990).</td>
<td>The distance in centimetres.</td>
</tr>
<tr>
<td></td>
<td>Four-square step test</td>
<td>The time taken to step in a sequence of forward, to the left, backwards and to the right, and then reversed. Each step is performed over an obstacle to increase difficulty (Dite &amp; Temple, 2002).</td>
<td>The time taken in seconds.</td>
</tr>
</tbody>
</table>
### Table 10 Pre- and post-intervention clinical outcome measures

<table>
<thead>
<tr>
<th></th>
<th>Sham group</th>
<th></th>
<th>Chiropractic group</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre n=11</td>
<td>Post n=10</td>
<td>Pre n=13</td>
<td>Post n=12</td>
</tr>
<tr>
<td>Female (n)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>5 (46%)</td>
<td>5 (50%)</td>
<td>6 (46%)</td>
<td>5 (42%)</td>
</tr>
<tr>
<td>Age (years)</td>
<td>72.55 (4.27)</td>
<td>72.9 (4.33)</td>
<td>74.23 (5.83)</td>
<td>73.75 (5.82)</td>
</tr>
</tbody>
</table>
| Cognitive function (MoCA) (0-30)
| (a) | 26.09 (1.92) | 26.90 (1.60)                     | 26.00 (2.16)       | 26.25 (2.67)                    |
| Dizziness (0-10)
| (b) | 4.00 (3.58)  | 3.50 (2.88)                      | 3.85 (2.12)        | 2.58 (2.64)                     |
| Dizziness handicap (DHI) (0-100)
| (b) | 44.00 (16.97) | 36.40 (20.11)                   | 40.77 (12.48)      | 28.33 (14.37)                   |
| Joint pain (NRS-11) (0-10)
| (b) | 2.27 (2.33)  | 3.30 (2.21)                      | 2.69 (2.02)        | 2.92 (2.84)                     |
| Neck pain (NRS-11) (0-10)
| (b) | 2.82 (1.78)  | 3.60 (2.12)                      | 4.38 (2.36)        | 2.75 (2.49)                     |
| Neck pain disability (NDI) (0-100)
| (b) | 24.18 (8.22) | 22.80 (6.20)                     | 24.94 (12.87)      | 19.07 (12.50)                   |
| Concerns of falling (FES-I) (16-64)
| (b) | 29.00 (5.71) | 26.70 (6.29)                     | 26.00 (5.61)       | 24.42 (5.21)                    |
| SF12 PCS (0-100)
| (c) | 36.20 (8.45) | 40.18 (10.98)                   | 42.12 (6.91)       | 43.96 (10.01)                   |
| SF12 MCS (0-100)
| (c) | 49.20 (10.79) | 49.98 (8.71)                     | 47.76 (9.75)       | 52.90 (9.45)                    |
| Mood:                          |            |                                 |                   |                                 |
| Depression (DASS) (0-21)
| (b) | 8.55 (4.99)  | 7.20 (6.20)                      | 5.38 (4.03)        | 3.50 (4.52)                     |
| Anxiety (DASS) (0-21)
| (b) | 8.73 (6.28)  | 6.20 (6.43)                      | 6.00 (2.58)        | 4.50 (2.97)                     |
| Stress (DASS) (0-21)
| (b) | 10.73 (5.61) | 7.60 (5.48)                      | 9.08 (6.09)        | 8.33 (7.02)                     |
| Physical function:            |            |                                 |                   |                                 |
| Functional reach (cm)
| (d) | 32.41 (5.90) | 30.60 (10.30)                   | 29.93 (11.75)      | 31.25 (8.37)                    |
| Step test sum (n)
| (d) | 27.09 (6.16) | 26.10 (7.08)                     | 25.46 (7.09)       | 26.08 (8.45)                    |
| Four square step test (seconds)
| (e) | 11.20 (2.51) | 14.18 (8.24)                     | 11.92 (2.95)       | 11.22 (3.18)                    |
| Timed up & go (seconds)
| (e) | 12.09 (2.87) | 12.36 (4.11)                     | 12.18 (2.70)       | 11.87 (3.67)                    |
| Correctly identified which group
| they were allocated to (n)     | 5 (50%)                            |                     | 8 (67%)                         |
| Treatment satisfaction (1-5)
| (f) | 3.60 (0.70)  |                                  | 3.58 (1.00)        |                                 |

Values displayed as mean(standard deviation) or number(percentage)

M – mean; SD – standard deviation; MoCA – Montreal cognitive assessment; NDI – neck disability index; DHI – dizziness handicap inventory; PCS – physical health composite score; MCS – mental health composite score; DASS – depression anxiety and stress scale

(a) a lower score indicates reduced cognitive function
(b) a higher score indicates greater symptoms
(c) a higher score indicated greater quality of life
(d) a higher score indicates greater physical function
(e) a faster time indicates greater physical function
(f) 1-I feel much worse 2-I feel worse 3-I feel the same 4-I feel better 5-I feel much better
Table 11 Proportion of improvement in primary clinical outcome measures

<table>
<thead>
<tr>
<th></th>
<th>Sham group</th>
<th>Chiropractic group</th>
</tr>
</thead>
<tbody>
<tr>
<td>% Improvement</td>
<td></td>
<td></td>
</tr>
<tr>
<td>NDI</td>
<td>19%*</td>
<td>19%</td>
</tr>
<tr>
<td></td>
<td>30%</td>
<td>58%</td>
</tr>
<tr>
<td></td>
<td>30%</td>
<td>33%</td>
</tr>
<tr>
<td></td>
<td>0%</td>
<td>25%</td>
</tr>
<tr>
<td>DHI</td>
<td>18%*</td>
<td>18%</td>
</tr>
<tr>
<td></td>
<td>30%</td>
<td>33%</td>
</tr>
<tr>
<td></td>
<td>50%</td>
<td>50%</td>
</tr>
<tr>
<td></td>
<td>20%</td>
<td>25%</td>
</tr>
<tr>
<td></td>
<td>40%</td>
<td>25%</td>
</tr>
<tr>
<td></td>
<td>20%</td>
<td>25%</td>
</tr>
</tbody>
</table>

*Minimal clinically important difference (MCID) for NDI is 19% (Cleland, Childs, & Whitman, 2008) and DHI is 18% (Jacobson & Newman, 1990)

Sample size calculation

The sample size for a fully-powered trial (derived from data in this feasibility trial with an effect size of $d=0.38$), using the DHI as the primary outcome measure, would require a group size of 150 (i.e. 75 per group). Alternatively, using NDI as the primary outcome measure (with an effect size of $d=0.46$), would require a group size of 222 (i.e. 111 per group).

Discussion

A fully-powered trial based on the current study would not be feasible in our setting using the current protocol. However, a trial may be feasible with modifications to the study location and recruitment strategies. Recruitment of this study achieved sufficient numbers to calculate sample sizes for potential larger trials. Blinding was acceptable in both groups.

Recruitment

We aimed for a sample size of 40 participants. However, recruitment did not reach this pre-defined arbitrary number, even with a six-month extension to the recruitment period. If conducted in the same setting, to reach the estimated sample size of 150 participants (using DHI as the primary outcome measure) would take more than four years, assuming a similar recruitment rate. This study found that using online
recruitment methods could be useful in targeting older Australians over a wider geographic area. On the other hand, newspaper advertisements, while more expensive, captured a local population. Considering the relatively high proportion (12%) of participants who could not make the travel commitment to our single location, for future studies we recommended having multiple sites with sufficient geographical spread to increase recruitment and retention or performing the study in a facility with a high concentration of older people with neck pain and dizziness such as a specialty clinic.

Older adults experiencing neck pain and dizziness often have co-morbidities. However, chiropractic intervention is unlikely to impact dizziness due to known vestibular or neurological origin, dizziness as a result of postural hypotension, or poly-pharmacy. Therefore, we recommend that the same exclusion of people with vestibular or neurological causes of dizziness be used for the larger study. Excluding these participants based on self-reported previous diagnoses, however, may not capture these individuals accurately. We recommend basing a future, larger trial in a rehabilitation setting such as a dizziness/falls clinic which provides access to clinical expertise and equipment to rule out vestibular, neurological, hypotensive and pharmacological causes of dizziness. Alternatively, the larger trial can be based on an effective referral system from a network of general medical practitioners. Exclusion of people based on cognitive-function testing has been shown to reduce the generalizability of findings (Trivedi & Humphreys, 2015), particularly in older people with pain (Monroe, Herr, Mion, & Cowan, 2013). However, the validity of self-reported measures of pain and function depends on intact memory and executive function. Participants in this trial who were excluded based on cognitive function were significantly disappointed to the extent that one of them lodged a complaint to the ethics committee. Future studies should consider how participants with potential impairments in cognitive function can be included, using outcome measures that are still able to capture self-reported pain and function. Alternatively, if a threshold of cognitive function is used in the exclusion criteria of future studies procedures need be
in place to direct excluded participants to providers of therapeutics for neck pain and
dizziness to avoid disappointment.

**Compliance with outcome assessment**

The assessment regime was not too onerous for the participants and was completed in a
timely manner. However, several participants missed individual questions on the
questionnaires, and had to be prompted by the investigator to fill these in. It was
necessary to have an investigator review completed questionnaires to check that all
questions had been completed at the end of the assessment session.

**Compliance with the intervention**

The drop-out rate for participants was acceptable, with less than 15% for each group.
However, this was for a relatively short intervention schedule of 4 visits over 4 weeks. It
cannot be determined from this study if a longer, more intensive or less intensive
schedule would have good compliance.

**Location**

Conducting the trial at a university campus meant that some participants became lost
trying to find the building location. Future studies should be conducted in an easy to find
location with convenient car parking facilities, and ideally with a choice of several sites to
capture participants who cannot travel long distances.

**Interventions and blinding**

The protocol of using the Activator II™ instrument (set on zero) as a sham-chiropractic
intervention appeared to achieve sufficient blinding in participants. This tool appears to
be a useful blinding tool for future similar studies, particularly ones in which the
experimental intervention consists of Activator II™-instrument delivered manipulation.
**Costs**

The costs and time to recruit sufficient numbers may be a challenge for a larger fully-powered RCT. Use of a network of chiropractic intervention sites may increase feasibility of recruitment. The cost of AUD$2,415 per participant may prove prohibitive if only small grant funding is available. To reduce this expenditure, the larger study could be based in a dizziness/falls clinic of a general or rehabilitation hospital. The use of a specialised or hospital recruitment setting would necessitate modification of this protocol, and our results may not be reflective of the participants recruited in such settings.

**Harms**

Fifteen out of 23 participants did not report any harms. Mild harms such as transient increases in neck pain or headache are common following chiropractic intervention (Maiers et al., 2014). However, participants in the sham group also reported these harms, so these may be related to natural and non-specific effects (Walker et al., 2011).

**Strengths and limitations**

Trials of non-pharmacological interventions for pain and dizziness in older people are scarce. This trial provides useful information in the Australian context on recruiting older people, and blinding for spinal manipulation, both of which are challenging. This is important information for future research. Furthermore, this was a feasibility study for determining effectiveness rather than efficacy. This necessitated that the intervention given reflected a ‘real-world’ combination of intervention strategies that Australian chiropractors would provide. Effectiveness studies by nature are not mechanistic and cannot identify the ‘active ingredient’ in the intervention package. But they do have higher external validity in their relevance and applicability to actual practice. In this sense, this was a trial comparing usual chiropractic care with sham chiropractic care. The intervention combination used here reflects the practice approach of a majority of Australian chiropractors (unpublished data), and follows contemporary practice
guidelines for the treatment of the older people (Hawk et al., 2017). However, it does not reflect every chiropractor’s practice style, particularly in its exclusion of manual manipulation of the neck. This limits the relevance of this study to trials of manual neck manipulation, as the biomechanics of manual manipulative thrusts are likely to be different from those delivered by an Activator instrument.

This trial was limited by the short-term follow-up, and no conclusions can be drawn about compliance with longer follow-up times. While the results of this trial advocate for conducting a fully-powered RCT at multiple locations, it did not test the feasibility of a protocol to ensure consistent recruitment and data collection across several sites. These issues should be investigated before such large-scale multi-centre studies are attempted. Another limitation of this study is that the participants were excluded based on self-reported previous diagnoses of dizziness, and were not uniformly screened by specialist medical staff to exclude other causes of dizziness. This may have made the cohort of participants somewhat heterogeneous. However, this heterogeneity reflects private practice that takes place within the primary care setting. Furthermore, this study is limited by including participants with very low intensities of dizziness and neck pain. There was no threshold for severity or intensity of dizziness or neck pain for inclusion. Setting of minimum DHI and NDI scores as inclusion criteria for future studies is recommended, although this would lead to a lower proportion of interested participants being eligible.

**Conclusions**

A large trial in an Australian university setting using the current protocol is not likely to be feasible primarily for financial and recruitment reasons. However, a fully-powered clinical trial may be feasible at an appropriate hospital or rehabilitation setting, which would require sample size of 150 (75 per group) or 222 (111 per group) using DHI or NDI as the primary outcome measure respectively. Activator II™-instrument-assisted sham
intervention provided acceptable blinding. The number and nature of the outcome measures used was not too onerous for the participants.

**Declarations**

**Ethics Approval and Consent to Participate**

The human ethics clearance was obtained from RMIT University’s human research ethics committee (HREC) (Approval number 29/13).

**Consent for publication**

Not applicable

**Availability of data and material**

The protocol and the datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

**Competing interests**

JH is on the editorial board, and SDF is the deputy-editor in chief, of Chiropractic & Manual Therapies. Neither played any part in the assignment of this manuscript to Associate Editors or peer reviewers and are separated and blinded from the editorial system from submission inception to decision. Otherwise, the authors declare no competing interests.

**Funding**

This project was supported by a grant from the Foundation for Chiropractic Research and Postgraduate Education (Denmark) to MFA and JH. JCK was also supported by an RMIT University postgraduate scholarship and a scholarship from the Chiropractors’ Association of Australia.

**Authors’ contributions**

JCK made a significant contribution to the design of the study. She also made a major contribution to securing of ethics approval and recruitment strategies. Furthermore, she
quantified almost all of the outcome measures, analysed and interpreted the results, and wrote the initial drafts of the manuscript. JH made a significant contribution to the design of the study, interpretation of the results and writing of the manuscript. SDF made an intellectual contribution to the design of the study and writing of the manuscript. MFA conceived and designed the study, supervised all aspects of its implementation and made a significant contribution to interpretation of results and writing of the manuscript.

Acknowledgements

We would like to thank: Dr Kelvin Murray for his assistance with recruitment of, and delivery of interventions to the participants; Dr Franziska Wright for her assistance with recruitment and quantification of outcome measures; Dr Suhair Shahwan for assistance with recruitment and administrative tasks; Professor Stephen Gibson for facilitation of the project and Dr Frances Batchelor for her training in physical performance assessment; Dr Stella Stylianou and Assoc. Professor Cliff Da Costa for advice on statistics; and Ms Laura Zark for editing the manuscript.
Chapter 7 – Discussion and conclusion

This thesis explored risks of falling in older adults with neck pain and/or dizziness and the potential improvements in concerns of falling and balance through manual therapy treatment of the cervical spine. A person’s balance and stability relies upon accurate proprioceptive information transmitted through the sensory system, which can be modulated in a number of different ways. This thesis explored the connection between neck pain, dizziness, concerns of falling and balance impairment. Furthermore, these associations were examined in older adults, and older adults with mobility impairment as classified by a threshold of less than 0.9m/s gait speed.

Through the research undertaken in this thesis (Chapter 3 - Neck pain, concerns of falling and physical performance in community dwelling Danish citizens over 75 years of age: A cross-sectional study), it was found that bothersome or intense neck pain was associated with concerns of falling, decreased mobility and impaired balance. Importantly, these relationships were only significant if the pain was of a high intensity and/or interfered with activities of daily living. Furthermore, these associations were confounded by other factors. As for interventions, the poor design of clinical trials in the published literature prevented a rigorous assessment of the effectiveness of non-pharmacological treatments for reducing dizziness and improving balance in older adults. The literature search (Chapter 4– The effects of non-pharmacological interventions for dizziness in older people: a systematic review) included clinical trials using manual therapy alone, and when combined with other non-pharmacological interventions such exercise. Published clinical trials of manual therapy for dizziness in older adults have been limited by a lack of control groups and inadequate blinding of participants and assessors. Therefore, no decision could be made on the effectiveness of these interventions.

In order to address the design weaknesses in the literature, a randomised, sham-controlled clinical trial of manual therapy was designed, and a pilot study was conducted.
(Chapter 6 Reducing selection bias in clinical trials of manual therapy for neck pain and dizziness in older adults.). This pilot study demonstrated that it is feasible to conduct a sham-controlled study in older adults, and that blinding of participants and outcome assessors is achievable without compromising the results of the study. However, this clinical trial design proved to be expensive, and any follow-up, fully-powered clinical trial may need modifications to the inclusion criteria and the study setting to increase the recruitment rate. The following three modifications should be considered for a successful clinical trial: i) a baseline cut-off of neck pain and/or dizziness intensity for participant inclusion; ii) conduct the study through a secondary rehabilitation setting to rule out confounding co-morbidities; iii) modifications to the recruitment strategy to enable recruitment of sufficient participants, such as including multiple sites to capture potential participants from a greater regional area.

The main findings to emerge from this thesis and their implications for future research and patient management are discussed in the following sections.

**Main research findings**

**Chapter 3 Bothersome neck pain is associated with increased concerns of falling and poor balance**

In order to establish a connection between ageing, neck pain, increased concerns of falling and poor balance, a cross-sectional study was conducted with older adults. Participants aged 75 years and over were surveyed regarding the presence of neck pain, concerns of falls and physical performance. In this cohort, one-in-four participants reported having experienced some neck pain in the previous four weeks, and one-in-twelve participants reported bothersome neck pain (defined earlier as pain interrupting daily activities or routines). These findings from a representative sample of older Danes confirm that neck pain is common, and often bothersome.
Neck pain was only significantly associated with self-reported concerns of falling and poorer performance on physical tasks when the pain was bothersome. Furthermore, when bothersome neck pain was adjusted for other key risk factors for falls (depression, concerns of falling, physical performance and previous history of a fall) it was no longer significantly associated with concerns of falling or physical performance. This shows that neck pain in older adults is part of a web of falls risk factors. Furthermore, the relationship between physical performance and bothersome neck pain became non-significant after adjusting for concerns of falling, symptoms of depression and history of a previous fall. Mood may play a key role in these relationships, with previous research showing that anxiety is associated with the relationship between concerns of falling, postural balance and risk of future falls (Delbaere, Crombez, van Haastregt, & Vlaeyen, 2009; Sturnieks, Delbaere, Brodie, & Lord, 2016).

While bothersome neck pain was significantly associated with concerns of falling and impaired physical performance, multi-site pain (neck pain with low back pain) was not. This finding is contrary to previous reports that general bodily pain at multiple sites is linked to reduced physical performance, as measured by the short physical performance battery (SPPB) (Patel, Guralnik, Dansie, & Turk, 2013). It is possible that the discrepancy is due to the way the groups were delineated in the present study, as the participants with multi-site pain did not necessarily have bothersome pain. Due to the small sample size, it was not possible do a subgroup analysis of participants with bothersome neck pain and bothersome low back pain. It is possible therefore, that most participants had low levels of neck and low back pain that did not interfere with their daily activities or routines. Regardless, the present study shows that pain is enough to bother activities of daily living even when the site of bothersome pain is restricted to the neck. This is likely to be due to proprioceptive afferents from the neck contributing to postural balance and stability. Indeed, experimental research has shown that proprioception is impaired by intense neck pain (> 7/10) but not by mild neck pain (2-4/10) (Madeleine et al., 2004; Vuillerme & Pinsault, 2009).
Chapter 4 Non-pharmacological treatment approaches improve non-specific dizziness and balance in older people

Chapter 4 systematically reviewed the current literature surrounding the topic of non-pharmacological interventions to improve dizziness in older adults. This study found that controlled, clinical trials published up to May 2014 consistently had a high risk of bias, with many clinical trials lacking adequate blinding or allocation concealment (selection bias). Under the umbrella of non-pharmacological interventions, isolating manual therapies as an intervention for the search criteria did not elucidate any controlled, clinical trials. This situation is in contrast to studies in younger populations, where three systematic reviews (Lystad et al., 2011; Reid & Rivett, 2005; Yaseen et al., 2018) have examined five RCTs (Du et al., 2010; Fang, 2010; Kang, Wang, & Ye, 2008; Karlberg, Magnusson, Eva-Maj, Agneta, & Moritz, 1996; Reid, Rivett, Katekar, & Callister, 2008). These trials collectively found moderate evidence for a significant reduction in dizziness symptoms following manual therapies. A number of non-controlled clinical trials using manual therapy for improving dizziness in older adults have been conducted; however, these were excluded from the systematic review because they lacked control groups (Hawk et al., 2007; Strunk & Hawk, 2009) and did not exclude participants without dizziness (Hawk et al., 2009; Hawk et al., 2007; Strunk & Hawk, 2009). Collectively these studies found small improvements (Hawk et al., 2009; Strunk & Hawk, 2009) or no change in dizziness (Hawk & Cambron, 2009; Hawk et al., 2009; Hawk et al., 2007; Strunk & Hawk, 2009). The lack of controlled, rigorous trials is surprising, considering that neck pain and dizziness are common in older people (Colledge et al., 1994; Gopinath et al., 2009; Hartvigsen et al., 2004; Hartvigsen et al., 2006; Hogg-Johnson et al., 2008; Kammerlind, Bravell, & Fransson, 2016; Palacios-Cena et al., 2015; Skillgate, Magnusson, Lundberg, & Hallqvist, 2012).

A recent controlled clinical trial has investigated manual therapy for dizziness and balance in older persons (Reid, Callister, Snodgrass, Katekar, & Rivett, 2015; Reid,
Rivett, Katekar, & Callister, 2014). This trial was not included in the systematic review because it was published after the search was conducted and because they did not exclude people who were less than 50 years old. However, the average age of participants was 62±12.7 (SD) years; therefore, the study is representative of older people, and is worth reporting on in the context of this thesis. This clinical trial reported significant improvements in dizziness intensity and frequency following two to six treatments of either sustained natural apophyseal glides (SNAG) mobilisation, Maitland mobilisation or a placebo intervention. This clinical trial was of high quality with blinding of participants and outcome assessors, and it included a placebo control arm. They did not find a significant improvement in neck pain compared to placebo for either mobilisation technique. However, there were significant improvements in dizziness in both intervention groups when compared to the placebo group. The improvements in dizziness were similar between both SNAG mobilisation and Maitland mobilisation techniques. Improvements in dizziness were seen immediately following the treatment schedule and persisted at the 12 week and 12 month follow-ups.

The lack of controlled, high quality trials in older populations prevents conclusions from being drawn regarding the effectiveness of manual interventions in this age group. Therefore, rigorous, controlled, and blinded clinical trials need to be conducted to investigate the effectiveness of these therapies in improving dizziness and the concerns of falls.

**Chapter 5 Neck pain influences balance in older people**

Previous studies of young adults by Ruhe and colleagues found that postural sway increases as the intensity of low back pain and neck pain increases (Ruhe et al., 2011b, 2013). Likewise, a systematic review of neck pain and postural sway found that neck pain is associated with increases in sway, particularly in the anterior-posterior direction (Ruhe, Fejer, & Walker, 2011a). However, findings from young adults cannot easily be generalised to older adults because older adults frequently have comorbid conditions
such as osteoarthritis, which also impair their mobility. It is not known whether neck or back pain affects balance or mobility in older adults who already have limited mobility due to pre-existing musculoskeletal conditions.

The first cross-sectional study of this thesis showed that neck pain is associated with impaired mobility and balance in a sample of older Danish residents. However, this cohort was an active community-dwelling group of individuals, so it was not possible to assess whether neck pain or low back pain influence stability and balance in patients with osteoarthritis. Therefore, the relationship between musculoskeletal pain, mobility and balance was explored in the second cross-sectional study. This study looked at neck pain intensity and balance in a sub-group of older Danes with mobility limitations.

Our second study found that intense neck pain (>5/10) in mobility-limited older Danes was associated with significantly greater COP sway, when compared to individuals with mild neck pain. Furthermore, in this mobility-limited group, intense low back pain (>5/10) was significantly associated with increased concerns of falling (Falls Efficacy Scale – International), compared to individuals without pain. In contrast, mild neck pain and mild low back pain were not associated with impaired balance or increased concerns of falling. This study demonstrated that high intensity neck pain is associated with impairments in standing balance in older people with limited mobility, and that concerns of falling are associated with intense low back pain. The findings from our second study are consistent with those from previous studies. For instance, in older adults, neck pain from severe osteoarthritis is associated with significantly increased postural sway (Boucher, Descarreaux, & Normand, 2008), while pain in older adults is associated with reduced activities and routines, increased concerns of falling and reduced mood (Patel et al., 2013; Stubbs et al., 2014a; Stubbs et al., 2014b).

The main clinical implication of our second study is that in older people with limited mobility, the presence of severe neck pain is likely to contribute to an increased risk of falling, due to a greater extent of postural sway. Thus, in addition to the clinical
imperative to reduce such pain, attention needs to be given to providing interventions that can reduce the risk of falls in these individuals.

**Chapter 6 Reducing selection bias in clinical trials of manual therapy for neck pain and dizziness in older adults.**

A thorough search and analysis of previous studies that had examined manual therapy as a treatment for dizziness in older people, demonstrated that most of these studies had poor methodological design. Specifically, they exhibited high risks of bias, particularly selection bias, detection bias (blinding of outcome assessor), and performance bias (blinding of outcome assessor). Furthermore, previous studies have included low numbers of participants. Therefore, the feasibility study performed for the current thesis calculated sample sizes for both neck pain (neck disability index) and dizziness (dizziness handicap inventory) as a primary outcome measures. The randomised controlled feasibility study designed and executed in the current thesis tested a study protocol by addressing these biases and provided a robust study design for further investigation.

The manual therapy intervention used in this feasibility study was an instrument-assisted spring-loaded device. This intervention was chosen due to the advanced age of the participants, and their correspondingly higher risk of osteoporosis. This device can be set to deliver a consistent force of thrust, which is difficult with manually applied techniques. Lower force techniques are recommended in older age populations when high-velocity low-amplitude techniques are contraindicated, such as when there is a risk of reduced bone density (Hawk et al., 2017). Additionally, the device can be placed with the patient’s cervical spine in a neutral position, removing the risk of stress and strain to the joints and soft tissues. Therefore, the sham intervention utilised was the same device set on ‘zero’ in order to mimic the intervention without providing the therapeutic effect. Participants in the intervention and sham groups both equally guessed their allocation, with five (50%) and eight (67%) in each group correctly guessing, respectively. Participants were requested not to talk about their treatment during the post-treatment
phase, and this instruction was complied with by all participants. The nature of the intervention was kept concealed by a strict protocol by the investigators.

This trial did not meet recruitment expectations due to fewer responses to public advertising than initially expected. Any future trial will need modifications to the recruitment strategy to achieve full power. Social media Facebook advertising produced more enquiries, but meant that many potential participants were excluded due to long travelling distance to the research site. For example, future fully-powered trials using a modified protocol of this feasibility study should aim to include multiple research sites to increase the inclusion of eligible participants.

This feasibility trial did not use a cut-off point of intensity of neck pain in recruitment. Considering the results of the two cross-sectional studies carried out in this thesis (Chapter 3 - Neck pain, concerns of falling and physical performance in community dwelling Danish citizens over 75 years of age: A cross-sectional study and Chapter 4– The effects of non-pharmacological interventions for dizziness in older people: a systematic review), this factor should be considered in any future study. Furthermore, the estimated effect size in the feasibility study (used for estimation of sample size calculation) was relatively modest (Cohen’s d=0.46). Based on the results of the cross-sectional studies, it may be assumed that any neck pain that is contributing to imbalance (and potentially dizziness) would need to be of moderate (>5/10) intensity to produce these changes. Therefore, interventions aimed at improving neck pain and balance should target people with a high intensity of neck pain.

Recruitment for this feasibility clinical trial proved to be challenging and expensive. The clinical trial was projected to run for three months; however, due to the challenges around recruitment, the project was extended by an extra six months, and only just over half (n=24) of the intended 40 participants were recruited. Ideally, the study would have continued until the required numbers of participants were acquired, however, due to time and budget constraints further recruitment into the clinical trial was ceased. It is
common for this to occur in clinical trials, with some authors suggesting that up to half of all clinical trials are unable to recruit their planned sample size, even after time extensions are granted (McDonald et al., 2006; Sully, Julious, & Nicholl, 2013).

**Limitations of the research presented in this thesis**

Limitations relevant to the present study have been presented at the end of each chapter. The discussion below highlights the limitations of the thesis more broadly, in the context of the clinical concepts upon which the topic was based, as well as an acknowledgement of some of the assumptions that were made.

One limitation of the current work is that two of the chapters utilised data that had been collected as part of a larger study, the Healthy Ageing Network of Competence (HANC) study. This HANC study was conducted for purposes and objectives that were unrelated to the concepts of this thesis. Had the data been collected for the specific purpose of the current thesis, additional patient information and data would have been collected. For example, the HANC study did not collect information on dizziness, and consequently it is not known whether dizziness was a significant contributor to the adjusted analysis in Chapter 3 - Neck pain, concerns of falling and physical performance in community dwelling Danish citizens over 75 years of age: A cross-sectional study. It may be argued that the retrospective nature of the analysis restricts the questions that can be asked of the data and it limits the conclusions that can be drawn.

A second limitation of the current work was the systematic review (Chapter 4 – The effects of non-pharmacological interventions for dizziness in older people: a systematic review), as there was a lack of high quality studies on the topic. This made it challenging to objectively assess the potential of non-pharmacological interventions to improve dizziness in older people. The RCT undertaken as part of this thesis was designed on the conceptual understanding that manual therapy may improve neck pain and in turn reduce dizziness and improve balance. However, due to some gaps in knowledge upon
this topic, determining the most clinically-effective dosage, the best outcome measures or
the optimal choice of intervention was made challenging. Consequently the protocol for
the RCT was guided by the clinical judgement and experience of the research team. This
limitation should be considered before future full-scale RCTs use this protocol.

The RCT was designed before we had access to the outcomes of our two cross-sectional
studies. With the wisdom that comes with hindsight, it is clear that the intensity of neck
and low back pain are critical factors in an individual's fear of falling and their loss of
balance. Therefore it is important that pain intensity is measured in any full-scale RCT.

Recruitment of participants into both cross-sectional studies and the feasibility trial used
exclusion criteria that included poor performance on tests of global cognitive function.
This exclusion criterion was based on the belief that cognitively impaired individuals may
be ill-equipped to fill in questionnaires and accurately complete the tasks required to
participate in the research. However, ethical and sampling issues are introduced when
excluding cognitively-impaired people. Taylor and colleagues have argued that it is not
justifiable to exclude individuals on the basis of outcomes on the MMSE and MoCA
(Taylor, DeMers, Vig, & Borson, 2012). Indeed, Monroe and colleagues (2013) advocated
that cognitively impaired individuals should be included, where possible, in geriatric
research and pain research (Monroe et al., 2013; Taylor et al., 2012). They claim that in
order to inform the care of older adults with pain it is necessary to examine the pain
experiences of older adults with cognitive impairment, as well as those without.

Excluding participants based on their level of cognitive impairment may dramatically
reduce the external validity of the findings (Trivedi & Humphreys, 2015)(Trivedi 2015).
Cognitive function is known to influence balance (Stijntjes 2015) and pain perception
(Berryman et al., 2014; Moriarty, McGuire, & Finn, 2011). It possible that by excluding
these participants, the studies in this thesis reached a different outcome. Indeed,
cognitive function as measured by MMSE was a cofounder in the relationship between
neck pain and physical performance, and neck pain with low back pain and physical
Implications of the findings described in this thesis

The review of literature conducted for this thesis revealed the paucity of data that are available from properly conducted clinical trials of manual therapy for the treatment of neck and low back pain in older people. Considering that 15% of older Australians, a significant proportion, seek chiropractic treatment predominantly for these conditions (Xue, Zhang, Lin, Da Costa, & Story, 2007; Xue et al., 2008), there is an urgent need to acquire an evidence-base to support the claims or assumptions of effectiveness. Such data are especially important when considering the financial burden that chiropractic treatments place on the healthcare system and on the health insurance industry, estimated to be AUD$905 million (Xue et al., 2008). To guide future research in the area, the present thesis proposed a model for a blinded, controlled clinical intervention study. A pilot trial of this model revealed some of the practical limitations that need to be considered when implementing this study design in the future.

The research undertaken in this thesis advances our understanding of the complex, inter-related factors that modulate balance and stability and in turn, may contribute to an increased risk of falls. It is evident that the concern of falling and the feeling of instability are heightened when a person is experiencing musculoskeletal pain. More specifically, the presence of bothersome neck pain, beyond a certain level of intensity, was shown to significantly impact upon the risk factors for falls. A clear implication of these findings is that older adults, who are at heightened risk of falling or have heightened concerns of falling, should be routinely examined and treated for neck pain in order to reduce the potential risk of their pain contributing to a fall.
This thesis also provides an opportunity to consider other non-pharmacological interventions to manage non-specific dizziness. Previous research on non-pharmacological management of this condition is heavily weighted towards exercise therapy. However, older persons who are concerned of falling may be unwilling to engage in regular structured exercise, and there are significant challenges in achieving good compliance (Franco et al., 2015). Similarly, the pharmacological treatment of chronic, severe pain is fraught with issues of opioid dependency and of the potential for poly-drug interactions (Volkow & McLellan, 2016). Non-pharmacological interventions such as manual therapy may provide a more practical solution to this problem. Although the passive treatment approach of manual therapy can create dependency, be expensive, and be time-intensive for the practitioner and the patient, it may nevertheless be a supplementary intervention for structured exercise regimes or analgesics.

Conclusions and suggestions for further work

Overall, this thesis contributes to the improved management of older people with neck pain and dizziness, by understanding the association between bothersome and intense pain and postural stability. Manual therapies may play a role in the management of these conditions, with flow-on benefits of reducing instability and falls risk; however, there is a need for further work to evaluate these therapies. This thesis has recommendations for conducting future small and large trials to achieve sufficient blinding, randomisation and selection of sample size for both neck pain and dizziness outcomes.

Neck pain is associated with increased concerns of falling and decreased physical performance in older adults. These relationships are confounded by a web of other factors. Future studies examining neck pain and instability in older adults should include measures of mood, concerns of falling, and previous history of falling. There is likely to be multi-directional causal factors between pain, mood and stability. Future studies
examining these relationships in older people need to be conducted to understand prevention of instability, falls, and target interventions to ameliorate these conditions.

There is currently insufficient evidence for the effectiveness of non-pharmacological interventions for treating dizziness in older people, due to the paucity of literature on this topic. Therefore, future rigorous controlled trials need to be conducted that target older adults. Future trials should contain a control group, have specific inclusion criteria for dizziness in older age groups, and appropriate blinding of participants and outcome assessors. Dizziness is a major contributor to personal and societal burden in older adults who have an increased risk of poly-pharmacy, compared to younger adults. Therefore, it is paramount that non-pharmacological interventions are examined in older people using high quality, rigorous study designs.

Intense neck pain, but not mild neck pain, is associated with reduced balance in mobility-limited older adults. Older adults with increased intensity of pain are at increased risk of mobility impairment, and it appears to be cumulative with other mobility impairments. Interventions, ideally non-pharmacological, should be evaluated to reduce the intensity of musculoskeletal pain.

Finally, it is feasible to run a large sham-controlled trial to examine effectiveness of spinal manipulative therapy for neck pain and non-specific dizziness in older people, with modifications to increase recruitment. Future, rigorous studies examining manual therapies are needed in older adults. These trials should target older adults with bothersome or intense neck pain, to determine if alleviating these factors reduces associated instability and falls risk.

This thesis provides recommendations on identifying older people at risk of instability, specifically that bothersome or intense pain is associated with reduced physical performance, impaired balance and increased concerns of falling. Neck pain and dizziness in older people may be reduced with manual therapies, and it is feasible to evaluate these therapies in rigorous randomised sham-controlled trials.
References


meta-analysis. *Epidemiology, 21*(5), 658-668. doi:10.1097/EDE.0b013e3181e89905


doi:10.1007/s40520-017-0876-7


MacKenzie, D. M., Copp, P., Shaw, R. J., & Goodwin, G. M. (1996). Brief cognitive screening of the elderly: a comparison of the Mini-Mental State Examination (MMSE), Abbreviated Mental Test (AMT) and Mental Status Questionnaire (MSQ). *Psychological Medicine, 26*(2), 427-430.


Appendices
### List of search terms

#### PubMed Search Terms

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>&quot;Randomised Controlled Trial&quot; [Publication Type]</td>
</tr>
<tr>
<td>2</td>
<td>&quot;Controlled Clinical Trial&quot; [Publication Type]</td>
</tr>
<tr>
<td>3</td>
<td>randomised[Title/Abstract]</td>
</tr>
<tr>
<td>4</td>
<td>placebo[Title/Abstract]</td>
</tr>
<tr>
<td>5</td>
<td>Clinical Trials as Topic[Mesh:NoExp]</td>
</tr>
<tr>
<td>6</td>
<td>randomly[Title/Abstract]</td>
</tr>
<tr>
<td>7</td>
<td>trial[Title]</td>
</tr>
<tr>
<td>8</td>
<td>1 OR 2 OR 3 OR 4 OR 5 OR 6 OR 7</td>
</tr>
<tr>
<td>9</td>
<td>&quot;Animals&quot;[Mesh] NOT &quot;Humans&quot;[Mesh]</td>
</tr>
<tr>
<td>10</td>
<td>8 NOT 9</td>
</tr>
<tr>
<td>11</td>
<td>&quot;Aged&quot;[Mesh]</td>
</tr>
<tr>
<td>12</td>
<td>&quot;Aged, 80 and over&quot;[Mesh]</td>
</tr>
<tr>
<td>13</td>
<td>&quot;Aging&quot;[Mesh]</td>
</tr>
<tr>
<td>14</td>
<td>aged</td>
</tr>
<tr>
<td>15</td>
<td>aging</td>
</tr>
<tr>
<td>16</td>
<td>elderly</td>
</tr>
<tr>
<td>17</td>
<td>11 OR 12 OR 13 OR 14 OR 15 OR 16</td>
</tr>
<tr>
<td>18</td>
<td>&quot;Dizziness&quot;[MeSH]</td>
</tr>
<tr>
<td>19</td>
<td>&quot;Vertigo&quot;[MeSH]</td>
</tr>
<tr>
<td>20</td>
<td>dizz*</td>
</tr>
<tr>
<td>21</td>
<td>vertigo</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>22</td>
<td>18 OR 19 OR 20 OR 21</td>
</tr>
<tr>
<td>23</td>
<td>&quot;Chiropractic&quot;[MeSH]</td>
</tr>
<tr>
<td>24</td>
<td>&quot;Physical Therapy Specialty&quot;[MeSH]</td>
</tr>
<tr>
<td>25</td>
<td>&quot;Osteopathic Medicine&quot;[MeSH]</td>
</tr>
<tr>
<td>26</td>
<td>&quot;Musculoskeletal Manipulations&quot;[MeSH]</td>
</tr>
<tr>
<td>27</td>
<td>&quot;Complementary Therapies&quot;[MeSH]</td>
</tr>
<tr>
<td>28</td>
<td>&quot;Manipulation, Osteopathic&quot;[MeSH]</td>
</tr>
<tr>
<td>29</td>
<td>&quot;Manipulation, Chiropractic&quot;[MeSH]</td>
</tr>
<tr>
<td>30</td>
<td>&quot;Therapy, Soft Tissue&quot;[MeSH]</td>
</tr>
<tr>
<td>31</td>
<td>&quot;Massage&quot;[MeSH]</td>
</tr>
<tr>
<td>32</td>
<td>&quot;Acupuncture&quot;[Mesh]</td>
</tr>
<tr>
<td>33</td>
<td>&quot;Cognitive Therapy&quot;[Mesh]</td>
</tr>
<tr>
<td>34</td>
<td>&quot;Vestibular Diseases/rehabilitation&quot;[Mesh]</td>
</tr>
<tr>
<td>35</td>
<td>&quot;Exercise/therapeutic use&quot;[Mesh]</td>
</tr>
<tr>
<td>36</td>
<td>&quot;Accidental Falls/prevention and control&quot;[Mesh]</td>
</tr>
<tr>
<td>37</td>
<td>&quot;Postural Balance&quot;[Mesh]</td>
</tr>
<tr>
<td>38</td>
<td>&quot;Physical Therapy Modalities&quot;[Mesh]</td>
</tr>
<tr>
<td>39</td>
<td>&quot;Exercise Therapy&quot;[Mesh]</td>
</tr>
<tr>
<td>40</td>
<td>chiropract*</td>
</tr>
<tr>
<td>41</td>
<td>physiotherap*</td>
</tr>
<tr>
<td>42</td>
<td>&quot;physical therapy&quot;</td>
</tr>
<tr>
<td>43</td>
<td>&quot;physical therapist&quot;</td>
</tr>
<tr>
<td>44</td>
<td>osteopath*</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>45</td>
<td>&quot;complementary therapies&quot;</td>
</tr>
<tr>
<td>46</td>
<td>acupuncture</td>
</tr>
<tr>
<td>47</td>
<td>&quot;dry needling&quot;</td>
</tr>
<tr>
<td>48</td>
<td>massage</td>
</tr>
<tr>
<td>49</td>
<td>&quot;soft tissue therapy&quot;</td>
</tr>
<tr>
<td>50</td>
<td>&quot;manual therapy&quot;</td>
</tr>
<tr>
<td>51</td>
<td>&quot;manual therapist&quot;</td>
</tr>
<tr>
<td>52</td>
<td>&quot;spinal manipulation&quot;</td>
</tr>
<tr>
<td>53</td>
<td>&quot;cervical manipulation&quot;</td>
</tr>
<tr>
<td>54</td>
<td>&quot;cognitive therapy&quot;</td>
</tr>
<tr>
<td>55</td>
<td>&quot;cognitive behaviour therapy&quot;</td>
</tr>
<tr>
<td>56</td>
<td>&quot;cognitive behavior therapy&quot;</td>
</tr>
<tr>
<td>57</td>
<td>&quot;vestibular rehabilitation&quot;</td>
</tr>
<tr>
<td>58</td>
<td>&quot;vestibular exercise&quot;</td>
</tr>
<tr>
<td>59</td>
<td>&quot;vestibular exercises&quot;</td>
</tr>
<tr>
<td>60</td>
<td>&quot;exercise therapy&quot;</td>
</tr>
<tr>
<td>61</td>
<td>&quot;fall prevention&quot;</td>
</tr>
<tr>
<td>62</td>
<td>&quot;falls prevention&quot;</td>
</tr>
<tr>
<td>63</td>
<td>&quot;postural balance&quot;</td>
</tr>
<tr>
<td>64</td>
<td>23 OR 24 OR 25 OR 26 OR 27 OR 28 OR 29 OR 30 OR 31 OR 32 OR 33 OR 34 OR 35 OR 36 OR 37 OR 38 OR 39 OR 40 OR 41 OR 42 OR 43 OR 44 OR 45 OR 46 OR 47 OR 48 OR 49 OR 50 OR 51 OR 52 OR 53 OR 54 OR 55 OR 56 OR 57 OR 58 OR 59 OR 60 OR 61 OR 62 OR 63</td>
</tr>
<tr>
<td>65</td>
<td>10 AND 17 AND 22 AND 64</td>
</tr>
</tbody>
</table>
List of excluded studies

<table>
<thead>
<tr>
<th>Article</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Aigner, Fialka, Radda, &amp; Vecsei, 2006)</td>
<td>Participants not dizzy</td>
</tr>
<tr>
<td>(Alessandrini, Napolitano, Micarelli, De Padova, &amp; Bruno, 2012)</td>
<td>Age – participants younger than 65</td>
</tr>
<tr>
<td>(Alkan et al., 2011)</td>
<td>Turkish language (Unable to be translated)</td>
</tr>
<tr>
<td>(Andersson, Asmundson, Denev, Nilsson, &amp; Larsen, 2006)</td>
<td>Age – participants younger than 65</td>
</tr>
<tr>
<td>(Andersson, Fredriksson, Jansson, Ingerholt, &amp; Larsen, 2004)</td>
<td>Age – participants younger than 65</td>
</tr>
<tr>
<td>(Araujo, Silva, Costa, Pereira, &amp; Safons, 2011)</td>
<td>Participants not dizzy</td>
</tr>
<tr>
<td>(Basta &amp; Ernst, 2011)</td>
<td>German language (Unable to be translated)</td>
</tr>
<tr>
<td>(Bergamaschi, Ferrari, Gallamini, &amp; Scoppa, 2011)</td>
<td>Participants not dizzy</td>
</tr>
<tr>
<td>(Cambi, Astore, Mandala, Trabalzini, &amp; Nuti, 2013)</td>
<td>Age – participants younger than 65</td>
</tr>
<tr>
<td>(Carrick, Oggero, &amp; Pagnacco, 2007)</td>
<td>Participants not dizzy</td>
</tr>
<tr>
<td>(Deho &amp; Colombo, 1990)</td>
<td>Italian language (Unable to be translated)</td>
</tr>
<tr>
<td>(Du et al., 2010)</td>
<td>Chinese language (Unable to be translated)</td>
</tr>
<tr>
<td>(Edelman, Mahoney, &amp; Cremer, 2012)</td>
<td>Age – participants younger than 65</td>
</tr>
<tr>
<td>(Fang, 2007)</td>
<td>Age – participants younger than 65</td>
</tr>
<tr>
<td>(Fang, 2010)</td>
<td>Chinese language (Unable to be translated)</td>
</tr>
<tr>
<td>(Guo, 2007)</td>
<td>Age – participants younger than 65</td>
</tr>
<tr>
<td>(Hahn, Van Beurden, Kempton, Sladden, &amp; Garner, 1996)</td>
<td>Participants not dizzy</td>
</tr>
<tr>
<td>Study Reference</td>
<td>Information</td>
</tr>
<tr>
<td>-----------------------------------------------------</td>
<td>------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Hansson, Månsson, &amp; Håkansson, 2004</td>
<td>Age – participants younger than 65</td>
</tr>
<tr>
<td>Hawk &amp; Cambron, 2009</td>
<td>No control group</td>
</tr>
<tr>
<td>Hawk, Cambron, &amp; Pfeifer, 2009</td>
<td>Not all participants suffered dizziness</td>
</tr>
<tr>
<td>Hawk et al., 2005</td>
<td>No control group</td>
</tr>
<tr>
<td>Holmberg, Karlberg, Harlacher, Rivano-Fischer, &amp; Magnusson, 2006</td>
<td>Age – participants younger than 65</td>
</tr>
<tr>
<td>Johansson, Akerlund, Larsen, &amp; Andersson, 2001</td>
<td>Dizziness had specific diagnosis</td>
</tr>
<tr>
<td>Karlberg, Magnusson, Malmström, Melander, &amp; Moritz, 1996</td>
<td>Age – participants younger than 65</td>
</tr>
<tr>
<td>Li, Cai, &amp; Gan, 2011</td>
<td>Chinese language (Unable to be translated)</td>
</tr>
<tr>
<td>Liu, 2005</td>
<td>Chinese language (Unable to be translated)</td>
</tr>
<tr>
<td>Marioni et al., 2013</td>
<td>Dizziness had specific diagnosis</td>
</tr>
<tr>
<td>Michels, Lehmann, &amp; Moebus, 2007</td>
<td>Age – participants younger than 65</td>
</tr>
<tr>
<td>McCarroll et al., 2012</td>
<td>Pharmaceutical intervention</td>
</tr>
<tr>
<td>Mraz et al., 2007</td>
<td>Age – participants younger than 65</td>
</tr>
<tr>
<td>Olszewski, Repetowski, &amp; Kuśmierczyk, 2007</td>
<td>Polish language (Unable to be translated)</td>
</tr>
<tr>
<td>Pavlou, Lingeswaran, Davies, Gresty, &amp; Bronstein, 2004</td>
<td>Age – participants younger than 65</td>
</tr>
<tr>
<td>Reid, Rivett, Katekar, &amp; Callister, 2008</td>
<td>Age – participants younger than 65</td>
</tr>
<tr>
<td>Reid, Rivett, Katekar, &amp; Callister, 2014</td>
<td>Age – participants younger than 65</td>
</tr>
<tr>
<td>Ricci, Aratani, Caovilla, &amp; Gananca, 2012</td>
<td>Protocol</td>
</tr>
<tr>
<td>Rzewnicki &amp; Rogowski, 2008</td>
<td>Polish language (Unable to be translated)</td>
</tr>
<tr>
<td>Reference</td>
<td>Study Details</td>
</tr>
<tr>
<td>-----------</td>
<td>--------------</td>
</tr>
<tr>
<td>(Tschan et al., 2012)</td>
<td>German language (Unable to be translated)</td>
</tr>
<tr>
<td>(Xiaoxiang, 2006)</td>
<td>Age – participants younger than 65</td>
</tr>
<tr>
<td>(Wildenberg, Tyler, Danilov, Kaczmarek, &amp; Meyerand, 2010)</td>
<td>Dizziness had specific diagnosis</td>
</tr>
<tr>
<td>(Wildenberg, Tyler, Danilov, Kaczmarek, &amp; Meyerand, 2011)</td>
<td>Dizziness had specific diagnosis</td>
</tr>
<tr>
<td>(Yardley et al., 2012)</td>
<td>Age – participants younger than 65</td>
</tr>
<tr>
<td>(Yardley, Beech, &amp; Weinman, 2001)</td>
<td>Age – participants younger than 65</td>
</tr>
<tr>
<td>(Yardley, Beech, Zander, Evans, &amp; Weinman, 1998)</td>
<td>Age – participants younger than 65</td>
</tr>
<tr>
<td>(Yardley et al., 2004)</td>
<td>Dizziness had specific diagnosis</td>
</tr>
<tr>
<td>(Zhang, Luo, &amp; Huang, 2008)</td>
<td>Chinese language (Unable to be translated)</td>
</tr>
</tbody>
</table>

**References**


stimulation. Brain Imaging and Behavior, 4(3-4), 199-211. doi:10.1007/s11682-010-9099-7


Ethics approval

Notice of Approval

Date: 23 April 2015
Project number: 29/13
Project title: Parameters of balance and dizziness in elderly populations and the effectiveness of neck manipulation in reducing neck pain and dizziness
Risk classification: More than low risk
Investigator: Dr Michael Azari
Approved: From: 19 August 2013 To: 18 August 2016

Terms of approval:
1. Responsibilities of investigator
   It is the responsibility of the above investigator to ensure that all other investigators and staff on a project are aware of the terms of approval and to ensure that the project is conducted as approved by HREC. Approval is only valid whilst investigator holds a position at RMIT University.
2. Amendments
   Approval must be sought from HREC to amend any aspect of a project including approved documents. To apply for an amendment use the request for amendment form, which is available on the HREC website and submitted to the HREC secretary. Amendments must not be implemented without first gaining approval from HREC.
3. Adverse events
   You should notify HREC immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
4. Plain Language Statement (PLS)
   The PLS and any other material used to recruit and inform participants of the project must include the RMIT university logo. The PLS must contain a complaints clause including the above project number.
5. Annual reports
   Continued approval of this project is dependent on the submission of an annual report.
6. Final report
   A final report must be provided at the conclusion of the project. HREC must be notified if the project is discontinued before the expected date of completion.
7. Monitoring
   Projects may be subject to an audit or any other form of monitoring by HREC at any time.
8. Retention and storage of data
   The investigator is responsible for the storage and retention of original data pertaining to a project for a minimum period of five years.
9. Special conditions of approval
   NIL

In any future correspondence please quote the project number and project title above.

A/Prof Barbara Polus
Chairperson
RMIT HREC

oe: Dr Peter Burke (Ethics Officer/HREC secretary), Dr Julie Kendall (student researcher).

K/R and Research Office/Human Ethics_RMIT_HREC/15/3929-13 Azari formal note of approval April 2015.docx
Advertising

RMIT UNIVERSITY

Chiropractic clinical trial on neck pain, dizziness and balance in the elderly

We are seeking 65-85 year old participants for a research project looking into neck pain, dizziness and balance. If you are interested in participating please contact us!

What is involved?
- Filling out questionnaires to assess your level of neck pain, dizziness, pain related disability and fear of falls
- Standing unassisted with your eyes closed to assess your balance
- Wearing insoles during a 5 minute walk to assess your balance
- Have your height and weight recorded
- Receive either real or sham chiropractic treatment for 4 weeks

We are looking for elderly participants who:

- Have suffered from neck pain for over three months

AND

- Have had dizziness for over three months

*RMIT University students ineligible

Contact

Dr Julie Kendall; julie.kendall@xxxx.edu.au 9925 xxxx

Contact Information

- Neck Pain and Balance in Elderly
  - Contact: julie.kendall@xxxx.edu.au
  - Phone: 9925 xxxx

- Neck Pain and Balance in Elderly
  - Contact: julie.kendall@xxxx.edu.au
  - Phone: 9925 xxxx

- Neck Pain and Balance in Elderly
  - Contact: julie.kendall@xxxx.edu.au
  - Phone: 9925 xxxx

- Neck Pain and Balance in Elderly
  - Contact: julie.kendall@xxxx.edu.au
  - Phone: 9925 xxxx

- Neck Pain and Balance in Elderly
  - Contact: julie.kendall@xxxx.edu.au
  - Phone: 9925 xxxx

- Neck Pain and Balance in Elderly
  - Contact: julie.kendall@xxxx.edu.au
  - Phone: 9925 xxxx
Dear …………,

You are invited to participate in a research project being conducted by RMIT University and the National Ageing Research Institute (NARI). Please read this sheet carefully and be confident that you understand its contents before deciding whether to participate. If you have any questions about the project, please ask one of the investigators.

Who is involved in this research project? Why is it being conducted?

This project is being conducted to determine the efficacy of chiropractic treatment for chronic neck pain and dizziness, as well as fear of falls in the community dwelling elderly population. This research is being conducted by the School of Health Science Chiropractic Discipline as part of PhD projects, supervised by Senior Research Fellow Dr Michael Azari. This research project has been approved by the RMIT Human Research Ethics Committee. This research is being funded by Foundation for Chiropractic Research and Postgraduate Education (Denmark) and RMIT University.

Why have you been approached?

You have been approached because you are a between 65 and 85 years of age with neck pain and dizziness or unsteadiness of 3 months duration or longer (either constant or intermittent). You have been approached through advertisements, through the RMIT on-campus clinics, through a local health practice or practitioner, social media, or through the National Ageing Research Institute (NARI).
**What is the project about? What are the questions being addressed?**

This project aims to answer if particular health conditions in the elderly are associated with dizziness and changes in balance. It also aims to find out if chiropractic treatment improves chronic neck pain and balance and reduces fear of falls in the community dwelling elderly population. We are aiming to recruit 40 participants for the chiropractic treatment part of this study. These participants will be recruited to one of two groups. Group A will receive a sham treatment which is expected to provide minimal therapeutic benefit for the participant, and will be used as a control to compare the results from the therapeutic group. Group B will receive chiropractic treatment which is expected to provide a therapeutic effect to decrease pain and improve balance and cognition.

**If I agree to participate, what will I be required to do?**

Participants will be interviewed over the telephone by an investigator to determine their eligibility for this study. Those considered eligible will be invited to attend an assessment session at which they will be assessed based on history and clinical examination to included or excluded from this study. This assessment will involve having your pain, disability, dizziness, fear of falls, mood, cognitive function and quality of life assessed by filling out questionnaires; your balance will be assessed by standing with your eyes open and closed, with and without vibration applied to your neck, and standing on foam, on a force plate; as well as some simple balance tasks involving stepping, sitting and walking. You will also be required during these balance tasks to wear a flat insole in your shoes to measure your balance. After this assessment, if you are included in this study, you will receive one treatment per week, for 4 weeks of treatment or sham treatment depending on the group to which you are randomly allocated. After the 4 weeks of treatment or sham treatment you will complete the same questionnaires and balance tasks, as well as be asked your satisfaction with the treatment you received. At the end of the trial you will be notified which group you were in, and if the results of the study indicate that the treatment is beneficial, and you were randomised to the sham treatment group you will have the opportunity of receiving 4 sessions of the therapeutic chiropractic treatment at that point.

**What are the possible risks or disadvantages?**

There is a risk that you may fall while standing on the balance plate, this will be minimised with a safety harness attached via straps around your torso and mounted to the ceiling. Due to random allocation you may be assigned to the minimal therapeutic, ‘sham’ group, this will mean you will not get the full treatment effect. At the end of the trial you will be notified which group you were in, and if the results of the study indicate that the treatment is beneficial, you will at that point have the opportunity of receiving 4 treatments of the therapeutic chiropractic treatment. There is a chance of temporary soreness and tenderness associated with the treatment, which is expected to be mild. There is a small chance of rib fracture following a manipulation. However, all these risks will be minimised, as the treatment will be provided by experienced practitioners who will use as gentle a manual technique as possible. There is also an extremely low chance (approximately a 1 in 100,000) of a stroke associated with chiropractic manipulation of the neck. However, most of the reported cases have been in people under the age of 45. In the extremely unlikely event that this occurs, you will be promptly sent for appropriate medical care. If you are unduly concerned about your responses to any of the questionnaire items or assessments or if you find participation in the project distressing,
you should contact Dr Michael Azari as soon as convenient. Dr Azari will discuss your concerns with you confidentially and suggest appropriate follow-up, if necessary.

**What are the benefits associated with participation?**

This study may benefit you by decreasing your neck pain, decreasing dizziness and improving your balance. This could improve your quality of life.

**What will happen to the information I provide?**

The information that you provide will be confidential and your data will be coded and not associated with your identity (de-identified). Any information that you provide can be disclosed only if (1) it is to protect you or others from harm, (2) a court order is produced, or (3) you provide the researchers with written permission. The information provided and collected by the researchers will be used in journal papers for publication and a PhD thesis. A plain language summary from this study will be made available to you upon request. Your individual data will also be sent to you at the conclusion of the study. The data will be kept securely at RMIT for 15 years after publication, before being destroyed.

**What are my rights as a participant?**

- The right to withdraw from participation at any time
- The right to request that any recording cease
- The right to have any unprocessed data withdrawn and destroyed, provided it can be reliably identified, and provided that so doing does not increase the risk for the participant.
- The right to have any questions answered at any time.

**Whom should I contact if I have any questions?**

If you have any further questions or queries about this research project please contact Dr Michael Azari

---

**Yours sincerely**

**Dr Michael Azari,**  
BAppSc(Chiro), BSc(Hons), PhD

**Other Investigators:**  
Professor Stephen Gibson, PhD  
Dr Frances Batchelor, BAppSc(Physio), PhD  
Professor Franz Fuss, MD, PhD  
Ms Julie Kendall, BAppSc, MClinChiro  
Mr Adin Ming Tan, BEng, MEng  
Associate Professor Simon French  
Professor Jan Hartvigsen  
Ms Franziska Wright
If you have any concerns about your participation in this project, which you do not wish to discuss with the researchers, then you can contact the Ethics Officer, Research Integrity, Governance and Systems, RMIT University, GPO Box 2476V VIC 3001. Tel: (03) 9925 2251 or email human.ethics@rmit.edu.au
CONSENT

I have had the project explained to me, and I have read the information sheet

1. I agree to participate in the research project as described

2. I agree:
   The following provide some common examples, but should be modified to suit:
   - to undertake the tests or procedures outlined
   - to be interviewed and/or complete a questionnaire

3. I acknowledge that:
   (a) I understand that my participation is voluntary and that I am free to withdraw from the project at any time and to withdraw any unprocessed data previously supplied (unless follow-up is needed for safety).
   (b) The project is for the purpose of research. It may not be of direct benefit to me.
   (c) The privacy of the personal information I provide will be safeguarded and only disclosed where I have consented to the disclosure or as required by law.
   (d) The security of the research data will be protected during and after completion of the study. The data collected during the study may be published, and a report of the project outcomes will be provided to me upon request. Any information which will identify me will not be used.

Participant’s Consent

Participant: ___________________________ Date: ______________
(Signature)

Witness:

Witness: ___________________________ Date: ______________
(Signature)

Participants should be given a photocopy of this PICF after it has been signed.
Details of RMIT’s Human Research Ethics Committee (HREC):
Telephone: +61 3 9905 2251 Email: human.ethics@rmit.edu.au
Recruitment letter

Parameters of balance and dizziness in elderly populations and the effectiveness of neck manipulation in reducing neck pain and dizziness

Dear Name,

Thank you very much for your interest in participating in our study Parameters of balance and dizziness in elderly populations and the effectiveness of neck manipulation in reducing neck pain and dizziness. I would like to confirm the details of your appointment:

Date: Date of appointment

Time: Time of appointment

Address: RMIT University
          Plenty Road
          Bundoora, Vic
          3083

Telephone: 03 9925 xxxx (Dr Michael Azari)
            03 9925 xxxx (Julie Kendall)

The Bundoora campus of RMIT University is easily accessible by either your own vehicle or public transport. Please find enclosed a map showing the location of RMIT University in Bundoora, and the most convenient parking location within the university campus.

If you drive please enter from Plenty Rd. You will need to collect your guest temporary parking permit at the security station (P14) on the left hand side of the drive after entering the campus. You may then park within any of the white parking spaces, we recommend utilising the carpark at the rear of building 201 (N3), there is also undercover parking in building 222, only a very short walk away (O2).

If you use public transport, you can catch the 86 tram to stop number 70 (Clements Dve & Plenty Rd). The study is in building 201, approximately 7-10 minute walk into the campus from the tram stop. When you arrive at RMIT University, please make your way to building 201, level 3 and enter the Research Hub reception.
I have enclosed with this letter a document entitled ‘Participant Information and Consent Form’. This form provides details about what participation in the project will involve. Please read it carefully and feel free to discuss it with a relative, friend or a health worker. I will be able to discuss the form with you and answer any questions you have when I meet you for your appointment on the above date.

Please bring with you to your appointment:

- Your normal glasses/eyewear
- A list of your current medications
- Please wear shoes and socks (no thongs or sandals) (you may be asked to remove your shoes and socks)
- Wear comfortable clothes, if appropriate slacks or shorts

The appointment will take up to two hours, and may be a little tiring for some participants. The appointment will include providing you with detailed information about the project and then, if you are happy to continue, a full assessment of your balance and walking with a physiotherapist.

Please do not hesitate to contact me if you have any queries or are unable to attend the appointment. My phone number is (03) your phone number.

Thank you once again for agreeing to participate in the program.

Kind regards

Dr Michael Azari
Senior Research Fellow
School of Health Sciences
RMIT University
# Montreal Cognitive Assessment (MOCA)

**Version 7.2 Alternative Version**

## Naming

| Animal | [ ] Gnu | [ ] Hippopotamus | [ ] [ ] |

## Memory

<table>
<thead>
<tr>
<th>Task</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>TRUCK</td>
<td>BANANA</td>
</tr>
<tr>
<td>1st trial</td>
<td>[ ]</td>
</tr>
<tr>
<td>2nd trial</td>
<td>[ ]</td>
</tr>
</tbody>
</table>

## Attention

<table>
<thead>
<tr>
<th>Task</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Read list of letters (1 digit correct)</td>
<td>[ ] 1 2 3 4 5 6 7 8 9 0</td>
</tr>
</tbody>
</table>

## Language

<table>
<thead>
<tr>
<th>Task</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Read list of numbers</td>
<td>[ ] 1 2 3 4 5 6 7 8 9 0</td>
</tr>
</tbody>
</table>

## Abstraction

<table>
<thead>
<tr>
<th>Task</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Similarities between objects (e.g., carrot - potato - vegetable)</td>
<td>[ ] diamond - ruby - [ ]</td>
</tr>
</tbody>
</table>

## Delayed Recall

<table>
<thead>
<tr>
<th>Task</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Without cue</td>
<td>[ ] TRUCK</td>
</tr>
<tr>
<td>Category cue</td>
<td>Multiple choice</td>
</tr>
</tbody>
</table>

## Orientation

<table>
<thead>
<tr>
<th>Task</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>Month</td>
</tr>
</tbody>
</table>

---

**Total Score:** [ ] /30

Adapted by: Z. Nasreddine MD, N. Phillips PhD, H. Chertkow MD
© Z. Nasreddine MD www.mocatest.org

**Normal Range:** 26–30

**Adapted from:** [12]
Neck Disability Index

This questionnaire has been designed to give us information as to how your neck pain has affected your ability to manage in everyday life. Please answer every section and mark in each section only the one box that applies to you. We realise you may consider that two or more statements in any one section Mine to you, but please just mark the box that most closely describes your problem.

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 can 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 causes extra pain  
☐ Pain prevents me lifting heavy weights off the floor, but I can manage if they are conveniently placed, 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 only lift very light weights

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 can't read as much as I want because of moderate pain in my neck  
☐ I can hardly read at all 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 not 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 can't 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 can't 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 can't drive my car at all

Section 9: Sleeping
- I have no trouble sleeping
- My sleep is slightly disturbed (less than 1 hr sleepless)
- My sleep is mildly disturbed (1-2 hrs sleepless)
- My sleep is moderately disturbed (2-3 hrs sleepless)
- My sleep is greatly disturbed (3-5 hrs sleepless)
- My sleep is completely disturbed (5-7 hrs sleepless)

Section 10: Recreation
- I am able to engage in all my recreation activities with no neck pain at all
- I am able to engage in all my recreation activities, with some pain in my neck
- I am able to engage in most, but not all of my usual recreation activities because of pain in my neck
- I am able to engage in a few of my usual recreation activities because of pain in my neck
- I can hardly do any recreation activities because of pain in my neck
- I can't do any recreation activities at all

Score: ___/50 Transform to percentage score x 100 = ___%points

Scoring: For each section the total possible score is 5. If the first statement is marked the section score = 0, if the last statement is marked it = 5. If all ten sections are completed the score is calculated as follows:

Example: 16 (total scored)

50 (total possible score) x 100 = 32%

If one section is missed or not applicable the score is calculated:

14 (total scored)

45 (total possible score) x 100 = 35.5%

Minimum Detectable Change (90% confidence): 5 points or 10% points

DIZZINESS HANDICAP INVENTORY

Name: ____________________________ Date: _________________________

Part I

Instructions: The purpose of this scale is to identify difficulties that you may be experiencing because of your dizziness or unsteadiness. Please indicate answer by circling “yes” or “no” or “sometimes” for each question. Answer each question as it pertains to your dizziness or unsteadiness problem only.

P1. Does looking up increase your problem? ____________________________
E2. Because of your problem, do you feel frustrated? ____________________________
F3. Because of your problem, do you restrict your travel for business or recreation? ____________________________
P4. Does walking down the aisle of a supermarket increase your problem? ____________________________
F5. Because of your problem, do you have difficulty getting into or out of bed? ____________________________
F6. Does your problem significantly restrict your participation in social activities such as going out to dinner, going to the movies, dancing, or to parties? ____________________________
F7. Because of your problem, do you have difficulty reading? ____________________________
P8. Does performing more ambitious activities like sports, dancing, household chores such as sweeping or putting away dishes increase your problem? ____________________________
E9. Because of your problem, are you afraid to leave your home without having someone accompany you? ____________________________
E10. Because of your problem, have you been embarrassed in front of others ____________________________
P11. Do quick movements of your head increase your problem? ____________________________
F12. Because of your problem, do you avoid heights? ____________________________
P13. Does turning over in bed increase your problem? ____________________________
F14. Because of your problem, is it difficult for you to do strenuous housework or yard work? ____________________________
E15. Because of your problem, are you afraid people might think you are intoxicated? ____________________________
F16. Because of your problem, is it difficult for you to go for a walk by yourself? ____________________________
P17. Does walking down a sidewalk increase your problem? ____________________________
E18. Because of your problem, is it difficult for you to concentrate? ____________________________
F19. Because of your problem, is it difficult for you walk around the house in the dark?  Yes  No  Sometimes
E20. Because of your problem, are you afraid to stay home alone?  Yes  No  Sometimes
E21. Because of your problem, do you feel handicapped?  Yes  No  Sometimes
E22. Has your problem placed stress on your relationships with members of your family or friends?  Yes  No  Sometimes
E23. Because of your problem, are you depressed?  Yes  No  Sometimes
F24. Does your problem interfere with your job or household responsibilities?  Yes  No  Sometimes
F25. Does bending over increase your problem?  Yes  No  Sometimes

---

**Part II**

*Instructions: Put a check in the box that best describes you.*

| ☐ Negligible symptoms (0) |
| ☐ Bothersome symptoms (1) |
| ☐ Performs usual work duties but symptoms interfere with outside activities (2) |
| ☐ Symptoms disrupt performance of both usual work duties and outside activities (3) |
| ☐ Currently on medical leave or had to change jobs because of symptoms (4) |
| ☐ Unable to work for over one year or established permanent disability with compensation paid (5) |

*STOP HERE*

<table>
<thead>
<tr>
<th>Yes</th>
<th>Sometimes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>P(7)</td>
<td>x1=___ + x2=___ + x0=___</td>
<td>Physical Items (28)</td>
</tr>
<tr>
<td>E(9)</td>
<td>x1=___ + x2=___ + x0=___</td>
<td>Emotional Items (38)</td>
</tr>
<tr>
<td>F(9)</td>
<td>x1=___ + x2=___ + x0=___</td>
<td>Functional Items (36)</td>
</tr>
</tbody>
</table>

**TOTAL (max 100 pts)**
Pain and Dizziness Intensity

How intense is your pain today? Please circle the number appropriate to how you feel, for each of the areas listed below.

*Please rate the intensity of the pain you feel today.*

<table>
<thead>
<tr>
<th>Any joint pain</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Very Severe Pain</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Neck Pain only</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Pain</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Very Severe Pain</td>
</tr>
</tbody>
</table>

*Please rate the intensity of your dizziness (unsteadiness)*

<table>
<thead>
<tr>
<th>Dizziness</th>
<th>0</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Dizziness</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Very Severe Dizziness</td>
</tr>
</tbody>
</table>
SF12 Questionnaire

This survey asks for your views about your health. This information will help you keep track of how you feel and how well you are able to do your usual activities.

Answer every question by selecting the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

1. In general, would you say your health is:
   
<table>
<thead>
<tr>
<th>Excellent</th>
<th>Very good</th>
<th>Good</th>
<th>Fair</th>
<th>Poor</th>
</tr>
</thead>
<tbody>
<tr>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
<td>○</td>
</tr>
</tbody>
</table>

2. The following questions are about activities you might do during a typical day. Does your health now limit you in these activities? If so, how much?

   a. Moderate activities, such as mowing a lawn, pushing a vacuum cleaner, bowling, or playing golf
   b. Climbing several flights of stairs

   Yes, limited a lot | Yes, limited a little | No, not limited at all
   ○ ○ ○

3. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

   a. Accomplished less than you would like
   b. Were limited in the kind of work or other activities

   Yes | No
   ○ ○
4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems such as feeling depressed or anxious?  
   a. Accomplished less than you would like  
   b. Did work or other activities less carefully than usual  

5. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?  
   Not at all  
   A little bit  
   Moderately  
   Quite a bit  
   Extremely  

6. These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

   How much of the time during the past 4 weeks...

   a. Have you felt calm and peaceful?  
   b. Did you have a lot of energy?  
   c. Have you felt downhearted and blue?  

7. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting friends, relatives, etc.)?  
   All of the time  
   Most of the time  
   Some of the time  
   A little of the time  
   None of the time  

Thank you for completing these questions!
FES-I

Now we would like to ask some questions about how concerned you are about the possibility of falling. Please reply thinking about how you usually do the activity. If you currently don’t do the activity (e.g. if someone does your shopping for you), please answer to show whether you think you would be concerned about falling IF you did the activity. For each of the following activities, please tick the box which is closest to your own opinion to show how concerned you are that you might fall if you did this activity.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Not at all concerned</th>
<th>Somewhat concerned</th>
<th>Fairly concerned</th>
<th>Very concerned</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cleaning the house (e.g. sweep, vacuum or dust)</td>
<td>1 □</td>
<td>2 □</td>
<td>3 □</td>
<td>4 □</td>
</tr>
<tr>
<td>Getting dressed or undressed</td>
<td>1 □</td>
<td>2 □</td>
<td>3 □</td>
<td>4 □</td>
</tr>
<tr>
<td>Preparing simple meals</td>
<td>1 □</td>
<td>2 □</td>
<td>3 □</td>
<td>4 □</td>
</tr>
<tr>
<td>Taking a bath or shower</td>
<td>1 □</td>
<td>2 □</td>
<td>3 □</td>
<td>4 □</td>
</tr>
<tr>
<td>Going to the shop</td>
<td>1 □</td>
<td>2 □</td>
<td>3 □</td>
<td>4 □</td>
</tr>
<tr>
<td>Getting in or out of a chair</td>
<td>1 □</td>
<td>2 □</td>
<td>3 □</td>
<td>4 □</td>
</tr>
<tr>
<td>Going up or down stairs</td>
<td>1 □</td>
<td>2 □</td>
<td>3 □</td>
<td>4 □</td>
</tr>
<tr>
<td>Walking around in the neighbourhood</td>
<td>1 □</td>
<td>2 □</td>
<td>3 □</td>
<td>4 □</td>
</tr>
<tr>
<td>Reaching for something above your head or on the ground</td>
<td>1 □</td>
<td>2 □</td>
<td>3 □</td>
<td>4 □</td>
</tr>
<tr>
<td>Going to answer the telephone before it stops ringing</td>
<td>1 □</td>
<td>2 □</td>
<td>3 □</td>
<td>4 □</td>
</tr>
<tr>
<td>Walking on a slippery surface (e.g. wet or icy)</td>
<td>1 □</td>
<td>2 □</td>
<td>3 □</td>
<td>4 □</td>
</tr>
<tr>
<td>Visiting a friend or relative</td>
<td>1 □</td>
<td>2 □</td>
<td>3 □</td>
<td>4 □</td>
</tr>
<tr>
<td>Walking in a place with crowds</td>
<td>1 □</td>
<td>2 □</td>
<td>3 □</td>
<td>4 □</td>
</tr>
<tr>
<td>Walking on an uneven surface (e.g. rocky ground, poorly maintained pavement)</td>
<td>1 □</td>
<td>2 □</td>
<td>3 □</td>
<td>4 □</td>
</tr>
<tr>
<td>Walking up or down a slope</td>
<td>1 □</td>
<td>2 □</td>
<td>3 □</td>
<td>4 □</td>
</tr>
<tr>
<td>Going out to a social event (e.g. religious service, family gathering or club meeting)</td>
<td>1 □</td>
<td>2 □</td>
<td>3 □</td>
<td>4 □</td>
</tr>
</tbody>
</table>

FES-I: Prof Lucy Yardley and Prof Chris Todd
DASS 21  

NAME __________________________ DATE ____________

Please read each statement and circle a number 0, 1, 2 or 3 which indicates how much the statement applied to you over the past week. There are no right or wrong answers. Do not spend too much time on any statement.

The rating scale is as follows:
0 Did not apply to me at all - NEVER
1 Applied to me to some degree, or some of the time - SOMETIMES
2 Applied to me to a considerable degree, or a good part of time - OFTEN
3 Applied to me very much, or most of the time - ALMOST ALWAYS

|   | 1. | 2. | 3. | 4. | 5. | 6. | 7. | 8. | 9. | 10. | 11. | 12. | 13. | 14. | 15. | 16. | 17. | 18. | 19. | 20. | 21. | TOTALS |
|---|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|----|-----|
|   |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |    |     |       |

FOR OFFICE USE

This document may be freely downloaded and distributed on condition no change is made to the content. The information in this document is not intended as a substitute for professional medical advice, diagnosis or treatment. Not to be used for commercial purposes and not to be hosted electronically outside of the Black Dog Institute website. www.blackdoginstitute.org.au
Satisfaction with Treatment

Allocation

1) Please circle the best response to indicate your satisfaction with the treatment

<table>
<thead>
<tr>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>I feel much worse</td>
<td>I feel worse</td>
<td>I feel the same</td>
<td>I feel better</td>
<td>I feel much better</td>
</tr>
</tbody>
</table>

2) Please circle the best response to indicate which treatment group you think you were in

I was in the sham treatment group | I was in the chiropractic treatment group
Dear Name,

Thank you very much for your participation in the study *Parameters of balance and dizziness in elderly populations and the effectiveness of neck manipulation in reducing neck pain and dizziness*.

This study has provided important information to design falls prevention strategies, devices and treatments to be used in future falls prevention clinical trials.

For your interest and reference here are the results of your participation in the study.

**RESULTS**

**Balance**

**Dizziness**

**Pain**

If you would like further clarification or information about your results, or the results of the whole study please contact Dr Michael Azari from RMIT University Phone: 9925 7744 or email: michael.azari@rmit.edu.au

Sincerely,

**Study Investigators:**
- Dr Michael Azari, BAppSc(Chiro), BSc(Hons), PhD
- Professor Stephen Gibson, PhD
- Dr Frances Batchelor, BAppSc(Physio), PhD
- Professor Franz Fuss, MD, PhD
- Ms Julie Kendall, BAppSc, MClinChiro
- Mr Adin Ming Tan, BEng, MEng
- Associate Professor Simon French
- Professor Jan Hartvigsen
- Ms Franziska Wright