The influence of dementia on falls, gait and rehabilitation

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Abstract

Background

Cognitive impairment is a risk factor for falls in older adults. There is some evidence that the ability to dual-task contributes to maintaining postural stability and that cognitive impairment may impair this ability, thereby increasing falls risk. This research aims to explore physical risk factors associated with cognitive impairment and falls in older adults with mild dementia. Potential interventions for these participants will be searched for, described and theoretically modelled to develop an intervention programme to reduce their falls risk.

Methods

A cross-sectional survey described gait, dual-task cost, balance and falls risk characteristics of participants with mild dementia. Potential interventions were identified using two systematic literature reviews. A realist review explored theoretical mechanisms underpinning exercise-based interventions in older adults with dementia. An intervention programme was developed and preliminarily tested during a 6-week, small sample, non-randomised feasibility study.

Results

Older adult participants (n 69; mean age 81 years) with mild dementia (mean MoCA 21) had an increased risk of falls (1.5 median falls in previous six months; 2.48 mean physiological profile assessment [PPA] falls risk score), poor gait pattern and reduced balance. Cognition was negatively associated with gait pattern in both in simple walking and dual-task conditions. Exercise was a frequently reported intervention, with combined physical and cognitive exercise-components showing efficacy at improving gait speed (weighted mean difference

[WMD] 0.08 [0.03-0.12] $Z=3.65$ [$p \leq 0.001$]) and balance (WMD 1.23 [0.69-1.77] $Z=4.48$ [$p<0.001$]) at a mild stage of cognitive impairment. Physiological-responses and encouragement were identifiable important mechanisms in these interventions. Findings were synthesised into a study protocol. Ten older adults (median age 84, range 69 to 89; 50% women) with mild dementia (median MoCA 21, range 16 to 26) were recruited and completed the developed intervention of combined physical and cognitive exercises. Mean differences between pre- and post-intervention assessment demonstrated improvement in falls risk, balance, and gait.

Conclusion

Mixed methods contributed to each component of development for this complex intervention. A combined physical and cognitive exercise-based programme was deliverable, feasible, and acceptable to older adults with mild dementia. A list of clinically-relevant recommendations for the content, delivery, and supervision of this intervention for an adequately powered, and randomised study, was produced.

Publications and dissemination

Publications

- Booth V, Logan P, Masud T, Harwood R, and Hood V. A feasibility study of a tailored physical and cognitive exercise intervention to reduce falls in older adults with mild dementia. *European Geriatric Medicine* (2016) Supplement 1(7), S142-S143.

- Booth V, Masud T, Hood V, Harwood R and Logan P. Understanding the Theoretical Underpinning of the Exercise Component in a Falls Prevention Programme for Older Adults with Mild Dementia: A Realist Review Protocol. *Systematic Reviews,* 2016; 5:119. DOI: 10.1186/s13643-016-0212-x

- Booth V, Hood V, & Kearney F. Interventions incorporating physical and cognitive elements to reduce falls risk in cognitively impaired older adults: a systematic review. *JBI database of systematic reviews and implementation reports*, 2016; 14(5), 110-135. DOI: 10.11124/JBISRIR-2016-002499

- Booth V, Logan P, Masud T, Hood V, van der Wardt V and Harwood R. Falls, gait and dual-tasking in older adults with mild cognitive impairment: A cross-sectional study. *European Geriatric Medicine*. 2015; 6:S104. DOI:10.1016/S1878-7649(15)30370-3

- Booth V, Hood V, and Kearney F. Interventions incorporating physical and cognitive elements to reduce falls risk in cognitively impaired older adults: a protocol. *The JBI Database of Systematic Reviews and Implementation Reports*. 2015; 13(8):5. DOI:10.11124/jbisrir-2015-2220

- Booth V, Logan P, Harwood R, and Hood V. Falls prevention interventions in older adults with cognitive impairment: A systematic review of reviews. *International Journal of Therapy Research*. 2015; 22(6):289-296. DOI:10.12968/ijtr.2015.22.6.289

Presentations

- Oral presentation at Centre for Advancement in Realist Evaluation and Synthesis 2nd International Conference, University of Liverpool, London Campus. October 2016. *Understanding the Theoretical Underpinning of the Exercise Component in a Falls Prevention Programme for Older Adults with Mild Dementia: A Realist Review Protocol*.

- Poster presentation at the European Union Geriatric Medicine Society, Lisbon. October 2016. *A feasibility study of a tailored physical and cognitive exercise intervention to reduce falls in older adults with mild dementia*.

- Poster presentation at the Alzheimer's Society Research Network Annual Research Conference, Manchester. July 2016. *A feasibility study of a tailored physical and cognitive exercise intervention to reduce falls in older adults with mild dementia*.

- Oral presentation at Journal Club, Division of Rehabilitation and Ageing, University of Nottingham. May 2016. *Understanding the Theoretical Underpinning of the Exercise Component in a Falls Prevention Programme for Older Adults with Mild Dementia: A Realist Review Protocol*.

- Oral presentation at the Sue Watson Post-Graduate Presentation event, School of Medicine, University of Nottingham. October 2015. *Falls, gait* *and dual-tasking in older adults with mild dementia: A cross-sectional survey*.

- Poster presentation at the European Union Geriatric Medicine Society, Oslo. September 2015. *Falls, gait and dual-tasking in older adults with mild cognitive impairment: A cross-sectional survey*.

- Symposium presentation at the European Union Geriatric Medicine Society, Oslo. September 2015. *Falls in cognitive impairment and dementia: identifying those at risk and developing novel interventions.*

- Poster presentation at the Alzheimer's Society Research Network Annual Research Conference, Manchester. July 2015. *Falls prevention interventions in older adults with cognitive impairment: A systematic review of reviews*.

- Oral presentation at Engage-Enthuse-Empower, Nottingham University Hospitals NHS Trust Research Conference, Nottingham. June 2015. *Falls, gait and dual-tasking in older adults with mild cognitive impairment: A cross-sectional survey*.

- Oral presentation at Journal Club, Division of Rehabilitation and Ageing, University of Nottingham. May 2015. *Using a Realist Review Method to Understand the Theoretical Underpinning of Falls Prevention Programmes for Older Adults with Mild Dementia*.

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Table of abbreviations

AD	Alzheimer’s disease
BATM	Balance And The Mind
BBS	Berg Balance Scale
CI	Confidence Interval
CMO	Context-Mechanism-Outcome
CMOc	Context-Mechanism-Outcome configuration
CONSORT	Consolidated Standards Of Reporting Trials
CV	Coefficient of Variance
DTC	Dual-Task Cost
FES-i	Falls Efficacy Scale - international
IQR	Inter-Quartile Range
JBI	Joanna Briggs Institute
HADS	Hospital Anxiety and Depression Scale
MAStARI	Meta-Analysis of Statistics Assessment and Review Instrument
MCI	Mild Cognitive Impairment
MCID	Minimal Clinically Important Difference
MD	Mean Difference
MDC	Minimal Detectable Change
mDTC	mean Dual-Task Cost

MMSE	Mini-Mental State Exam
MoCA	Montreal Cognitive Assessment
MRC	Medical Research Council
MRT	Middle-Range Theory
NHS	National Health Service
NICE	National Institute of Clinical Excellence
NIHR	National Institute for Health Research
PPA	Physiological Profile Assessment
PrAISED	Promoting Activity, Independence and Stability in Early Dementia
PT	Physiotherapy
RAMESES	Realist And Meta-Narrative Evidence Syntheses - Evolving Standards.
RCT	Randomised Control Trial
REC	Research Ethics Committee
SD	Standard Deviation
TIDieR	Template for Intervention Description and Replication
TUG	Timed Up and Go
UK	United Kingdom
VD	Vascular Dementia
WMD	Weighted Mean Difference

Preface

Completing a PhD in the field of dementia has been one of the best decisions of my life. As a physiotherapist specialising in neurology, it was not part of the natural progression of my career. My peers and seniors did not possess, nor aspire to complete PhDs. Since completing a master's degree in research methods in 2010, I have been determined to learn more, enthralled with the possibilities that research can offer to directing and improving patient care.

Dementia has always been a difficult area for the physiotherapist. My experience of working in an outpatient falls clinic brought the challenges of assessment, participation and discharge to the fore for me. Why could I not achieve the same improvements that I was seeing in my usual fallers in my dementia patients? The frustration of providing ineffective treatments, being bound by set timeframes, with no service from which to seek specialist advice, was overwhelming. When the opportunity came to pursue a PhD, after a thoughtful pause, I jumped straight in and have never looked back.

This PhD is funded through a clinical training fellowship with the Alzheimer's Society and Healthcare Management Trust. The involvement of the Alzheimer's Society has been revolutionary in the ongoing support, monitoring, and development of both myself as the researcher and this project as a whole. However, all decisions and work in the project have been my own. An example of this has been the decision to explore realist methods of enquiry and integrate a realist review within the thesis. The reasoning for using realist review is given in the introduction and relevant chapter. The employment of the methods is justified methodologically, but also encompasses my philosophical position as a researcher and aspiration to learn more about an innovative research method in health.

Chapter 1. Introduction

Summary

In this introductory chapter, the thesis principles and assumptions are outlined. The introduction starts by describing the features of dementia, mild cognitive impairment, and falls. Definition of terms and the participant sample are clearly outlined, before exploring the causal pathways leading to falls in these participants. Potential interventions which may address this problem are identified, summarised, and synthesised. The research questions are then defined, setting the structure for the research.

1.1. Background

"One sad realisation, whilst away for a couple of days walking in the Lake District was how much worse my walking has become. No one prepares you for this possibility."

Wendy Mitchell, Early Onset Dementia blogger, 2016

1.1.1. Dementia

Wendy Mitchell illustrates an underlying problem for people at the start of their dementia journey. Impairments of gait and mobility in persons with dementia are not recognised or treated within today's health service. Falls are costly to both the National Health Service (NHS) and the individuals experiencing them. A paradigm shift from "reactive" to "proactive" care is required, particularly within long-term conditions such as dementia. Research can provide the evidence required to support that shift, by reviewing existing knowledge; developing and operationalising new ideas; and evaluating, critiquing, and implementing better practice.

Dementia is a global and irreversible loss of cognitive functions accompanied by a reduced ability to perform activities of daily living and a variety of neuropsychiatric symptoms [1]. By 2021 there will be over one million people in the UK with dementia, and one third of adults aged over 65 will eventually develop dementia [2]. Dementia is progressive, incurable, and "*not part of the normal ageing process*" ([3], p1). The term describes a collection of conditions, including Alzheimer's disease (AD), vascular dementia (VD), Parkinson's dementia, and Lewy-body dementia. The most prevalent of the dementia subtypes is Alzheimer's disease (AD) [4] with 62% attributed to this diagnosis

[2]. Vascular dementia (VD) is the second most common [4, 5] (17% [2, 4]), followed by dementia with Lewy bodies (4% [6]), frontotemporal dementia (2% [2]), and other rarer causes such as Huntington's disease [5]. Mixed dementia describes where more than one subtype of dementia is diagnosed in an individual [5] and has varying incidence of between 12% [6] and 22% [7].

The cause of dementia depends upon the type diagnosed. Vascular changes which compromise the brain's blood supply and function cause vascular dementia [5]. Underlying vascular disorders such as hypertension, hyperlipidaemia, stroke, diabetes, and obesity are contributors, as well other risk factors such as diet and smoking [4, 5]. AD by contrast has numerous genetic and environmental risk factors that cause the characteristic amyloid plaques and neurofibrillary tangles found in post-mortem examination [8]. Despite the differing pathological changes, both AD and VD result in cell death and reduced neurological function. "*No two people with dementia are the same*" ([2], p12), with progression and loss of cognitive function occurring at varying rates and to differing degrees.

Strategies to alter the dementia pathway focus on prevention or risk reduction and targeted therapeutic drugs [8]. Finding effective treatments and improving the lives of people with dementia and their carers has been brought to the fore with political and policy developments [9-11].

1.1.2. Rationale for focus on mild impairments of cognition

Mild cognitive impairment (MCI) is an at-risk state for developing dementia [12-15]. Often depicted as a stage within the cognitive impairment continuum [16], it has been described as a "*transition phases between healthy aging and dementia*" ([15], p19). Over half of the population identified with MCI will develop dementia [17]. Progression rate into dementia is approximately 15% per annum, although there is discussion regarding prevalence rates between the different types of MCI [15].

MCI is a condition that is characterised by a reduction in cognition without an associated loss of ability in complex functional tasks [18]. The exact prevalence of MCI is difficult to ascertain, with studies reporting between 3% and 19% in adults over 65 years [19]. Cause of MCI is attributed to a number of factors that include "*cholinergic dysfunction, white-matter lesions and cerebral infarctions, extracellular amyloid deposition, and intracellular neurofibrillary tangle formation*" ([12], p1264).

Diagnosis of MCI is considered when memory loss beyond what is expected of normal ageing is experienced. There is considerable heterogeneity within MCI, with four recognised sub-groups: amnesic, non-amnesic, single, and multiple domain [20]. Accurate diagnosis of MCI type will aid the inclusion of this population within research studies [20], improve the specificity and efficacy of interventions [21], and increase the accuracy of prediction of potential progression to dementia diagnosis [14]. For this thesis, the concept that correct and early diagnosis can steer the provision of correct interventions is key [15]. By intervening at this stage in the condition, the progression to dementia may be slowed. Petersen and colleagues provide a brief explanation [16].

> *"Patients so identified may be an ideal population for intervention because they are reasonably healthy, and therapeutic retardation of their clinical progression would have a significant impact both on individuals and on society in general. These patients do not have sufficiently severe*

pathology to render therapeutic modalities ineffective." ([16], p68)

Indeed, the diagnostic criteria make it clear that whilst memory has been affected, there is limited functional impairment within this population. Implementing an intervention is therefore feasible. This point within the cognitive impairment continuum is potentially a critical opportunity to make a difference to these individuals and their futures.

At present, there are no robust treatments to reduce the risk of progressing from MCI into Alzheimer's disease and other dementias. Current interventions can be split into pharmacological and non-pharmacological. Pharmacological interventions have investigated the use of drugs to reduce symptoms such as memantine, donepezil, rivastigmine, and galantamine [22]. At present, there are no pharmacological interventions that can stop dementia.

In general, pharmacological interventions have limited effects [23]. This may be due to a number of factors, outlined by Petersen [21] in response to poor results from a rivastigmine trial in MCI [24], including: trialling medications in stage or condition they have not been developed for; tools for diagnosis of MCI and AD not developed in the country of recruitment; inaccurate screening and diagnosis of recruited participants; and poor design resulting in potentially sub-therapeutic doses. With methodological issues limiting the results of such trials, issues regarding accurate diagnosis are relevant. Management of risk factors currently has the most convincing evidence, such as controlling systolic hypertension [12, 15].

Non-pharmacological interventions have shown more encouraging results. Introducing compensatory or behavioural strategies using cognitive rehabilitation to maintain cognitive function has also shown promising results [25]. However, exercise has demonstrated the most significant impact on cognitive function in large cohort studies [26, 27] and meta-analysis of trials [28, 29], although there is uncertainty due to limited number of high-quality trials [30].

Completing at least 150 minutes of physical activity per week has also shown to improve cognitive function (cognitive section of the Alzheimer disease Assessment Scale) in older adults with MCI [31]. Lautenschlager et al [31] demonstrated a significantly different mean difference (MD) ($p=0.02$, MD; exercise=-0.87, control=1.29) when comparing physical activity to a control education group at 6 months. A small sample study (n=33) also demonstrated improvements in executive function (digit-symbol [$F_{1,26}=4.18$; $p=0.05$] and verbal fluency [$F_{1,25}=4.87$; $p=0.04$]) following an aerobic intervention [32]. Despite gender differences in effects from the intervention, Baker et al [32] did surmise that exercise is a promising non-pharmacological intervention.

These studies focused on interventions aiming to influence cognitive function in MCI. However, dementia and cognitive impairment (CI) also influence an individual's functional and physical ability. These characteristics need to be outlined.

The rationale for focusing on mild levels of cognitive impairment has been outlined in this chapter. Before proceeding the terminology used to refer to this population needs to be defined. The term MCI refers to a specific diagnosis rather than a description of the level of impairment. The following literature summaries and research studies are not limited according to MCI diagnosis or categorised MCI sub-types. Dementia is also a diagnosed condition. However, it is frequently used as an umbrella term for those individuals with identifiable cognitive impairment inclusive of the different dementia sub-types (such as AD or VD). The term mild dementia has therefore been adopted as a description of persons with a cognitive impairment, at a mild level, who may or may not have a specific diagnosis of MCI or dementia sub-type, but who have all been identified from a cognitive screen or assessment. Mild dementia will subsequently be used to describe intended participants in the following chapters.

1.1.3. The physical cost of cognitive impairment

Dementia eventually has many physical manifestations including problems with swallow, the bladder and other autonomic functions. Some of the earliest physical manifestations are effects on gait and balance, the most notable result of which is falling. Older adults with dementia have double the risk of falling compared with age matched individuals. Between 60% and 80% of people with dementia fall within a year [33-35].

A fall has been defined as "*unintentionally coming to the ground or some lower level and other than as a consequence of sustaining a violent blow, loss of consciousness, sudden onset of paralysis as in stroke or an epileptic seizure*" [36]. Many falls occur during completion of daily activities or tasks [34]. The economic impact on health services from falls in this population is substantial, with an estimated annual cost to the UK of over £2.3 billion [37]. Health and social care costs increase considerably in the year following a fall [38]. Falls can result in low mood, loss of confidence, fractures, time in hospital, increased care and support, increased carer burden and strain, restricted mobility, and death [34].

Cognitive impairment is one of many risk factors for falls in older adults [39-41]. In a systematic review of falls risk factors in people with dementia, Harlein et al [39] identified eight categories associated with increased falls risk; "*disease-specific motor impairments, impaired vision, type and severity of dementia, behavioural disturbances, functional impairments, fall history, neuroleptics and* *low bone mineral density*" ([39], p927). However, many were similar to the risk factors for adults without cognitive impairment, such as motor impairment features within both populations [42]. Motor impairments include abnormal gait, reduced muscular strength, and poor balance [42].

Impairment of balance and coordination were first identified in mild dementia populations by Franssen et al [43]. The study reported significant differences in balance measures, such as single leg stance and tandem walking (walking heel-to-toe), in those with mild dementia or AD compared with healthy older adults [43]. Franssen et al [43] hypothesised that in those with cognitive impairment, reduced neural "plasticity", less efficient central processing and sensory integration, reduced compensatory postural adjustments, and slower movement patterns were influential characteristics.

The conclusion that those with mild dementia or AD were at "*greater risk of sustaining falls and other injuries"* (p467) was later confirmed by Allan et al [44]. A prevalence survey of gait and balance disorders in people with dementia identified that all dementia sub-groups had a greater risk and history of falls [44]. There are "*multiple links between gait, cognitive function and falls*" ([45], p1521) which needed further exploration in people with mild cognitive problems.

1.1.4. The gait of people with cognitive impairment

Gait must be defined before describing its associations with falls and cognitive impairment. Gait is "*a method of locomotion involving the use of the two legs, alternately, to provide both support and propulsion…with at least one foot being in contact with the ground at all times*" ([46], p48). Gait is controlled by a complex neural network of ascending information, cortical integration, and descending control [47]. A large part of gait is automatic. Central pattern generators provide the reciprocal, automatic neuronal continuation of a gait pattern [48]. The interplay of information between the brain and spinal cord, with influences from ascending sensory feedback of peripheral receptors and descending neuromodulation [49], occurs without higher cortical control. The multiple levels of neural control work synergistically to provide "*a stable gait and a highly consistent walking pattern*" ([50], p556). However, gait should not be considered as a simple automatic motor task [51, 52]. Cognition plays a crucial role in the control of gait.

As we age, our walking speed and ability to maintain a consistent walking pattern deteriorates [53]. Normal ageing is associated with reduced lower limb strength and increased postural sway. This in turn produces a wider base of support, and reduced gait speed and step-length [54]. Older adults with cognitive impairment have normal ageing processes, as well as the effects of their cognitive impairment. Most studies that characterise changes in gait pattern and parameters in older adults with cognitive impairment compare these with healthy older age-matched adults, inferring that differences are due to the cognitive impairment and not normal ageing processes. Stratifying differences in gait patterns will theoretically identify how cognition influences gait, and subsequently what characteristics of gait can be targeted to reduce the risk of falling. Previous research has identified three main dimensions of gait that are associated with risk of falling: gait speed, gait variability, and the dual-task paradigm.

1.1.4.1. Gait speed

Gait speed is the pre-eminent gait characteristic used in clinical trials and it "*reflects the final common expression of locomotor control*" ([55], p1539). Walking speed is reduced in persons with dementia [51, 56]. The reduction in gait speed has been attributed to a decrease in step-length [44], and an increase in support time, often reported as "double support percentage" [56, 57]. The changes to gait in a person with dementia are significantly different from the healthy older adult population [57]. Overall, there is an inverse relationship between dementia severity and gait speed; as dementia severity increases gait speed decreases [56]. However, changes have also been noted in earlier stages of cognitive impairment. Gait speed and stride length were lower in samples of people with MCI compared to age matched adults with no cognitive impairment [58]. Gait speed was significantly reduced in people with vascular dementia when compared to persons with Alzheimer's disease [56].

1.1.4.2. Gait variability

Gait variability may provide "*a more discriminative measure of gait performance than routine spatio-temporal measures such as average gait speed or step time*" ([59], p443). Originally ignored as "noise", fluctuations between strides are now recognised as reflecting important underlying influences on gait, such as neural control, pathological and ageing changes [50]. Different parameters can be used to describe gait variability and have been noted by Lord et al [59] to be associated with different aspects of gait. Step-length and step-time variability describe the step cycle, providing insight into how rhythmical and consistent the step cycle is.

Stride variability is influenced by stride frequency and stride-length [60]. Older adults with cognitive impairment have increased gait variability [61]. Stride-length and step-width variability were significantly different in older adults with AD when compared to age-matched controls (stride-length variability increased and step-width variability decreased) [61]. Some studies have associated specific gait characteristics, such as variability, with specific dementia diagnoses. Verghese et al [58] identified that older adults with amnesic MCI had worse variability measures in their gait parameters than healthy older adults.

Stride-length variability was associated with fall risk among older adults who fall regularly, rather than gait speed, stride-length, or stride-time [62, 63]. The variability in gait pattern (stride to stride variability) is a strong indicator and the best independent gait parameter for predicting increased risk of falls [62, 63]. Theoretically it is the variability in step-time and length that results in increased rate of falls, as well as the measure being an indicator of problems with gait pattern in persons with cognitive impairment [64].

There has only been one prospective study looking in detail at all the physical components associated with falls in older adults with cognitive impairment [65-67]. In a series of papers, Taylor et al [65-67] examine a relatively large sample of older adults with cognitive impairment (n=177) [65], describing gait parameters (single and dual-task); neuropsychological, physical, and functional measures; and falls rate and risk. Participants were recruited from both independent community-dwelling and "low-level care" facilities, and included both mild and moderate severity cognitive impairment. Whilst this is a relatively minor issue, considering the heterogeneity already anticipated between different types of mild dementia, this variance within the sample hinders making definitive conclusions and further prospective, cross-sectional survey data on mild dementia samples is required.

1.1.4.3. Dual-task paradigm

New ideas are often generated from unusual observations during routine clinical practice. It is from this origin that the dual-task paradigm developed. A clinical observation was reported by Lundin-Olsson et al [68], describing that those who had a history of falls were observed to "*stops walking when talking*" ([68], p617). This concept has been further developed into both an assessment and treatment approach.

The dual-task paradigm involves the observation of gait during a secondary task, and has become the standard way to assess the interaction between cognition and gait [69]. The change in performance when comparing a single to a dual task is termed the "dual-task cost" (DTC). DTC can be quantified using any objective performance measure. For example, changes in gait parameters such as velocity have most frequently been used [70]. The task performance measurements can involve speed (i.e. reaction time) or accuracy (i.e. number of correct answers) to determine the cost of completing two tasks simultaneously.

Areas of the brain or networks underlying executive function have been identified as controlling dual-tasking [71]. Yogev-Seligman et al [71] outlined three theories which may explain the observed DTC: "capacity-sharing", "bottle-neck", and "multiple resource". "Capacity-sharing" describes the performance of two attention-demanding tasks when attentional resources are limited in capacity, causing deterioration in performance of at least one of the tasks. "Bottle-neck" describes the situation when two tasks are processed by the same neural processor or networks at the same time. "Multiple resource" occurs when processing requires several different resources, therefore if the same resources are required, a dual-task interference will occur (and vice versa). Assessing an individual's ability to dual-task provides insight into that individual's executive functions and functional or clinical presentation of dysfunction [72].

Neuroplastic changes have been demonstrated within adults with mild dementia [73]. Neural plasticity is a broad term that refers to the ability of different levels of the central nervous system to change in structure and function, for both normal development and following injury [74, 75]. Plasticity of the CNS has been studied through various methods of neuroimaging techniques such as positron emission topography, functional magnetic resonance imagery, transcranial magnetic stimulation, and motor evoked potentials [74].

Studies using such techniques have identified changes to brain structure and function following exercise-based interventions [76]. Lustig [76] simplifies the identification of both increases and decreases in activation: "*Increases in size or activation levels are hypothesized to represent increased use of the processes mediated by a region; decreases in size or activation indicate decreased use (or increased efficiency)*" ([76], p510).

It has been hypothesised that these changes in cerebral activation and location in older adults following exercise vary according to the stage of motor training or skill acquisition [77, 78]. An increase in cerebral activation indicates structural and functional changes within the brain during in the initial stage of skill acquisition, where physical activity is novel and building capacity. A decrease in activation relates to greater efficiency in structure and function, present in the later stages of skill acquisition when a skill has been learnt and is conducted with greater speed and autonomy. DTC could follow a similar hypothesis and indicate level of skill acquisition; a higher DTC could be experienced when a new skill or task is introduced, and a lower DTC following practice and as skill attainment improves. This is a novel rationale for the introduction of DTC as an outcome measurement that has not been developed in the literature to date. However, the neuroimaging studies have been based on healthy older adults and the literature underpinning the mechanisms for neural plasticity in adults with cognitive impairment is not as well-developed [73, 76].

DTC is normal and seen in healthy young adults [79, 80]. It has been reported that there is no DTC in young healthy adults for postural sway [81] or step-time variability [82], however gait speed is reduced during completion of a second task. This change in speed could be considered the normal cost from completing a dual-task within healthy adults of any age [83]. As age increases, there is a larger additive cost on speed but not accuracy during a dual-task [83]. The effects of cognitive impairment on speed and accuracy within a dual task assessment are less understood.

An increasing number of studies have used DTC [84]. A few associate DTC with falls risk. Beauchet et al [52] identified that slower gait speed whilst dual-tasking was "*associated with recurrent falls*" in frail older adults. DTC has been shown to identify people who fall in community settings when gait speed is normal [85]. Montero-Odasso et al [85] reported that people with MCI had greater DTC compared to those without cognitive impairment (gait variability CV% from single to dual-task; MCI=2.68±1.31 to 9.84±10.13, Control=1.86±0.66 to 3.74±3.31), and that these changes were markers for falls risk. This is particularly evident in the gait variability measures [67, 85].

However, whether dual-task assessment adds value to discriminating between "fallers" and "non-fallers" is debated. Following their meta-analysis, Menant et al [70] reported that "*both single and dual task paradigms are equivalent in their predictive and discriminative validity when gait speed is used*" ([70], p102). Few studies have reported gait variability measures and there were insufficient data to synthesise [70]. There is a lack of evidence regarding dual-task assessments in all gait parameters, and particularly in people with mild cognitive impairment.

1.1.5. Why does gait change with cognitive impairment and why should it be assessed?

1.1.5.1. Why does gait change?

Some studies have looked to anatomy to answer why gait patterns change in people with dementia, correlating neuroimaging with gait parameters.

Annweiler et al [86] identified that measures of stability during gait (stride time variability and gait speed) were associated with neural function in the primary motor cortex. Measures of neurochemistry (magnetic resonance spectroscopy) and neuroimaging (magnetic resonance imaging) indicated inflammatory damage, and changes to motor cortex volume were associated with gait stability and speed in participants with MCI [86]. Temporal lobe atrophy has been associated with poor motor performance [87]. The prefrontal cortex is associated with executive function [88] and lateral prefrontal cortex associated with the ability to coordinate two tasks being completed at the same time (dual-tasking) [89]. The prefrontal cortex also has a functional relationship with the hippocampus, through the entorhinal cortex and the nigrostriatal system. The hippocampus assists in integrating sensory information with voluntary motor activity, specifically associated with head direction, spatial orientation, and navigation [51]. All of these aspects are integral for gait. Degeneration of the hippocampus causes reduced memory and is characteristic of cognitive impairment in AD [90].

Cognitive function can be sub-categorised into domains. Executive function is an umbrella term which, rather than being defined, describes a collection of cognitive processes involved in decision-making [91]. These higher-order cognitive processes "*use and modify information from many cortical sensory systems in the anterior and posterior brain regions to modulate and produce behaviour*" ([71] p330) and are made up of a core group of components. The five major constituents of executive function are volition, planning and decision making, purposive action, effective performance (action monitoring), [92] and cognitive (or response) inhibition [93]. Executive dysfunction has been specifically correlated to changes in gait pattern [72]. The theoretical reasons for why limitations in executive function alter gait pattern and result in falls have been explored [71]. Disruption to these executive functions will alter gait in different ways [71]. These have been summarised and collated in Table 1.1.

EF component	Description of component	Effect on gait
Volition	The capacity for intentional behaviour, formulate a goal or intention, and motivation.	Reduced drive and ability to initiate gait. Potentially result in decreased mobility.
Planning and decision making	The identification and organisation of the steps and elements needed to carry out an intention or achieve a goal.	Difficulty mobilising around complex environments safely. Inefficient, incorrect or risky choices. Loss of direction.
Purposive action	The translation of an intention or plan into an activity. Requires initiation, maintenance, switching and stopping of complex behaviour in orderly and integrated manner.	Difficulty mobilising around complex environments safely. Inability to alter path around changing environments. Uncoordinated or inefficient movements.
Effective performance (action monitoring)	The ability to monitor, self-correct and regulate the intensity, tempo and other qualitative aspects of delivery.	Inability to alter path or physical performance around changing, complex environments. Potentially result in increased gait speeds.
Cognitive (response) inhibition	The ability to ignore irrelevant sensory in-puts, overcome primary reflexes and filter out distractions to solve problems and respond discriminately to features of the environment.	Difficulty maintaining consistent gait pattern. Easily diverted attention away from gait. Potentially result in interrupted, variable gait patterns.

Table content adapted from material by [71, 92, 93]

Table 1.1: Executive function components and possible effects on gait

Despite these clear anatomical and clinical associations, mobility and gait-specific interventions are not part of routine care within dementia services.

1.1.5.2. Why should gait be assessed?

Reasons for identifying the characteristics and changes of gait in persons with dementia include diagnosis, improved knowledge, and targeted interventions [52].

Identifying the characteristics of gait associated with different types of dementia may be a method to improve early diagnosis [52].

Scherder et al [51] stated "*gait and gait-related motor disturbances are present in all subtypes of dementia, even in the early and pre-clinical stages*" ([51], p492). In an early study, the presence of observed neurological gait abnormalities (such as marked postural sway, short steps or wide base of support) was a significant predictor of the risk of developing dementia [94]. The association between change in gait parameters (pace, rhythm and variability) and cognitive decline and dementia diagnosis has been further reported [95]. Verghese et al [95] grouped gait parameters together for the analysis of a longitudinal study, and identified that rhythm and variability were associated with increased risk of developing dementia within 5 years (adjusted for age, sex and education).

Changes to gait pattern may occur earlier than falls or identification of memory complaints. In a community-dwelling older population, gait variability was identified as a predictive factor for future falls before gait velocity deteriorated [62]. There is little difference between standard clinical balance and functional mobility tests in adults with and without cognitive impairment [20]. Petersen et al [20] reported ceiling effects were easily reached and tests were not subtle enough. Therefore, gait analysis provides a more sophisticated measure to "*detect subtle changes in gait*" ([51] p489).

Identification of DTC could be an indicator for further assessment, particularly considering simple tests such as stopping walking when talking [68]. DTC is a measure that can be conducted within a hospital or home setting. Gait assessment and DTC are clinically relevant, independent outcome measures. Completing a gait assessment is practical and familiar for the participant and, depending upon the dual tasks used, simple to complete. Dual-task assessments are also "*representative of real-life situations where falls are likely to occur*" ([85] p293) [96]. The outcome is relatively inexpensive to perform, particularly considering the potential to identify older adults that are at risk of costly falls [52].

Identifying key gait characteristics within people with dementia will also develop knowledge about theoretical pathway leading to falls [52]. Different gait characteristics may be associated with different types of dementia, therefore by gaining greater diagnostic accuracy, the ultimate aim is to help people with dementia be more active, safely. Research should be focused on developing specific, effective interventions in this patient population.

1.1.6. Interventions to reduce falls in people with cognitive impairment

Implementing an intervention, advice, or service at the mild impairment stage may theoretically limit progression into diagnosed dementia. Therefore, the same could be hypothesised regarding falls: by implementing an intervention early, can falls risk be reduced in people at all stages of the cognitive impairment continuum? Currently, there are no standard physical interventions provided for people with cognitive impairment at the mild stage.

1.1.6.1. Interventions to reduce falls

Falls prevention rehabilitation aims to reduce the factors or components which cause or increase the chance of an individual falling. Falls risk factors are described by Lord et al [34] (Figure 1.1).

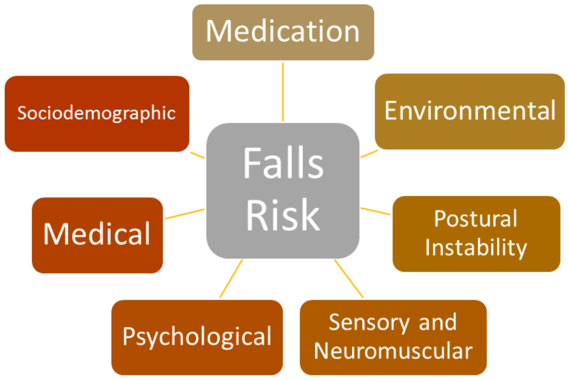


Figure 1.1: Falls risk factors described by Lord et al [34]

Among healthy older adults, falls rehabilitation programmes work by addressing multiple factors and impairments to reduce the risk of future falls. Some risk factors, such as sociodemographic characteristics including living alone and advancing age, cannot be modified and are instead used to identify individuals at high risk [34]. It is recommended that falls prevention programmes consist of multifactorial assessment and intervention including: strength and balance retraining, home hazard assessment and intervention, vision assessment and referral, and medication review with modification or withdrawal [97]. NICE guidelines report that cognitive impairment is a risk factor for falls, but provide no guidance on how to manage that risk [97].

Some of the strongest evidence for reducing fall rates in healthy older adults is for exercise at the correct dose and intensity [98]. Results from pilot work show promise at reducing falls in people with cognitive impairment. Wesson et al [99] reported a lower rate and risk of falls in a small pilot study of a tailored multicomponent falls prevention programme in older adults with dementia. The results were statistically uncertain due to the small sample size but demonstrated that it is feasible and practical to tailor an intervention to both the physical and cognitive ability of an individual in order to reduce falls.

Wesson et al have progressed to a larger randomised controlled trial to determine the effectiveness of their multicomponent (exercise, and home safety modification) falls intervention [100]. Despite promising results there is a dearth in the literature regarding interventions designed to reduce falls for mild dementia populations. Many exercise or physical intervention studies in older adults with cognitive impairment have focused on physical measures, with promising results emerging [101-105]. More good quality studies that record and report rate of falls and risk of falls are required.

1.1.6.2. Dual-task training

DTC is an indicator of the relationship between cognition and physical ability, specifically gait. Moreover, the cost during a dual-task (due to reduced cognitive flexibility, processing speed, task prioritisation, and selective inhibition) is a potential causal mechanism for the increased occurrence of falls in this population. Theoretically, training an individual's ability to dual-task could reduce the occurrence of falls by challenging balance and improving balance ability through postural strategies; improving ability to dual-task and correctly allocate attentional resources; training in a stimulating and changing environment; or by increasing cognitive flexibility through practice and repetition. It is proposed that training in a dual-task paradigm by combining physical and cognitive tasks within a falls rehabilitation programme will improve an individual's ability to dual-task and reduce their risk of falls.

A number of studies have examined dual-task training as an intervention. Trials have been conducted in healthy older persons [106-108], osteoporotic women [109], people who have fallen [110], and nursing home populations with severe dementia [111]. Systematic reviews in the field have been positive but do not feature meta-analysis.

Pichierri et al [112] reported that cognitive or motor-cognitive interventions positively affected physical functioning, such as postural control, walking abilities, and general functions of upper and lower extremities in their literature review. Of 28 included studies, six focused on combined motor-cognitive interventions with varied populations, interventions, and intensities.

A systematic review by Wang et al [113] of 30 papers on cognitive-motor interference or dual-task training identified improvements in gait and balance and in preventing falls in older adults. However, this review did not categorise according to those with or without a cognitive impairment, and included low quality papers, making conclusions uncertain. In this way, there is a gap within the evidence base regarding a synthesis of studies solely sampling cognitive impairment populations in dual-task interventions.

1.1.6.3. Realist methods of enquiry

Traditional methods of evidence synthesis aim to determine the effectiveness of an intervention, answering the question "does it work?" typically through use of evidence with low risk of bias and high confidence about causality (RCTs). Positivist methods only accept that for which there is direct evidence. This approach alone is inadequate and a poor way to study complexity and heterogeneity. There are big evidence gaps for specific circumstances and populations, therefore increasing the risk that research areas which are difficult to study are neglected. Heterogeneity within populations and conflict regarding outcomes may require a less traditional synthesis method to address the current research aims.

Realist methods of enquiry are increasingly used as an alternative approach within health research. Realistic evaluation [114] has been used in public health and increasingly for health interventions as a theory-driven approach, promoted by the Medical Research Council (MRC) as a suitable evaluative method within processes evaluation [115].

The ontology of realistic evaluation has foundation within critical realism and work from Bhaskar [116, 117], Harre [118], Collier [119], and Archer [120]. From a philosophical perspective, the descriptions of a “stratified reality”, in which the Real, the Actual and the Empirical are layers of reality interacting and influencing each other are adopted within a practical approach [114].

Realistic evaluation is a critique and practical option which sits between traditional Positivism and Constructivism philosophies [121]. It can be argued that Positivists consider only the Empirical (that which we can touch, feel, hear, and see) within strict, reproducible environments. It is understandable that this method of enquiry is justified in health care settings, where interventions, interactions, and environments are complex.

Originally developed in criminology and social policy, researchers have used realism to explore policy from multiple perspectives. In this way, researchers do not just consider a policy from an Empirical layer of understanding (i.e. does it work?), but are able to look beneath at causal relationships of the context and mechanisms in that situation (i.e. who has it worked for and why has it worked?). Pawson explains that realist enquiry uses a “*generative model of causality*” which explains that “*to infer a causal outcome (O) between two events (X and Y), one needs to understand the underlying mechanism (M) that connects them and the context (C) in which the relationship occurs*” ([122], p21-22). It is this nature of exploring the context and mechanisms underlying an intervention, asking the traditionally quoted research question of “what it is that works, for whom, and in what context?”, that builds explanation, understanding, and inference from previously published material in a synthesis.

Approaching a literature synthesis from the realist perspective adds detail into the theoretical underpinning of falls interventions in older adults with cognitive impairment, whilst providing a novel perspective to the field and the researcher's development. By considering a broader range of evidence, the uncertainty is shifted from generalisability to causality, whilst using methods that are transparent and reproducible.

1.1.7. Summary

Mild dementia has been presented as an at-risk stage for developing further impairments and possible diagnosis. Implementing interventions at this point in the cognitive impairment continuum could prevent the physical costs and resultant increased falls risk. Further work is needed to ascertain relationships between cognition, gait, including dual-task cost, balance and falls risk, and to develop the theoretical model underpinning a falls intervention in people with mild dementia. Systematic review is needed to collate the studies within cognitive impairment samples that have used falls outcomes, and to synthesise and build upon the material that has already been published. With the plethora of studies available within different patient populations, novel methods for synthesising the literature need to be taken into account. Overall, there is a gap in the current literature for tailored and specific interventions for persons with cognitive impairment, drawing on sound theoretical models and reasoning.

1.2. Theoretical model

The literature presents a complex picture of why people with mild dementia fall, what may disrupt this pattern of physical cost and falls, and where evidence supports falls interventions in these individuals. A conceptual model will be presented to simplify the literature, the researcher's reasoning, and the theoretical underpinning of this thesis.

Multicomponent falls prevention interventions assess and address modifiable risk factors [97]. The model underpinning falls interventions in adults with cognitive impairment follows the same premise, but features specific modifiable risk factors associated with cognitive impairment. The risk factors are well evidenced and categorised [34]. A linear model conceptually orders the components leading to a fall: an individual with certain falls risk factors, when in a certain situation, will experience a fall (Figure 1.2).

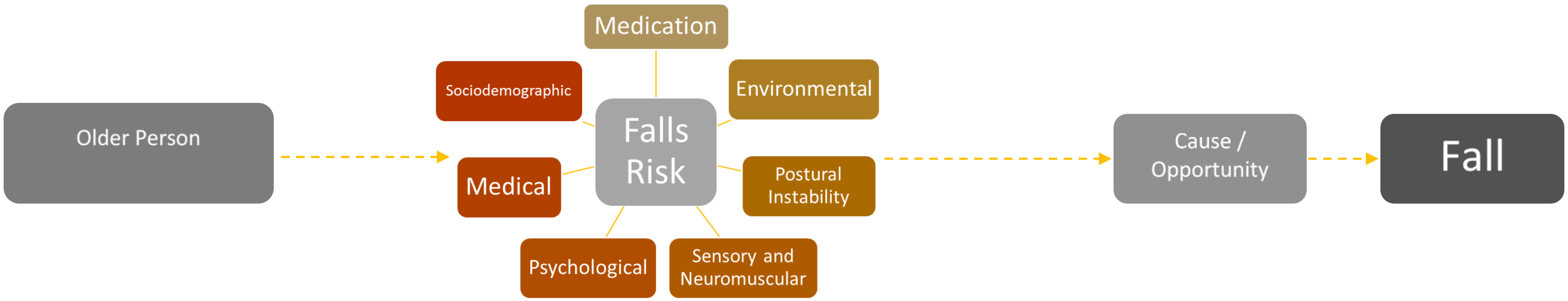


Figure 1.2: Linear model of conceptual components leading to a fall.

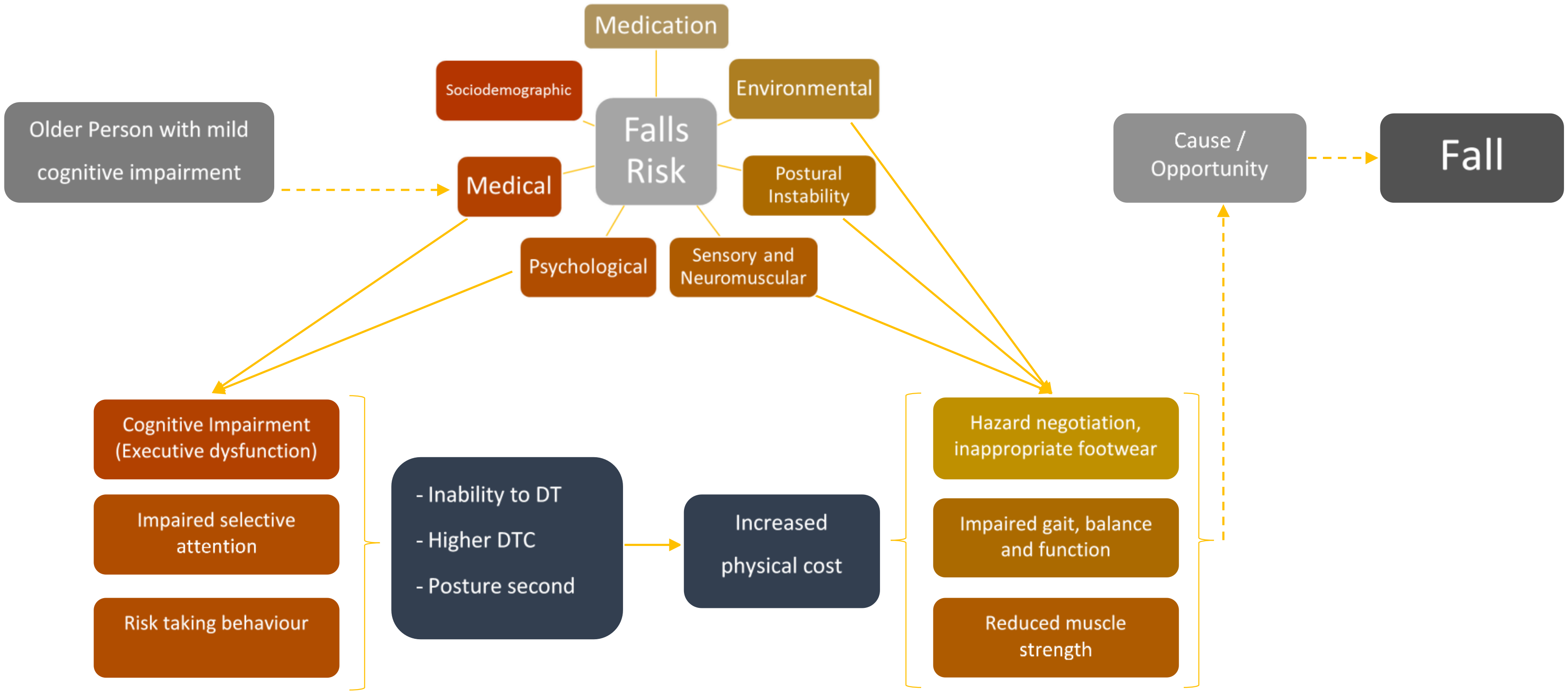


Figure 1.3: Linear model of conceptual components leading to a fall in older adult with mild dementia.

The model can be populated with greater detail regarding the key components within a theoretical model of a person with dementia experiencing a fall (Figure 1.3).

Executive dysfunction is a medical risk factor, comprising impaired selective attention and risk taking behaviour [34]. Impaired executive function is reflected in worse dual-task performance, greater DTC, and potential "posture second" strategy. This leads to increased physical cost experienced by these individuals. This can result in a fall during activity when combined with physical risk factors of reduced muscle strength, and impaired gait, balance, function, and environmental negotiation. A cause or opportunity element has not been elaborated as these are not specific to someone with cognitive impairment. An example of a cause or opportunity relevant to dual-task ability includes mobilising in a busy or unfamiliar environment.

The research aims and questions need to be defined. For example, are these theoretical components present within people with dementia? Are they modifiable and if so, which components show most ability to change? Can dual-task training bring about those changes?

1.3. Aim, objectives, research questions and thesis structure

1.3.1. Research aim

The primary aim of this thesis is to:

a) Explore the influence of mild dementia on gait, balance and falls risk, in order to produce evidence based recommendations for falls prevention programmes that are relevant to this population.

1.3.2. Objectives of the research

The objectives are therefore to:

1. Identify and summarise current treatments for cognitively impaired patients at risk of falling.
2. Explore the relationship between cognitive impairment, gait parameters, balance measures, and falls risk.
3. Develop and test the feasibility of an innovative falls prevention intervention for adults with cognitive impairment.

1.3.3. Research questions

The research questions that this thesis will answer are displayed with the corresponding thesis chapters (Table 1.2).

Research Question	Thesis Chapter
How does cognitive impairment affect gait parameters, including dual-task ability, balance measures and falls risk? Is there a relationship between these components?	2
What interventions are used to reduce falls in older adults with cognitive impairment?	3 & 4
Has dual-task training been tested in older adults with cognitive impairment?	4
How do exercise-based interventions reduce falls in older adults with cognitive impairment, in what circumstances and why?	5
Does an exercise-based dual-task intervention programme improve an individual's ability to dual-task? Does an exercise-based dual-task intervention programme improve other risk factors in an older adult with cognitive impairment?	6

Table 1.2: Research questions and corresponding chapters

1.3.4. Research structure

Structure of the research presented follows the research questions (Figure 1.4). Falls interventions in older adults with mild dementia can be considered a complex intervention as defined by the Medical Research Council (MRC), particularly in consideration of the number of interacting components identified in the theoretical model, and the heterogeneity in those receiving the intervention (such as severity of cognitive impairment, comorbidities, type of impairment, and habitual activity) [123]. The use of falls rate and risk as an outcome is also heterogeneous, with variance in how falls are measured and reported.

The following research is situated in the "Intervention Development" stage according to the MRC framework. The framework advises on designing and evaluating complex interventions that feature four, non-linear but systematically considered, phases: development, feasibility and piloting, evaluation, and implementation [123].

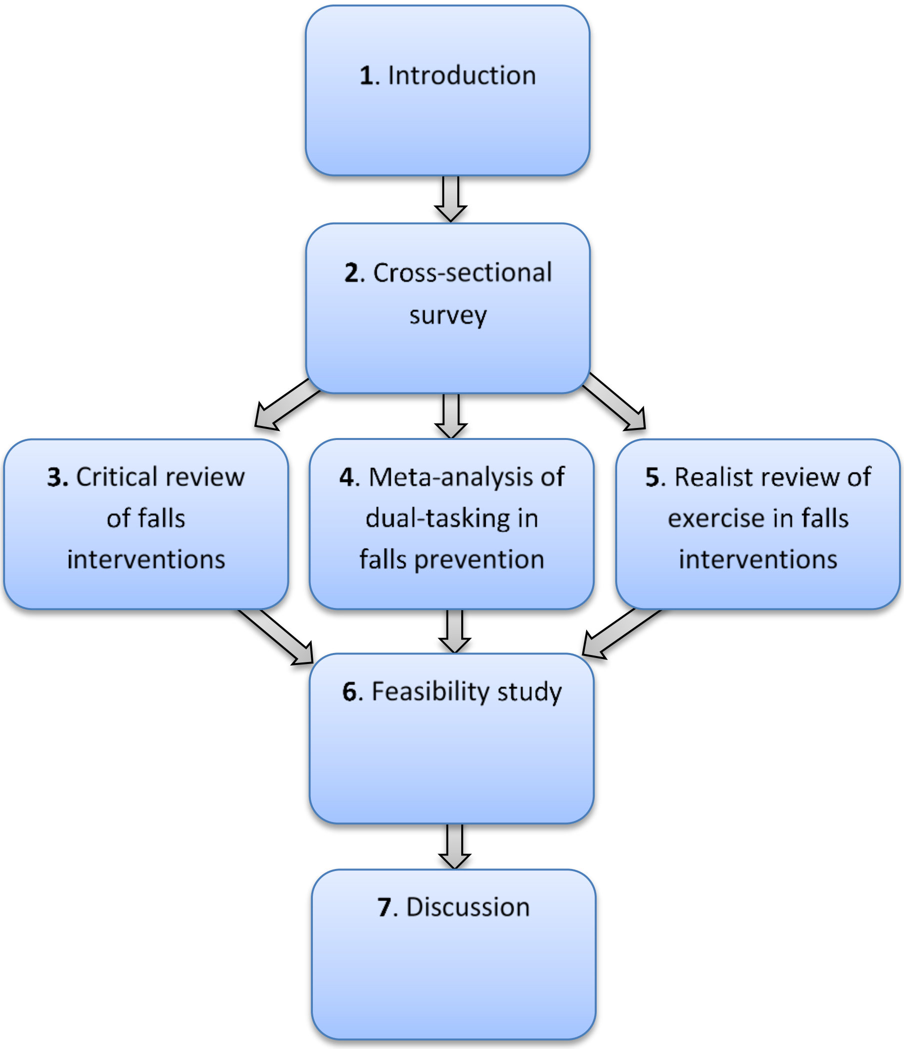


Figure 1.4: Research structure and chapters.

Initially, a cross-sectional survey will explore how mild dementia can affect people's gait. The data from standardised assessments of gait, dual-task costs, falls, and cognitive ability are presented and questioned in Chapter 2, to provide evidence that justifies the focus on this patient population. The dual-task paradigm is used as a method to explore the influence of cognition on gait and its influence on falls risk.

Once the problem is evidenced, interventions that have been used to reduce falls in older people with cognitive impairment are considered. The literature is reviewed using three different methods of evidence synthesis. Firstly, the literature on falls prevention for people with dementia is presented via a systematic "umbrella" review of falls interventions (Chapter 3).

Secondly, a detailed review of dual-task interventions in people with mild dementia is presented (Chapter 4). The review will question if dual-task training has been tested in older adults with cognitive impairment, and will draw conclusions through meta-analysis on effect sizes of dual-task based interventions at reducing falls and falls related outcomes in the target population.

Thirdly, Chapter 5 takes a different methodological approach to questioning and interpreting the literature. A realist review method is used to identify context-specific information on what exercise components of a falls intervention might work for older adults with cognitive impairment, under what circumstances, to what extent, and how? This review focuses on the theory underpinning the falls programme, developing and testing programme theories against the literature, in order to better understand how the exercise component of a falls intervention actually works.

The conclusions from all three reviews will be synthesised to inform the content of an exercise-based and dual-task training falls intervention programme for older adults with cognitive problems. Chapter 6 presents a feasibility study investigating a falls prevention intervention, targeted at improving gait, balance, and dual-task ability, specifically for people with cognitive problems. The intervention will be based on using dual-task concepts to train and improve single and multiple tasks, measured through gait and falls risk and developed from the evidence and explanation building of the preceding chapters.

A summary of the main findings is then presented (Chapter 7), before critically appraising the methods used, identifying limitations, and making recommendations for clinical practice and future research in the field.

Chapter 2. Gait, balance, fall risk and global cognition in older adults with mild dementia: a cross-sectional survey

Summary

Gait speed and step-variability, particularly in a dual-task paradigm, are quantifiable measures to evaluate the role of cognition on gait. In this chapter, a cross-sectional survey is described. Data from standardised assessments of cognition, gait, balance, and falls risk provide quantitative information on a sample of 69 older adults with mild dementia (MoCA 15-25/30). Spatiotemporal gait parameters using the GAITRite gait analysis system were recorded under single task and dual-task conditions. Mean dual-task cost (mDTC) was calculated using physical (gait speed) and cognitive measures. Data are presented as descriptive statistics, correlations, and inferences from logistic regression.

The 69 participants (mean age 81 years; n=38 women) with mild dementia had an increased risk of falls (median falls in previous six months=1.5; mean physiological profile assessment [PPA] falls risk score=2.48), poor gait pattern, and reduced balance. The mDTC was calculated during two cognitive tasks, with a verbal-fluency task producing the greatest cost. A statistically significant relationship between global cognition and gait parameters ($p<0.05$), falls risk ($p<0.01$), and balance ($p<0.01$) is evident. Falls were experienced in the previous six months by approximately one third of the sample. Gait parameters, balance and falls risk scores were significantly different between those that had or had not fallen. Logistic regression identified gait speed and falls risk scores

as the most strongly associated variables, with the best fit model including both physical and cognitive components.

Older adults with mild dementia experienced falls, with cognition negatively associated with gait pattern within both a simple walking and dual-task paradigm. An mDTC exceeding levels for healthy older adults was discussed, suggesting there may be a benefit of assessing such measures in falls intervention research with this population. However, mDTC was not associated with future falls in this sample. This study corroborates and progresses our understanding of the influence of cognitive impairment on measures of gait, DTC, balance and falls, and sets the scene for the development of an intervention to address falls in older adults with mild dementia.

Reference: V. Booth, P. Logan, T. Masud, V. Hood, V. Van Der Wardt, R. Taylor, and R. Harwood. Falls, gait, and dual-tasking in older adults with mild cognitive impairment: A cross-sectional study. *European Geriatric Medicine* 6S1 (2015) S32–S156.

2.1. Introduction

Cognitive impairment is a risk factor for falls [97]. Risk of falls is increased in older adults even with MCI [35]. The interplay between cognition, gait, and falls has been reviewed previously [45, 124] and outlined within the Introduction (Chapter 1).

Cognition plays a crucial role in the control of gait. The premise that gait is a pure motor, automated task has been superseded. Authors such as Hausdorff convincingly argue that even "simple" gait should be considered "*a complex cognitive task that is associated with higher-level cognitive function*" ([96], p541). There are multiple cognitive domains which have been identified as influential on gait and subsequently falls risk. For example, slow reaction time is associated with an increased risk of falls [125, 126] and influences the ability to recover from an unexpected loss of balance when standing or related to gait [124].

Executive function is an umbrella term to describe a collection of cognitive processes which together plan, initiate, monitor, and review actions [127]. Components of executive function, such as volition, planning and decision making, purposive action, effective performance and cognitive inhibition, have all been described in their relation to gait and falls risk [71].

Executive function also incorporates the ability to allocate, switch, and manipulate attention [124]. Attention is important for completing simultaneous or dual tasks, such as walking and talking at the same time [128]. Impaired attention could inhibit switching of cognitive resources during completion of multiple or dual-tasks, particularly within complex environments or changing situations when increased resources could be needed to maintain a safe walking pattern and postural control.

Executive dysfunction has been associated with an altered gait pattern [72, 129] and an increased risk of falls [50]. As we age our gait pattern naturally changes, becoming slower and more variable [53]. Gait changes extending beyond normal ageing are subtle but detectable at even mild degrees of cognitive dysfunction [43, 58]. Gait speed is slower and stride length shorter in individuals with cognitive impairment compared to age-matched older adults with no impairment [58]. Gait parameters have been used to predict falls [130] and distinguish between fallers and non-fallers in mild to moderate dementia [131].

Balance deteriorates as we age [132] and measures of balance ability, such as the Berg Balance Scale [133], can help to distinguish between healthy older adults that are or are not falling [134]. Some studies report that balance is not severely affected in mild stages of cognitive impairment [135]. The ability to maintain postural control is a contributing component to falls risk in healthy older adults [34] and follows a similar pattern of deterioration during dual-task assessment as gait. Gait and balance assessment in people with cognitive impairment could therefore increase knowledge about why this population is at increased risk of falls [52].

Gait analysis provides a sophisticated measure to "*detect subtle changes in gait*" ([51], p489). Gait speed is a relatively straightforward and clinically useable measure. However, other spatial variables such as step-length require more time-consuming or sophisticated methods and equipment. Observation is a valuable component of clinical gait assessment, but has limited reliability [136, 137], relying on clinician experience to produce a broadly qualitative measure. Spatiotemporal gait analysis requires time and equipment not usually available within the NHS. Systems such as the GAITRite gait analysis system [138] provide a potential bridge between the quantifiable gait analysis of research studies and the standard clinical setting.

Gait assessments have been completed under different conditions and techniques, i.e. different walking speeds [57] and additional tasks [139]. The dual-task paradigm has become the standard method to assess the influence of cognition on gait [69] (Chapter 1).

Initially reported as clinical observation and "quick" assessment tool [68], research on dual-tasking as an assessment [70] and intervention [140, 141] is steadily increasing. The change in performance when using the dual-task paradigm as an assessment can produce a percentage measure of the change, termed the dual-task cost (DTC) [142]. As a percentage, this variable allows for comparison across different dual-tasks and different participant abilities, but gives no indicator of the initial variable level before it is transformed. For example, two participants could both have a 50% DTC for gait speed, but one participant mobilises at 0.5 m/s while the other at 1.0 m/s. The DTC has not been well reported in the literature to date but its use, and particularly the implementation of a mean DTC (incorporating the change in both tasks of the dual-task assessment), has been advocated [142, 143].

The difficulty and type of cognitive task are also cause for discussion. Within the literature, there is a great variety of tasks used as the secondary, cognitive task. The dual-tasks include manual [67], memory [144], visual [145], auditory [146], and verbal tasks [85], of varying difficulty and in various patient populations. The task used could be important as different tasks utilise different cognitive skills and processes. However, it could be argued that the task is unimportant as any secondary task will challenge executive functioning and therefore promote the desired attentional demand. There is currently a lack of standardisation and optimisation of testing procedure regarding dual-task assessments.

Under dual-task conditions, adults with a mild dementia experience reduced gait velocity [147] and increased gait variability [85, 148]. In a recent paper detailing gait parameters in single and dual-task conditions, Taylor et al [67] reported that the dual-task activities adversely affect gait parameters in older adults with cognitive impairment (n=64), but a comparison of the dual-task gait parameters could not distinguish fallers from non-fallers in this population (overall value measures [excluding cadence] Wilks' $\lambda=0.9$, $F=0.6$, $p=0.8$ or variability measures Wilks' $\lambda=0.9$, $F=0.5$, $p=0.7$).

This follows another recent review of 30 articles (including 33 samples) and 4144 participants by Menant et al [70], who concluded that the addition of a dual-task did not enhance the ability to discriminate between fallers and non-fallers. However, Menant et al [70] could only combine results via meta-analysis on gait speed in older adults, and cautioned that other gait parameters (such as gait variability) may hold greater value and the limited publication of results for other parameters prevented their inclusion in the analysis.

DTC is an emerging area in the literature, and there is considerable heterogeneity in dual-task choice, assessment protocols, and publication of results [84]. For example, Taylor et al [67] may not have observed differences between fallers and non-fallers as the additional dual-task may not have been at the correct level of difficulty for the degree of impairment in their participant population [85]. It is, therefore, the aim of this analysis to explore a relatively large and consistent sample of older adults with mild dementia, using a variety of dual-task assessment conditions, and reporting findings as dual-task cost.

2.2. Aims, objectives, and hypothesis

2.2.1. Survey aim

The primary aim of this study was to evaluate falls risk, balance, and spatiotemporal gait measures in single and dual-task conditions in a sample of older adults with mild dementia.

2.2.2. Research question

The research question was: in a population of older adults what is the effect of mild dementia on measures of balance, gait, dual-task cost, and falls?

2.2.3. Objectives

The objectives of the analysis were:

a) Describe the balance ability, gait parameters, dual-task cost and falls risk characteristics of a sample of older adults with mild dementia.
b) Explore the relationships between cognition, balance, gait and falls.
c) Determine if older adults with mild dementia are experiencing falls and if so what physical characteristics contribute to those falls.

2.2.4. Experimental hypothesis

Survey Objectives	Hypothesis
a)	Compared to age-matched older adults, older adults with a mild dementia will have reduced balance ability, altered gait parameters, increased dual-task cost and an increased falls risk.
b)	An association exists between global cognition and gait parameters, including dual-task cost, falls risk and balance. Cognitive impairment will be associated with decreased gait speed, increased gait variability, increased dual-task cost, increased falls risk, and reduced balance [41, 53, 149]. These relationships will be larger than could have occurred by chance.
c)	Older adults with mild dementia experience more falls than age-matched older adults. Older adults with mild dementia who are experiencing falls will have a statistically and clinically significant difference in gait speed, gait variability, and dual-task cost compared to those that are not experiencing falls. Cognitive impairment, gait, dual-task cost, and balance will contribute to predicting if an individual will experience future falls.

Table 2.1: Experimental hypothesis according to objectives

2.3. Methods

2.3.1. Participants

Participants were drawn from a cross-sectional survey of older persons with mild dementia completed between 2013 and 2014. The sample was purposively recruited from Memory Clinics and Falls Services within Nottinghamshire.

Inclusion criteria:

- over 65 years of age,
- have cognitive impairment at a mild stage (Mini Mental State Exam [MMSE] 21-26, Montreal Cognitive Assessment [MoCA] 15-25, or Test Your Memory [TYM] 30-45),
- be a resident of the identified area,
- be available for the assessments with or without a family member or carer.

Exclusion criteria:

- lacking the mental capacity to consent to participate,
- inability to speak or understand good English,
- MMSE score affected by visual or hearing impairment,
- physical disabilities or uncorrected sensory impairment that prevents undertaking of tests (such as being unable to see or hold a pen),
- unable to walk without human help.

Ethical approval was gained (NRES reference number: 13/EM/0161). Informed written consent was gained for all participants.

2.3.2. Apparatus

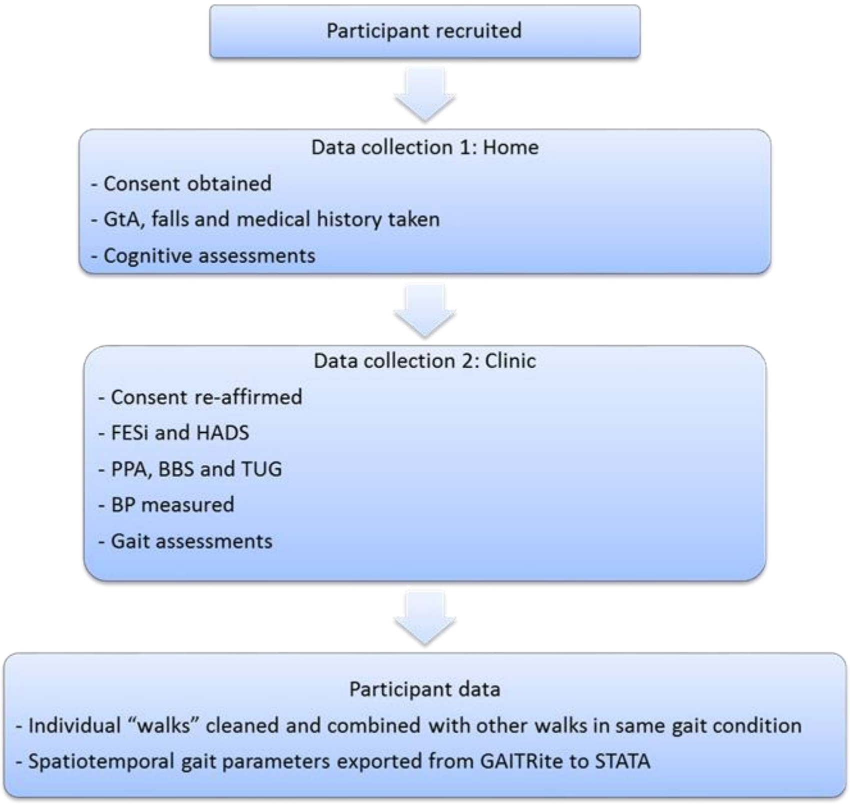
Spatiotemporal gait measurements were collected using a GAITRite electronic walkway (5.75mx0.9mx3.2mm) [138]. The GAITRite mat was placed on the floor and connected to a computer via an interface box. There were no attachments to the participant, and the device was pre-calibrated by the manufacturer. The instrumented walkway has pressure sensors which detect the timing and location of each footstep along the walkway in order to calculate the spatiotemporal parameters. The GAITRite has shown a high test-retest reliability for spatiotemporal gait measures of gait speed, cadence, and step-length in healthy older adults [150] and people with Alzheimer's disease [151]. The reliability and validity of the GAITRite system have been established in healthy participants [152-155] and older adults with Alzheimer's disease [151]. Protocols are available for assessing spatiotemporal gait in older adults [139, 156].

2.3.3. Procedure

The survey data collection method was standardised (Figure 2.1). Cognitive and physical variables were taken over two separate two-hour visits. Once participants had consented, the cognitive assessments were completed in the participant's home (Data Collection 1). The cognitive assessments were standardised scales to measure a range of executive function domains (volition, planning and decision making, purposive action, effective performance and cognitive or response inhibition [92, 93]). These results have been published elsewhere [157]. In the initial session (Data Collection 1) all participants completed a MoCA [158], and a Guide to Action (GtA) falls assessment [159], and had demographic and fall history collected.

Participants then attended an outpatient rehabilitation clinic for the physical assessments (Data Collection 2). Transportation was provided for participant and carer attendance as required. Two researchers were present and completed the physical outcomes via a standardised protocol (Appendix 1). Data were recorded on standardised forms (Appendix 2). Falls history was obtained through questioning participants on the number of falls experienced in the previous 6 months (0, 1, 2, 3 or ≥4). Psychological variables included; the Hospital Anxiety and Depression score (HADS) [160] and Falls Efficacy Score – International (FES-i) [161]. The balance variables included the Physiological Profile Assessment (PPA) [40], Berg Balance Score (BBS) [133], and Timed Up and Go (TUG) test [162]. The Physiological Profile Assessment (PPA) short form test measured five components of balance (vision, proprioception, lower limb strength, reaction time and postural sway) to provide a falls risk score [40]. The equipment and computer programme (to determine the falls risk score) were standardised and supplied through Neuroscience Research Australia [163].

The BBS measured a range of static and dynamic balance postures through a fourteen item scale (see Appendix 2 for scoring). Balance postures were completed in order and standardised instructions given to determine the total score (max score 56 points). The TUG is a dynamic balance and functional mobility measure [162]. The time taken for the participant to rise from a chair, walk three meters to a marker, turn, and return to sitting is recorded and repeated three times to compute a mean time taken (seconds).



Legend: GtA=Guide to Action, FESi=Falls Efficacy Scale international, HADS=Hospital Anxiety and Depression Scale, PPA=Physiological Profile Assessment, BBS=Berg Balance Scale, TUG=Timed Up and Go, BP=Blood Pressure

Figure 2.1: Flow diagram of survey data collection.

To calculate the DTC, measurements of both tasks were taken in a standardised order:

a) seated counting backwards from 50 to 1, in ones,
b) seated verbal fluency (naming words beginning with a provided letter),
c) single quiet walking,
d) walking counting backward from 50 to 1, in ones,
e) walking verbal fluency task (naming words beginning with a provided letter, different to seated task).

Spatiotemporal gait variables were collected for the physical part of the dual-task, and time taken (seconds) and number of non-repeated words for the cognitive part. The tasks chosen for this analysis were two verbal fluency tasks: backward counting from 50 to 1, in ones, and naming words beginning with a specific letter. Both of these tasks were used previously in the literature and normative data from healthy older adults have been published to allow for comparison in the analysis [65, 164]. Audio recording during the dual-task conditions was used to confirm the accuracy of the cognitive task component and was deleted as soon as possible following data entry.

Each participant was given the same instructions and prompts prior to and during each walking condition (Appendix 2). Participants were instructed to walk along the GAITRite mat at their normal walking pace for each walking condition. One research assistant remained with the participant during all walks, with another stood at the computer interface with the walkway. All walks were recorded and were started and finished two metres beyond each end of the walkway to ensure a constant walking pattern. Participants were able to rest between each set of walks. Each participant completed five walks for each walking condition (see Figure 2.2) to enable a minimum of 30 steps [139]. Walking aids were permitted if required. The GAITRite software can distinguish and remove walking aid tracks from the final spatiotemporal gait measurements with manual processing. Two researchers were instructed how to do this manual processing (VB and VH) (Figure 2.3).

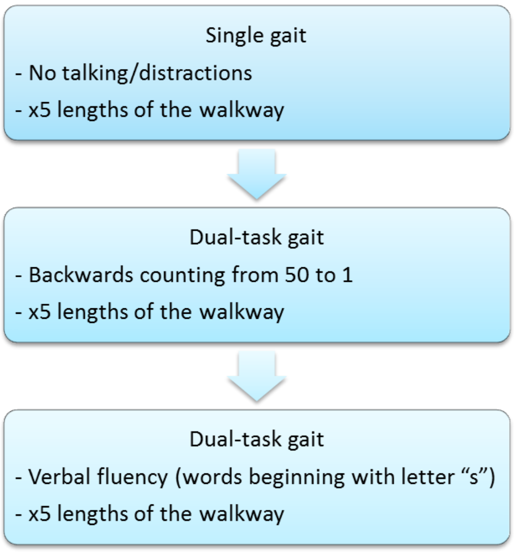


Figure 2.2: Flow diagram of gait assessment

2.3.4. Data Analysis

Data were anonymised at collection using participant identification numbers on all paper and electronic data sheets and forms. Data were immediately uploaded onto a secure database and stored on both a password protected computer and university server. Statistical analysis was completed using STATA software after discussion with a medical statistician. The analysis was pre-planned and described according to the aims previously set out.

Sample descriptives: For all sample characteristics, data were plotted on histograms to identify the correct measures of central tendency. For non-normally distributed variables, the median and interquartile ranges are presented. Otherwise, the mean, standard deviation (±), and range are presented. Age, gender, anxiety and depression scores, global cognition, fear of falling, the risk of falling, the number of falls in the previous six months, balance score, and functional gait are described.

Gait variables of interest were identified from literature within the field for single and both dual-task walking conditions [106, 164-167]. The gait variables of interest were: velocity (m/s), step-length, step-width, double support (%), step-time variability, and step-length variability. Variability was calculated using the coefficient of variance (CV) which is a common and standardised format to express the ratio of the standard deviation of scores to the mean [165]. The processing of gait parameters was completed using a standardised procedure (see Figure 2.3).

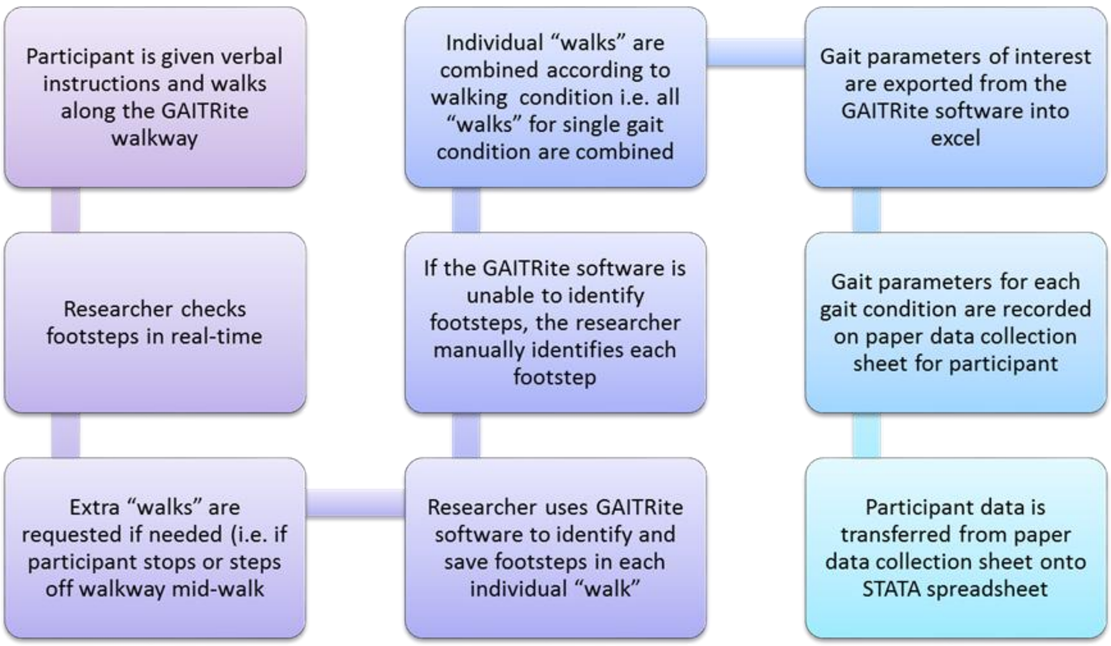


Figure 2.3: Processing procedure for gait variables using the GAITRite

Dual-Task Cost: The dual-task cost (DTC) was calculated according to the formula below and provides detail regarding the cost of completing a cognitive task on the participant's gait.

$$\frac{dual - single}{single} \times 100$$

Legend: dual=variable under dual-task condition, single=variable under single-task condition

Equation 1: Dual-task cost (DTC)

The DTC was calculated for each participant for both the motor (gait speed [m/s]) and cognitive (counting time [seconds] and a total number of words given) tasks. These DTCs are used to determine the mean DTC (mDTC) for each walking condition using the formula below.

$$\frac{motorDTC + cognitiveDTC}{2}$$

Equation 2: Mean dual-task cost (mDTC)

The mDTC combines results from both the tasks completed at the same time (motor and cognitive). By combining the results (Equation 2), the measure becomes an average of the cost accrued within both tasks of that one assessment. For example, in the backwards counting task, the gait parameter of interest (gait speed) and the time taken to count (seconds) are both calculated into DTC and then averaged into the mDTC for that task.

Theoretically, the mDTC eliminates any task preference that the individual made while completing the dual-task assessment [142]. Inadvertently an individual may focus more on one component. For example, Bloem et al. [168] identified that individuals with Parkinson's disease adopted a "posture second" strategy during dual-task tests, giving the cognitive task a higher priority than their walking or balance. It has been reported that healthy older and younger adults will prioritise their gait and balance over the cognitive task [82, 168, 169].

Beurskens and Bock [142] advocate the use of mDTC, describing how any variation in task prioritisation is negated as the cost on both tasks are considered and combined. Histograms determined the mDTC distribution and presented it via a measure of central tendency. If non-normally distributed, the variable was transformed before the completion of t-tests to determine the difference between dual-task conditions.

Associations with gait parameters: Correlations using Pearson's r coefficient provided information on the relationship between: a) falls risk (PPA) and gait (speed, variability measures, and mDTC), and b) global cognition (MoCA) and gait (speed, variability measures, and mDTC). The coefficients were presented in table format with the p-value identifying the statistical significance of the correlation.

Association with falls history: A dichotomous variable categorising participants who had experienced a fall within the past six months was computed and classified the participants into *Faller* or *Non-Faller*. The gait parameters and DTC of the two groups were described according to the appropriate measure of central tendency. Data were presented in table format to compare the statistics. T-tests were used to determine if there is a statistically significant difference between the groups. A binomial logistic regression was run to determine if falling (*Fallers* versus *Non-Fallers*) was influenced by the physical or cognitive characteristics recorded in this sample and to determine statistically significant contributing components. These were presented as Estimated Odds Ratios and predicted probability (of a fall).

Factors independently associated with falling: Factors influencing the odds that an individual with mild dementia will fall were determined from the theoretical model (Chapter 1.2), summary of literature (Chapter 1.1 and Chapter 2.1), and the associated components already reported (Chapter 2.4.2.). The initial model was adjusted for all of these predetermined and justified components. These include: age and sex (male) to describe the sample; cognition (MoCA) and mDTC to represent cognitive variables; gait speed (m/s), balance (BBS) and falls risk (PPA) to represent physical variables.

A multivariate analysis with stepwise elimination was conducted. Likelihood ratio (LR) determined the best model of parameters that influence whether an older person with mild dementia will fall or not [170]. Five models were proposed (Table 2.2). The full model included all seven independent variables (*fmodel*). To test the hypothesis that mDTC had no effect on falls experienced, a model excluding this variable was derived (*n1model*). DTC is linked to cognition and is potentially a physical result of an inability to divide attention to multiple tasks (Chapter 1.1.5). Therefore a third model (*n2model*) was proposed, in which the hypothesis that neither mDTC nor cognition influenced falls and so both mDTC and cognition scores (MoCA) were excluded. To test the hypothesis that the physical characteristics were more influential than the cognitive components, the fourth model (*n3model*) omitted the physical variables of gait speed and balance (BBS).

Model	Explanatory variables included in model
fmodel	Sex, age, cognition, gait speed, mDTC, falls risk and balance
n1model	Sex, age, cognition, gait speed, falls risk and balance
n2model	Sex, age, gait speed, falls risk and balance
n3model	Sex, age, cognition, and mDTC
intercept_only	n/a

Table 2.2: Different models of variables for stepwise elimination

2.4. Results

2.4.1. Description of sample characteristics

Seventy-six participants were recruited into the cross-sectional survey. Of these, seven subjects failed to complete all measures, therefore a sample of 69 (females=38) participants who had completed cognitive and all physical outcome measures were included in this analysis.

Histograms identified that age, global cognition (MoCA score), and falls risk (PPA score) were normally distributed (see Appendix 3). Mean, standard deviation (SD), and range have been presented for these variables in Table 2.3. Number of falls reported in six months, anxiety and depression score (HADS), fear of falling (FES-i), balance score (BBS), and functional mobility (TUG) were non-normally distributed (see Appendix 3). Median and inter-quartile range (IQR) are presented (Table 2.3) and data required transformation before further statistical testing.

	Mean	SD	Range	
			Min.	Max.
Age (yrs)	80.8	6.52	67	94
Global cognition (MoCA)	21.1	3.71	12	29
Falls Risk (PPA)	2.5	1.67	-0.63	5.88
	Median	**-**	**IQR**	
			25th	**75th**
Number of falls	1.5	-	1	3
Anxiety and Depression (HADS)	10	-	7	17
Fear of falling (FES-i)	24	-	20	29
Balance (BBS)	50	-	38	54
Functional mobility (TUG) (secs)	12.2	-	9.7	17.9

Legend: SD=Standard Deviation, Min=Minimum, Max=Maximum, yrs=years, MoCA=Montreal Cognitive Assessment, PPA=Physiological Profile Assessment, IQR=Inter-Quartile Range, HADS=Hospital Anxiety and Depression Score, FESi=Falls Efficacy Scale international, BBS=Berg Balance Scale, TUG=Timed Up and Go, secs=seconds.

Table 2.3: Description of survey sample characteristics

32% (n=22) of the sample reported at least one fall in the previous six months. 71% (n=49) of the cohort walked independently without any aid. Spatiotemporal gait measures are presented in Table 2.4 for the three gait conditions: single-task (ST), backward counting dual-task (DT), and verbal fluency dual-task (DT).

DTC was calculated for each participant under each dual condition (backward counting and verbal fluency) for the cognitive and physical task. Table 2.4 summarises for the mean DTC (mDTC) for each dual condition.

	Normal ST	Backward Count DT	Verbal Fluency DT
	Mean (SD) or *Median (IQR)		
Gait speed (m/s)	0.88 (0.32)	0.72 (0.29)	0.62 (0.25)
Step-length (m)	0.51 (0.14)	0.46 (0.15)	0.44 (0.14)
Step-width (m)	0.11 (0.04)	0.12 (0.04)	0.13 (0.04)
Double support (%)	*32.8 (28.1-39.2)	*36 (29.1-45.3)	*37.4 (32.4-46)
Step-time variability (CV%)	*5.2 (3.6-7.4)	*7.3 (4.9-9.8)	*8.1 (6.2-11.5)
Step-length variability (CV%)	*6.0 (4.7-9.3)	*7.8 (5.6-10.5)	*8.6 (6.4-12.3)
mDTC (%)	-	*16.7 (1.6-72.7)	*26.6 (1.2-125.3)

Legend: ST=single-task, DT=dual-task, SD=standard deviation, *=non-normally distributed, IQR=inter-quartile range, m/s=meters per second, m=meter, %=percentage, CV%=co-efficient of variance percentage, mDTC=mean dual-task cost.

Table 2.4: Description of survey sample gait parameters

The mDTC for both variables were positively skewed (see Appendix 4) and were therefore log transformed before further statistical analysis. A paired t-test identified a statistically significant difference between the mDTC for the two DT walking conditions (Table 2.5). There was a significantly greater mDTC for the verbal fluency task compared to the backward counting task.

Gait Measure	Backward Count DT (Mean/SD)	Verbal Fluency DT (Mean/SD)	Mean Difference	95% CI	P value
mDTC (%)	21.16 (14.6)	31.15 (20.4)	-0.39	-0.62, -0.18	≤0.001

Legend: DT=dual-task, SD=standard deviation, CI=confidence interval, %=percentage, mDTC=mean dual-task cost.

Table 2.5: Mean difference from paired t-test of survey sample mDTC

2.4.2. Associations between gait, fall risk and global cognition

Three gait measures were identified from the literature as key markers for gait instability: speed, step-time variability, and step-length variability [139]. Gait variability measures across all gait conditions were non-normally distributed and were log transformed for parametric testing (see Appendix 5 for transformed histograms). Scatter graphs were plotted for each correlation to identify the existence of a non-linear relationship (Appendix 6). All variable pairs were suitable for correlation. A Pearson's r coefficient was completed on global cognition (MoCA) and gait (speed, variability measures, mDTC), falls risk and balance. Coefficient and p-values are presented (Table 2.6).

		Gait speed (m/s)	Step-time variability^ (CV%)	Step-length variability^ (CV%)	mDTC backwards count (%)	mDTC verbal fluency (%)	Falls risk (PPA)	Balance^ (BBS)
Global Cognition (MoCA)	Co-efficient	0.39	-0.24	-0.25	-0.32	-0.02	-0.47	0.34
	p-value	0.01	0.05	0.04	0.01	0.89	≤0.00	≤0.00

Legend: m/s=meters per second, ^=transformed variable CV%=coefficient of variance percentage, mDTC=mean dual-task cost, %=percentage, PPA=physiological profile assessment, BBS=berg balance scale, MoCA=montreal cognitive assessment.

Table 2.6: Correlation coefficients for gait, falls risk, and balance against global cognition

Measures of gait, including mDTC in backward counting, falls risk and balance were weakly but significantly correlated with global cognition at a p-value <0.05 (Table 2.6). There was no correlation between global cognition and the mDTC for verbal fluency. As global cognition increased, gait speed increased, the variability of step-time and step-length decreased, the cost experienced within the backward counting condition decreased, falls risk decreased, and balance increased. These are moderate to weak associations or inverse associations and could be confounded by other factors (e.g. age or sex) or causal pathways (for example pathologies such as dementia, osteoarthritis, muscle weakness, reduced speed and falls) [66].

The mDTC for both backward counting and verbal fluency demonstrates that there is a cost to individual completing two tasks at once (walking plus cognitive task) when compared with normal single task gait (Table 2.4). As global cognition reduces, there is a greater average cost when doing a backward counting dual-task. However, there was no correlation identified within this sample for the average cost experienced during a verbal fluency dual-task, and either falls risk or global cognition.

2.4.3. Participants who have fallen versus those who have not

2.4.3.1. Comparisons

The sample was grouped according to self-reported falls in the previous six months, and dichotomously grouped into *Fallers* or *Non-Fallers*. Data from one participant was missing, therefore the data sample consisted of 68 participants. The gait parameters, mDTC, falls and balance outcomes are grouped according to *Fallers* or *Non-Fallers* (Table 2.7).

Histograms identified gait speed, step-length, step-width, and falls risk were normally distributed and were described using mean (SD) (Appendix 7). Double support, step-time variability, step-length variability, mDTC, and balance were non-normally distributed and therefore described using median (IQR). Non-normally distributed variables were transformed using logarithm, reciprocal or cube, dependent upon strength and direction of skew. T-tests were completed to determine significant differences in gait, mDTC, falls risk and balance between *Fallers* and *Non-fallers* (Table 2.7). The mean difference (MD), 95% confidence interval (CI) and p-values are presented (Table 2.7).

Measure		Fallers (n=22)	Non-Fallers (n=46)	Mean Difference	95% CI	P-Value
		Mean (SD) /*Median (IQR)				
Gait speed (m/s)	Single	0.64 (0.28)	0.99 (0.28)	0.35	0.19, 0.49	≤0.01
	Back-Count	0.51 (0.23)	0.82 (0.25)	0.32	0.19, 0.44	≤0.01
	Verb-Fluency	0.46 (0.24)	0.70 (0.23)	0.24	0.12, 0.37	≤0.01
Step-length (m)	Single	0.41 (0.13)	0.56 (0.12)	0.15	0.09, 0.22	≤0.01
	Back-Count	0.35 (0.13)	0.51 (0.14)	0.16	0.09, 0.23	≤0.01
	Verb-Fluency	0.34 (0.13)	0.48 (0.11)	0.14	0.08, 0.21	≤0.01
Step-width (m)	Single	0.12 (0.03)	0.11 (0.04)	-0.01	-0.03, 0.01	0.22
	Back-Count	0.13 (0.04)	0.12 (0.04)	-0.01	-0.03, 0.01	0.27
	Verb-Fluency	0.13 (0.03)	0.12 (0.04)	-0.01	-0.03, 0.01	0.35
Double support^ (%)	Single	*37.9 (34.6-44.4)	*30.6 (26.9-33.9)	-0.23	-0.33, -0.13	≤0.01
	Back-Count	*45.9 (38.2-51.5)	*31.3 (28.4-38.7)	-0.29	-0.41, -0.19	≤0.01
	Verb-Fluency	*46.5 (39.5-54.9)	*34.9 (30.8-41.9)	-0.28	-0.42, -0.14	≤0.01
Step-time variability^ (CV%)	Single	*7.74 (5.2-10.8)	*4.1 (3.2-5.8)	-0.60	-0.88, -0.32	≤0.01
	Back-Count	*9.4 (7.3-15.7)	*6.3 (4.8-8.6)	0.04	0.01, 0.08	0.02
	Verb-Fluency	*9.8 (7.9-17.1)	*7.8 (5.6-9.2)	0.04	0.01, 0.07	0.01
Step-length variability^ (CV%)	Single	*9.1 (6.4-12.7)	*5.6 (4.3-7.9)	-0.51	-0.80, -0.22	≤0.01
	Back-Count	*12.1 (7.4-14.3)	*6.9 (5.1-8.7)	-0.56	-0.83, -0.29	≤0.01
	Verb-Fluency	*12.8 (9.7-15.0)	*7.7 (5.4-9.4)	-0.57	-0.82, -0.32	≤0.01
mDTC^ (%)	Single	-	-	-		-
	Back-Count	*21.7 (11.9-33.2)	*15.9 (10.5-22.4)	-0.23	-0.58, 0.12	0.19
	Verb-Fluency	*26.2 (14.6-41.3)	*27.9 (21.1-33.9)	0.14	-0.22, 0.51	0.44
Falls Risk (PPA)		3.33 (1.65)	2.05 (1.53)	-1.28	-2.01, -0.47	≤0.01
Balance^ (BBS)		*41 (33-46)	*53 (47-55)	50286	25139, 75432	≤0.01

Legend: n=number, SD=standard deviation, IQR=inter-quartile range, CI=confidence interval, m/s=meters per second, m=meters, ^=transformed variable, *=non-normally distributed, CV=coefficient of variance, mDTC=mean dual-task cost, PPA=physiological profile assessment, BBS=berg balance scale

Table 2.7: Comparison of outcomes according to falls experienced

There was a statistically significant decrease in gait speed and step-length, and increase in step-time variability and step-length variability in the *Fallers* compared to the *Non-Fallers* group. This significant difference was apparent across single and dual-tasks. There was no statistically significant difference between the mDTC and the step-width, whether participants had fallen or not. Falls risk was significantly higher and balance ability significantly worse in those who had experienced falls.

2.4.3.2. Factors independently associated with falling

The likelihood chi-square test statistic is 24.87 which is statistically significant at the 1% level ($p=\leq 0.00$) (see Appendix 8a). Therefore, the overall model is statistically significant.

Predictor	Estimated Odds Ratio	p-value	95% CI
Age	0.93	0.19	0.83, 1.04
Sex (male)	0.59	0.45	0.15, 2.36
Cognition (MoCA)	1.07	0.46	0.88, 1.31
Gait speed (m/s)	0.004	0.02	0.00, 0.35
mDTC (back-count)	0.99	0.69	0.95, 1.04
Balance (BBS)	1.03	0.63	0.91, 1.16
Falls risk (PPA)	1.63	0.05	0.99, 2.67

Legend: CI=confidence intervals, MoCA=montreal cognitive assessment, m/s=meters per second, mDTC=mean dual-task cost, BBS=berg balance scale, PPA=physiological profile assessment

Table 2.8: Estimated odds ratios for variables influencing falls experienced

Gait speed (p=0.02) and falls risk scores (p=0.05) were statistically significant (Appendix 8b) (Table 2.8). The likelihood of having a fall was reduced as gait speed increases. The odds ratio for gait speed (m/s) of 0.004 was transformed using natural log to determine an OR 0.58 per 0.1m/s (Appendix 2.8b). Therefore an increase in gait speed of 0.1 m/s decreases the odds of falling by 42% (OR 0.95). The likelihood of having a fall is increased as the falls risk score (PPA) increases. A unit increase in falls risk score increases the odds of falling by 63% (OR 1.63). For both of these coefficients, we can be 95% certain that these results are not due to chance. However, the other coefficients (age, sex, MOCA, mDTC, and balance) demonstrate no significant difference in falls categorisation. These results indicate that falls experienced in this sample are not significantly influenced by age, gender, general cognition, or the average cost accrued in gait and cognition while completing a secondary task.

Figure 2.4 demonstrates that all the predicted values span between 0 (no fall) and 1 (fall) but that most are featured closer to the 0 with a mean of 0.33 (Appendix 8c).

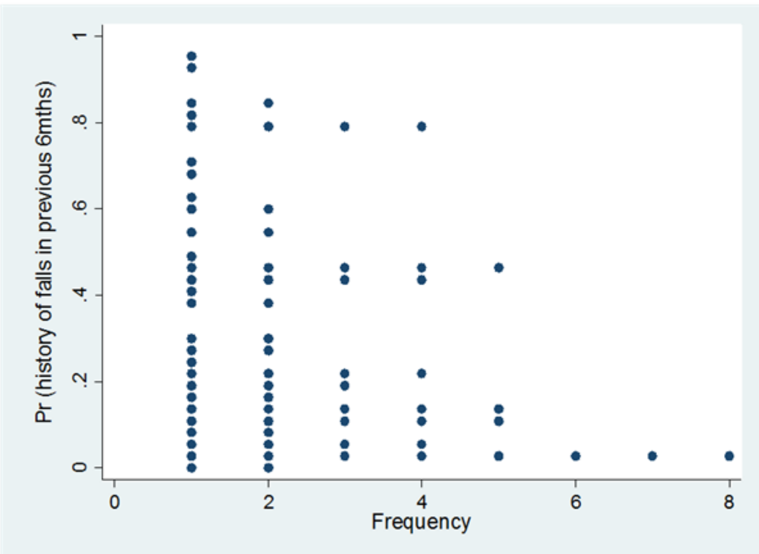


Figure 2.4: Dot plot of history of falls frequency in previous six months

Predicted probabilities can also be described according to the independent variables (Appendix 8c). At the mean gait speed of the whole sample (mean=0.88m/s), there is a 24% chance that a fall will be experienced (95% CI 11, 37). Going from the fastest gait speed to the slowest gait speed will increase the chance of falling by 96%. As gait speed reduces by one standard deviation (centered on the mean, ±0.32), there will be a 76% increased chance of falling (Appendix 8d). The range of gait speed in this sample is limited, without a linear relationship between gait speed and falls experienced. Therefore the chance of falling will not continue along a linear trajectory.

At the mean falls risk score (mean PPA=2.5), there is a 25% chance that a fall will be experienced (95% CI 12, 38). Going from the highest falls risk score to the lowest will increase the chance of falling by 57%. As the falls risk score reduces by one standard deviation (centred on the mean, ±1.67), there will be a 75% chance of falling. For every unit reduction in falls risk score, there is a 7% increased chance of falling (Appendix 8e). As with gait speed, there is not a linear relationship between falls risk and falls experienced.

Model	Explanatory variables included in model	LR chi^2 (within *fmodel*)	p-value
Fmodel	Sex, age, cognition, gait speed, mDTC, falls risk and balance.	-	-
n1model	Sex, age, cognition, gait speed, falls risk and balance.	0.17	0.68
n2model	Sex, age, gait speed, falls risk and balance.	0.81	0.67
n3model	Sex, age, cognition, and mDTC.	22.39	≤0.01
intercept_only	n/a	24.87	≤0.01

Legend: LR=likeihood ratio, mDTC=mean dual-task cost.

Table 2.9: Likelihood ratio models for analysis of robustness of models for falls experienced

Two of the LR tests were not statistically significantly different from the full model (*n1model* nested in *fmodel*, LR chi^2 = 1.17, p=0.68; *n2model* nested in *fmodel*, LR chi^2 = 0.81, p=0.67) (Table 2.9). The null hypotheses that neither the mDTC or the mDTC and cognition had an independent effect on falls risk was not rejected. The LR test between the *n3model* and full model is statistically significantly different (*n3model* nested in *fmodel*, LR chi^2 = 22.39, p=≤0.01). Therefore, the hypothesis that gait speed, falls risk, and balance have no effect on falls risk can be rejected. The full model provides the best fit for the data and indicates that gait speed, falls risk, and balance variables influence the likelihood of an individual experiencing falls (Appendix 8f).

A further LR test was used to test the null hypothesis that the effects of all the independent variables being simultaneously equal to zero. A model with no independent variables (*intercept_only*) was statistically significantly different from *fmodel* (*intercept_only* nested in *fmodel*, LRX^2 = 24.87, p=≤0.01) and therefore the null hypothesis (that none of the variables influence the likelihood of experiencing a fall) can be rejected (Appendix 8g).

In consideration of the LR modelling, the hypothesis that cognition and mDTC will influence falls, cannot be accepted. There is statistical significance attributed to the inclusion of the physical outcome measures. However, because of the statistical difference of the *intercept-only* model, we can also infer that the cognitive components do have some influence, although not to the same degree as the physical components. Therefore, the full model is the better model. This model can be further tested for robustness before conclusions are drawn. The predicted values from our full model correctly classified 75% of the predicted scores against the actual scores (Appendix 8h). The overall fit of the model using McFadden's Pseudo-R^2 demonstrates a good fit, as the Pseudo-R^2 of 0.29 is within the recommended values of 0.2 to 0.4 (Appendix 8i).

2.5. Discussion

The aims of this study were to describe physical characteristics of gait, mDTC, balance, and falls risk in older adults with mild CI; to explore associations between these characteristics and their relation to cognition; and compare to these characteristics between those that are or are not already reporting falls. Results from a cross-sectional survey are presented, and the key findings summarised and compared with the literature.

2.5.1. Description of balance, gait, dual-task cost and falls risk

This sample of older adults (mean age 80.75yrs ±6.52) with mild dementia (mean MoCA score 21.12 ±3.71) were at a high risk of falls as measured by the PPA (mean PPA score 2.48 ±1.67). 31.8% (n=22) of the sample reported a fall within the previous six months. Participants had had an average of 1.5 falls (median) in the previous six months. Fear of falling (median FESi = 24) also indicated an increased risk of falls (>23, [125]). Functional mobility (median TUG 12.2 secs) was under the cut-off indicating high risk of falls for a community-dwelling older population (>13.5 secs, [171]). The distribution of functional mobility (TUG) speed was non-normally distributed and skewed to the left, indicating a clustering of measurements below the mean. Overall, balance was poor (median Berg scale 50), but the sample was non-normally distributed and skewed to the right, and over 50% of the sample scored towards the ceiling of the measure (max score 56). Both the balance and functional mobility scores corresponded with the distribution of reported falls within the sample.

All gait parameters demonstrated worse gait pattern and walking ability in older adults with mild dementia compared with normative values (Table 2.10) [164]. Compared with the sample from Hollman et al, gait speed was slower, step-length was shorter, step-width was wider, and double support phase was longer, demonstrating a slower and compensatory walking pattern [164]. Step-time variability and step-length variability were both higher, demonstrating more variability within single task, normal walking.

All gait parameters deteriorated during the dual-task walking conditions and were consistent with previous findings [69]. Gait parameters in the verbal fluency dual-task walking condition were more adversely affected compared to the gait parameters recorded during the backward counting dual-task. When compared with normative values [106], during backward counting, gait speed was slower, step-length shorter, and step-time variability higher. During the verbal-fluency task, gait speed was slower, step-length shorter, and step-time variability were higher [166]. Unfortunately, there are no published norms to compare all gait parameters for all the dual-task conditions completed, therefore only gait speed, step-length, and step-time variability are used as indicators. The variability in step-time (CV% median=7.31) was comparable to the step-time variability documented in another published sample with cognitive impairment (Beauchet et al [149]; mean step-time variability CV=7.6 ±6.7), demonstrating that the study sample was in line with previous findings.

In keeping with the original hypothesis, mDTC was calculated for both dual-task conditions, using both the physical (gait speed) and cognitive (time taken to count backward; the number of words for verbal fluency) cost. There are no published results of the mDTC within a similar sample, therefore only the physical DTC could be compared. Gait speed decreased when the secondary task was added (-18% backward counting and -28% for verbal fluency tasks respectively).

The DTCs recorded in this study were greater than those previously reported from a healthy older adult group (DTC -16% in verbal fluency by Galletly and Brauer, [166]), and older adults who had fallen (DTC -19% in backward counting by Trombetti et al. [106]). However, these results were comparable to a cognitively impaired sample who also completed a backward counting task (Taylor et al, [67], DTC in velocity = -17 ±19,). Interestingly, the sample by Taylor et al [67] also found a difference in DTC between individuals who had experienced falls (higher DTC) than those who had not (DTC in velocity fallers = -24 ±17, and non-fallers = -17 ±19). The results by Taylor et al [67] were comparable to the differences found in this study between fallers and non-fallers (mDTC fallers = 22 [12-33], non-fallers = 16 [11-22]), despite the use of mDTC rather than pure physical DTC.

	Normal ST		Backward Count DT		Verbal Fluency DT	
	Survey data	Normative data [164]	Survey data	Normative data [106]	Survey data	Normative data [166]
Gait speed (m/s)	0.88 (0.32)	1.01 (0.15)	0.72 (0.29)	0.83 (0.23)	0.62 (0.25)	-
Step-length (m)	0.51 (0.14)	0.55 (0.07)	0.46 (0.15)	1.09 (0.17)	0.44 (0.14)	-
Step-width (m)	0.11 (0.04)	0.08 (0.04)	0.12 (0.04)	0.08 (0.04)	0.13 (0.04)	-
Double support (%)	*32.8 (28.1-39.2)	29 (4.6)	*36 (29.1-45.3)	25.9 (7.2)	*37.4 (32.4-46)	-
Step-time variability (CV%)	*5.2 (3.6-7.4)	5.5 (2.6)	*7.3 (4.9-9.8)	5.3 (6.3)	*8.1 (6.2-11.5)	-
Step-length variability (CV%)	*6.0 (4.7-9.3)	5.9 (2.7)	*7.8 (5.6-10.5)	4.8 (3.9)	*8.6 (6.4-12.3)	-
mDTC (%)	-	-	*16.7 (1.6-72.7)	19^	*26.6 (1.2-125.3)	16^

Legend: ST=single-task, DT=dual-task, SD=standard deviation, *=non-normally distributed, IQR=inter-quartile range, m/s=meters per second, m=meter, %=percentage, CV%=co-efficient of variance percentage, mDTC=mean dual-task cost, ^calculated from data presented in paper therefore no SD.

Table 2.10: Comparison between survey data and published normative data for gait parameters

2.5.2. Associations between cognition, balance, gait, and falls

A statistically significant correlation between global cognition, gait parameters, mDTC (backward counting), falls risk, and balance was found in this sample of persons with mild dementia. All correlations were weak, with falls risk having the largest (inverse) association with cognition. As cognitive impairment worsens (reducing the cognitive score), gait speed becomes slower, step-length and step-time become more variable, the cost of completing two tasks concurrently increases, the risk of falls increases, and balance ability reduces. These correlations were consistent with the initial hypothesis. mDTC for verbal fluency was not statistically correlated, with a coefficient of -0.02. Executive function, attention, and processing speed have previously been associated with reduced performance in gait measures (such as gait speed and step-time) [172, 173]. Taylor et al [41] also identified strong relationships between balance positions and falls, with postural sway being a strong predictor for falls in their sample of mild to moderate cognitively impaired older adults.

2.5.3. Comparison of fallers versus non-fallers

Comparison of gait, including mDTC, falls risk, and balance between those that had or had not fallen were specified before analysis of the data set. There were statistically significant differences in gait measures within all walking conditions (single and both dual-tasks), balance, and falls risk among the older adults that had and had not fallen in the previous six months. Older adults with mild dementia who had experienced a fall walked slower, had shorter steps, spent longer in the stance phase of gait, were more variable in their step-length and step-time, had reduced balance, and were more at risk of further falls. The mDTC was not different according to the previous experience of fall, nor was the step-width. Taylor et al [67] also reported that the dual-task walking conditions (walking while carrying water, and walking while backward counting) did not discriminate between those that had or had not fallen in their study. However, Taylor et al [67] only reported the physical DTC. Whilst the literature and study findings suggest that mDTC does not have a role in predicting nor discriminating between fallers, it does not remove the potential importance of DTC within the theoretical model underpinning why this population are at a higher falls risk. The researcher believes this study is the first to report mDTC for older adults with mild dementia.

Gait speed and falls risk were statistically significantly associated with history of falls in the binomial logistic regression. When an older adult with mild dementia had a higher falls risk score and slower gait speed, they were more likely to have experienced a fall. The results of the regression supported the previous t-test comparisons and correlations, and direct attention to the most influential falls risk factors in this population: gait speed and falls risk scores. However, the best-fit model included cognitive characteristics of global cognition and mDTC, as well as physical characteristics of gait speed and balance. The variables within the model only accounted for 75% of the predicted versus the actual scores and therefore there is potential that other influential characteristics have not been measured and included in this study.

Taylor et al [41] completed a multivariate analysis to identify factors associated with falls in their sample of older adults with mild to moderate cognitive impairment. Their key factors were slightly different (postural sway, coordinated stability score, and depression), which could be attributed to the slightly lower cognitive scores in their sample or the difference in some variables collected in comparison to this study. There are also some clinical factors that may influence the risk of falling (such as comorbidities, medication use) which were not measured in this sample and therefore not included in the logistic regression.

Artero et al [174] identified that depression and taking anticholinergic drugs were more prevalent in those with mild dementia compared with healthy older adults. While not exploring the issue of falls in this population, this does indicate that other factors may account for both the underlying cognitive impairment as well as the falls experienced.

Gait speed has previously been identified as a key predictor of falls in healthy older adults [175]. Gait parameters have also been identified as discriminating between fallers and non-fallers in community-dwelling [67] and institutionalised [130, 131, 176] populations with cognitive impairment. The multiple characteristic model within this study highlights the importance of a multifaceted assessment of cognition, gait and balance measures within mild dementia populations. Overall, gait, balance, and cognition need to be measured to fully assess the risk of future falls in older adults with mild dementia.

2.5.4. Study limitations

The data were collected as part of a cross-sectional study, with the main aim to determine the prevalence of falls risk factors in people with mild dementia. While the sample size was adequate to describe and determine the prevalence, further multiple-sub-group analysis could not be completed using potentially relevant variables, such as educational level or specific cognitive domain deficit. Many of the variables presented non-normally distributed data. Therefore, summary descriptives were presented as medians (IQR) within the results section.

The sample was purposive with certain inclusion and exclusion criteria used to inform of prevalence in persons with mild dementia. For example, the criteria that all participants must be able to mobilise independently could have skewed the range of gait ability within the sample. It was not the aim of completing correlations to determine cause or effect, merely to identify associations. Therefore, despite this study increasing the knowledge base within this field and providing a valuable progression of dual-task gait results, the scope of the results is limited. The weaker associations with global cognition could be due to the use of global cognition grading as inclusion criteria for the survey. Therefore, the range of cognitive scores would be restricted and consequently have a smaller variation of global cognition scores than gait parameters or falls risk scores.

Documentation of falls was through self-report which allows potential under-reporting and misrepresentation of the true number of falls experienced. How an individual perceives or records a fall was not asked during data collection. Accurately documenting falls is a recognised and well-discussed issue within falls research [34, 177]. Despite improvements in technological measures [178], falls diaries are at present the recommended practice within research studies, but were not suitable for this cross-sectional survey design [34].

The statistical analysis, particularly the logistic regression, was limited on contributing factors from the relatively small size of the sample. Following recommendations, only six variables were chosen to be included within the binominal logistic regression [179], despite the potential for more confounding or contributing factors. The model was also not tested for linearity, leaving the potential that the included variables were non-linear and therefore disrupting the conclusions drawn from the regression and model [180].

Variables such as a balance and falls risk are likely to be highly correlated, therefore the problem of collinearity is also possible.

A further limitation is the gait analysis. A small group of research assistants completed the data collection and just two researchers performed the gait data analysis and collation. The GAITRite system uses algorithms to identify steps et cetera, but during complex walking patterns, the system requires the user to confirm or manually identify the steps. Human error in the analysis is a potential source of bias which the research team attempted to counteract by limiting the number of researchers and using the GAITRite algorithms where appropriate. The GAITRite support team was also contacted to ensure the researchers were completing the correct method of processing.

The GAITRite system is the gold standard for temporal-spatial gait analysis, and its reliability and validity have been well documented [152-155]. However, there are other gait analysis systems available, such as the Cartesian Optoelectronic Dynamic Anthropometer (CODA) 3D motion analysis system, which provides kinematic and kinetic parameters for lower limb joints as well as spatiotemporal parameters of gait [181]. While the reliability of these systems is good [181, 182], the additional kinematic and kinetic information would not have enhanced the results of this study, as parameters of interest (spatiotemporal gait parameters) were collected via the GAITRite system. Accelerometers, worn on the body over a length of time, allow the measurement of gait to continue outside a clinic or gait laboratory, providing insight into community or "every-day" gait parameters at both a specific (spatiotemporal gait variables) and a more general (amount of activity) level [55].

The development of these systems is on-going, particularly in relation to the capture of real-life falls [183], but the choice of gait analysis system is dependent upon the research question. While collecting information on everyday mobility and gait characteristics of older adults with mild dementia outside a clinic setting would be valuable, it was the intent of this study to characterise and differentiate between single and dual-task gait parameters, therefore requiring a controlled environment.

Coefficients of variance (CV) were used to express variability of step-length and step-time. The CV is a percentage and therefore considered a generalisable measure. However, there are other expressions of variability, such as within-person SD [139]. As the CV is determined from the SD, both of these expressions of variability are related [139] but due to its more frequent use, the CV was used in this study (such as Hollman et al [164]; Taylor et al [67]). Variability measures are notoriously unstable and therefore require a strict protocol and a certain number of steps to contribute to the measures reliability [96]. Stride variations could have been used instead of step variations, as used within Hollman et al [164]. However, by using strides more data would need to be collected. For every stride there are two steps, therefore in the same distance walked there would be twice the number of steps than strides [139]. While reliability is high for gait velocity using a small number of strides, it is not for gait variability parameters [164], therefore the amount of data collected should accommodate for the reliability of all parameters.

The mDTC was recently introduced into this field of research and is not well reported in the literature, making it difficult to compare these study findings. Transforming mean data from published materials would produce mDTC but not the SD. The DTC is a summary measure, indicating of the difference between the single and dual-task, but not where those single or dual-task results are within normal ranges. For example, a DTC of 1% is very small, but if that difference is in gait speed, it does not indicate if that gait speed is fast or slow, merely the difference between the two. Therefore, the DTC should not be considered as an independent measure, but in relation to the measure of central tendency. The mDTC results were heterogeneous, with large ranges and non-normal distribution.

The mDTC relies on accurate recording of both the physical and cognitive component of the dual-task. The inconsistencies present within this study's results could be attributed to the inaccurate recording of the cognitive component of the task (time taken to count backward and the number of words). The manner of recording the cognitive task was consistent through audio recording and standardised instructions and documentation. However, how the task was measured allows for potential inaccuracies. For example, within the backward counting task, time taken to complete the task was used to measure success, the implication being a faster time was more successful. However, an individual may take less time to complete the task by being more inaccurate, such as missing out numbers. The backward counting task was used in previous studies, but the details regarding how the success of the task is measured are limited [67]. If mDTC is to progress as an illustration of how cognition influences physical ability, then the measure needs to be standardised in regard to task, method, recording, and reporting.

The order in which the dual-tasks were completed may have influenced the results. The verbal fluency task was always completed last (Appendix 2), thereby allowing fatigue to influence performance within this measure. Any influence of fatigue would have been consistent across the participants. However, this may explain why the verbal fluency dual-task results have consistently demonstrated poorer gait performance. Randomisation of testing procedure would have counteracted this effect but would have needed greater participant numbers to achieve the desired intent and should be considered for future studies.

There was a statistically significant difference between the mDTC of the two tasks (MD -0.39; $P \leq 0.01$). Complexity of the dual-task could have resulted in these differences. Schwenk et al [141] also reported differences between two different intensity dual-tasks within their dementia sample, identifying that the more challenging task caused "*drastic DTC in almost all temporospatial gait variables*" (p1966). The dual-task needs to be at the correct level of challenge for the individual to reach the threshold of cognitive resources [141]. The variance found in this study mDTC could be attributed to a variance in how difficult the individuals found the cognitive tasks. Despite these limitations, this is the first study to report the mDTC in mild dementia in relation to their risk and history of falls. As such this constitutes progress in the field of study of falls in persons with cognitive impairment.

2.6. Conclusion

Older adults with mild dementia experience falls and have a marked increase in the risk of future falls. Negative changes in gait pattern are evident in individuals at the mild stage in the cognitive impairment continuum, and deterioration in gait pattern and dual-task ability is associated with reduced global cognition. An mDTC exceeding levels for healthy older adults is present and measurable in older adults with mild dementia, although further work needs to develop the consistency and reporting of the measure. There is a significant difference in gait performance, balance ability, and falls risk in those older adults with mild dementia who have fallen compared with those who had not. Gait speed and falls risk scores can indicate those that are more likely to experience a fall. While cognition and mDTC did not predict an individual's propensity to experience falls, they do contribute to a multifaceted model of characteristics that will influence falls risk in older adults with mild dementia. This study provides a valuable addition to the literature within this field and supports the justification for exploring the development of an intervention to address falls in older adults with mild dementia.

Chapter 3. Falls prevention interventions in older adults with cognitive impairment: an umbrella review

Summary

Cross-sectional survey results in Chapter 2 identified that older adults with cognitive impairment at a mild level are at an increased risk of falls. This information provides evidence for the problem initially discussed in Chapter 1 and raises questions concerning whether interventions can reduce this risk. Chapter 3 is a critical umbrella review that explores review material on falls prevention interventions in older adults with cognitive impairment. The main content of the chapter has been published [184] and is reproduced here with minimal adaptations.

A critical, systematic, review of review method was used. Five large electronic databases, MEDLINE, EMBASE, AMED, CINAHL, and the Cochrane electronic library, were searched. The search terms 'falls', 'rehabilitation', 'falls prevention', 'interventions', 'cognitive impairment', 'dementia', and 'Alzheimer's disease', were used. All available reviews were marked against predetermined inclusion and exclusion criteria. Seven reviews met the inclusion criteria. Only one of the included reviews had a homogeneous population of adults with a cognitive impairment. Exercise was the most commonly reported intervention, included in 91 studies and all seven reviews. Multifactorial and multicomponent falls prevention programmes were also frequently reported. Evidence of efficacy was inconsistent for all interventions.

In conclusion, evidence for falls prevention interventions for adults with cognitive impairment is varied and inconclusive. When compared to literature for falls interventions in healthy older adults, in general both primary and synthesis studies in older adults with cognitive impairment are lacking in quality, number, and homogeneity of sample population and interventions. Promising results are emerging and a more specific analysis of combined cognitive and physical interventions is required to explore efficacy (Chapter 4).

Publication: Booth V, Logan P, Harwood R, Hood V. Falls prevention interventions in older adults with cognitive impairment: A systematic review of reviews. *International Journal of Therapy & Rehabilitation*. 2015;22(6).

3.1. Introduction

Current guidelines recommend that falls prevention programmes consist of multifactorial assessment and intervention including: strength and balance training, home-hazard assessment and intervention, vision assessment and referral, and medication review with modification or withdrawal [97]. There have been many literature reviews on the effectiveness of falls interventions in older adults [185, 186]. Few have taken into account people with cognitive impairment [187]. Currently there are no established or published fall prevention programmes which attempt to address cognitive impairment, although it is recognised that this should be considered [124].

A number of reviews have investigated falls interventions in various cognitively impaired populations [187-189]. Meta-analysis of falls prevention programmes in adults with cognitive impairment has previously been undertaken [189]. The review by Guo et al [189] included studies with mixed populations, including all degrees of severity and institutionalised and non-institutionalised participants, making it difficult to conclude which patient population benefits from the intervention. In comparison, there have been many published reviews concerned with falls interventions in healthy older adults, with clear endorsements for treatment content and duration [98] within specific patient groups [185, 186].

The extent to which studies of falls prevention programmes have included populations with cognitive impairment needs clearly identifying and reporting. Clarity on types of interventions used would also assist in developing an intervention specifically designed for persons with cognitive impairment. A synopsis of the evidence of falls prevention interventions for older adults with cognitive impairment is warranted due to the number of reviews within this topic area.

Synthesis of the review results will provide a clear direction on types of interventions, as well as indicating what is still unknown. An umbrella review methodology was indicated considering the number of reviews in the field, potential broad participant samples, and usefulness of compiled and summarised findings to direct intervention development [190]. Grant and Booth have described an umbrella review as "*aggregating findings from several reviews that address specific questions*" ([190], p103). Completing another systematic review of the falls intervention literature on primary studies would not provide the overarching picture required for intervention development, and would only repeat previously published material. Therefore, the research question proposed was: what are the findings of reviews on falls prevention interventions for older adults with cognitive impairment?

3.2. Methods

The primary purpose of this synthesis was to collate and describe previous literature reviews investigating interventions to reduce falls in adults with cognitive impairment, providing a summary of the evidence in this area to date. An umbrella review method [190] was utilised to summarise the review literature considering the number of reviews already published in this field.

The electronic databases MEDLINE, EMBASE, AMED, CINAHL, and the Cochrane electronic library, were searched using the terms 'falls', 'rehabilitation', 'falls prevention', 'interventions', 'cognitive impairment', 'dementia', and 'Alzheimer's disease'. The search was completed in March 2015 and the review published in its entirety in May 2015. Reference lists of retrieved studies were searched manually and the source of all included material was documented (Figure 3.1). The titles and abstracts of identified studies were read and matched against the inclusion criteria.

Inclusion criteria were that reviews must be available in English, report a literature search or synthesis method, include an adult population with a cognitive impairment recognised through cognitive testing (e.g. Mini-Mental State Examination) or diagnosis (e.g. dementia, Alzheimer's disease), and investigate an intervention whose primary aim was to reduce falls. Reviews were excluded if they were inaccessible to the author (i.e. non-English language), did not include falls as an outcome or intervention, used proxy measures for falls (i.e. fractures, balance), only used drugs as an intervention, or did not study a population with a cognitive impairment.

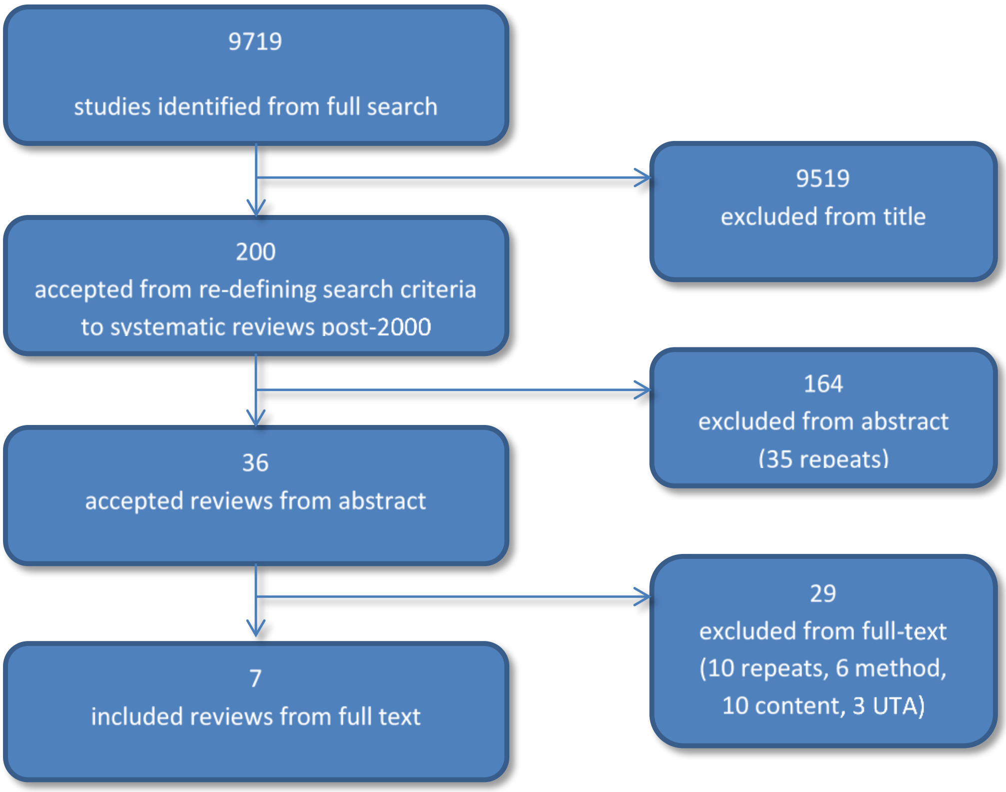
For inclusivity, reviews with mixed populations (those with and without cognitive impairment, community or institutionalised) were included. Due to the number of reviews identified, reviews published before 2000 were excluded to ensure the identification of recent evidence and capture of material published prior to those dates [191]. Reviews involving other neurological diagnosis (e.g. stroke, multiple sclerosis, Parkinson's disease) as the cause for cognitive impairment were also excluded due to the likely impact of physical symptoms on falls risk in those populations.

Search criteria were purposefully broad as mixed populations and interventions are common within this field of research. The researcher completed the search and all included papers were reviewed for inclusion and quality appraised independently by two researchers (VB and VH). Any discrepancies were discussed with a third researcher. The included reviews were critiqued for quality independently by two researchers (VB and VH) using the Joanna Briggs Institute (JBI) Critical Appraisal Checklist for Research Synthesis [192]. This quality measure was used as recommended by the JBI: Methodology for Umbrella Reviews [192], and rated the inclusion of topics such as review question, inclusion criteria, search strategy, critical appraisal, and data extraction methods (Appendix 9).

Due to the variety of review methods (i.e. narrative, meta-analysis), a quality measure was required to provide clarity on how the reviews synthesised material and therefore achieved their results and recommendations. Data involving participant details, number of studies included, intervention types, results and conclusions, and effect sizes were extracted (Appendix 10).

3.3. Results

The search process identified seven reviews to be included (Figure 3.1). On occasion, the same study was identified from different electronic databases (identified as 'repeats' within Figure 3.1). Reasons for exclusion of reviews at full text stage are provided (Appendix 11).



Legend: UTA=unable to access

Figure 3.1: Flow diagram of identified reviews for umbrella review

Only one review included an exclusively cognitively impaired population [193]. The other six reviews included mixed populations of adults with and without cognitive impairment [185, 186, 188, 189, 194, 195]. The populations, outcomes, and summaries from the included reviews were varied (Table 3.1).

Review Authors and Method	Number of included studies; Relevant to dementia/cognitive impairment; Total number of studies in review	Population, Prevalence of dementia and Setting	Outcome Measures	Summary of findings
Cognitively impaired populations – dementia				
Tilly and Reed (2006) Tilly and Reed [193] Systematic review No meta-analysis	Population-relevant studies n=11	Persons with dementia. Long-term care.	1. Falls 2. Unsafe wandering 3. Use of physical restraints	• Most success in falls prevention with individually-tailored interventions. • Identifying causes of falls and individual's abilities, in combination with both fall prevention and injury reduction, reduced falls and fractures. • Single interventions or uniform approach was generally unsuccessful. • Use of physical restraints was not effective in preventing falls or reducing wandering. • Little evidence on interventions related to wandering.
Mixed populations – with and without dementia or cognitive impairment				
Oliver et al (2007) [195] Systematic review Meta-analysis and meta-regression	Population-relevant studies n=7 Total studies n=43	Older persons. Mixed population. Care home and hospital.	1. Rate ratios for falls 2. Fractures 3. Relative risk for falls	• Multifaceted interventions in hospital had a modest effect at reducing rates of falls. Hip protectors in care home setting had a modest effect on rate of fractures. • Insufficient evidence for all other interventions in both settings. • Prevalence of dementia within the study population did not modify the effect size of the interventions.
Jensen and Padilla (2011) [194] Systematic review No meta-analysis	Population-relevant studies not specified Total studies n=13	Persons with dementia. Mixed populations. Setting not specified.	1. Falls (not specified by authors)	• The review was limited by small sample sizes, heterogeneity of samples, and poor methodology for reporting falls. In high quality studies a significant reduction in falls was found as a result of physical training. • Close supervision and activity-based interventions may be effective for high-risk patients with dementia (1 study). • Enhanced falls risk education for nursing staff was likely to reduce falls among nursing home residents.

Cameron et al (2012) [186] Cochrane Review Meta-analysis	Population-relevant studies n=7 Total studies n=60	Older persons. Mixed populations. Care facilities and hospitals.	1. Rate of falls 2. Number of fallers	• More studies were conducted in care homes than in hospitals. • Cognitive score did not affect treatment effect in multifactorial interventions during sub-group analysis. • Sub-group analysis indicated that exercise as a single intervention did not reduce falls in frail elderly in hospital or care facilities but results were inconsistent between studies. • Evidence for multifactorial fall prevention interventions in care facilities and hospitals was inconsistent, dependent upon the patient group, individual ability, setting, and staff delivering. Overall, the rate of falls and risk of falling suggested possible benefits, but this was inconclusive.
Gillespie et al (2012) [185] Cochrane Review Meta-analysis	Population-relevant studies n=67 Total studies n=156	Older persons. Mixed populations. Community-dwelling.	1. Rate of falls 2. Number of fallers	• The most common interventions were exercise as a single intervention or multifactorial interventions. Exercise (individualised or group), home safety (when delivered by an OT) and multifactorial assessment and individually based interventions were effective at reducing falls. • Vitamin D supplementation did not reduce falls unless Vitamin D levels were low. • Only one trial had a specific population with Alzheimer's disease. This investigated vitamin and calcium supplementation and found no reduction in the proportion of fallers but reduced risk of fracture.
Winter et al (2013) [188] Systematic review No meta-analysis	Population-relevant studies n=7 Total studies n=11	Older adults with cognitive impairment. Mixed populations. Community-dwelling.	1. Number of falls 2. Proxy measure of falls	• Evidence was inconclusive and limited for community dwelling older adults with cognitive impairment. More evidence was available from care home or institutional settings. • Evidence for and against exercise was balanced.
Guo et al (2014) [189] Systematic review Exploratory meta-analysis	Population-relevant studies n=12 Total studies n=111	Older persons. Mixed populations. Community and institutionalised.	1. Risk of falls	• For adults with cognitive impairments single exercise intervention was associated with a positive effect in community setting (one trial results). • In an institutionalised setting, positive effects were found from combinations of multiple and multifactorial interventions. • Exercise and education have the potential to reduce falls.

Table 3.1: Description of included reviews

The included reviews were quality appraised using a checklist [192] (Table 3.2). Three reviews scored the maximum (score=11) on the checklist, two of which were Cochrane Collaboration reviews [185, 186]. The two reviews which scored the lowest (score=4) included the oldest, which was hindered by poor reporting of method and rigour [193]. The other was a continuation from a review series, and therefore did not report the search method in detail and presented the results in a narrative description [194]. All but one review had appropriate inclusion criteria, including randomised or quasi-experimental controlled trials. Guo et al [189] specifically included only interventions deemed effective in the literature. Four reviews completed meta-analyses [185, 186, 189, 195].

Included reviews	Total quality appraisal checklist score (max=11)
Tilly and Reed [193]	4
Oliver et al [195]	9
Jensen and Padilla [194]	4
Cameron et al [186]	11
Gillespie et al [185]	11
Winter et al [188]	11
Guo et al [189]	7

Table 3.2: Critical appraisal scores for included reviews

Nineteen different individual interventions were documented. Most (n=13) had fewer than ten evaluation studies reported (Table 3.3). Exercise, multifactorial and multiple interventions were the most frequently reported. No intervention had a consistent, significant reduction in falls across all included reviews.

Exercise was the most frequent single intervention included in every review (n=91 studies). The reported effect of exercise on falls was mixed, with only two reviews reporting significant reduction in falls following exercise [185, 189]. Gillespie et al [185] reported rate of falls ratio was 0.71 (95% CI 0.63 to 0.82) (29% relative risk reduction) and falls risk ratio was 0.85 (95% CI 0.76 to 0.96) (15% relative risk reduction). Guo et al [189] reported reduced rate of falls ratio was 0.78 (95% CI 0.66 to 0.94) (22% relative risk reduction). Positive results were reported in another two reviews but were not statistically significant [193, 194].

When the effect of exercise was reviewed according to setting, findings were mixed, both between and within reviews. Cameron et al [186] reported a significant effect of exercise in a hospital setting, based on two papers, but reported no effect in care homes based on thirteen study results. Both reviews reporting significant results for exercise were in non-institutionalised settings [185, 189]. Heterogeneity from meta-analysis was reported in one review [186] and differed between care homes (I^2=70%) and hospital (I^2=0%) studies.

Multifactorial and multiple interventions were differentiated within the included reviews. Multifactorial interventions were defined as an intervention or programme that had more than one component or facet to the intervention. Multifactorial interventions were frequently reported, with 83 studies included within six reviews. There was no consensus as to whether multifactorial interventions reduced falls, as most of reviews (n=4) reported positive but not statistically significant results. Heterogeneity was high for rate of falls across the studies in the three reviews which reported this (i.e. I^2=85% from Gillespie et al [185]). There was slightly less heterogeneity apparent in studies completed in hospital (I^2=59% Cameron et al [186]; I^2=80% Oliver et al [195]) versus in a care home (I^2=84% Cameron et al [186]; I^2=87% Oliver et al [195]).

Multiple interventions were classified as combinations of single, distinct interventions, completed either simultaneously or consecutively. Multiple interventions were documented in 30 studies across four reviews. There were no significant effects on falls from multiple interventions with three reviews reporting their results as mixed [185, 186, 193]. Heterogeneity was not reported for the trials of multiple interventions in any of the published reviews.

Only one review commented on how falls were defined among their included studies as a determinant for inclusion [185]. Prospective daily calendars returned on a monthly basis [196] for duration of follow-up were the preferred method reported by Gillespie et al [185].

Interventions	Number of reviews	Number of studies	Findings (number of reviews with that conclusion)
Exercise	7	91	Significant reduction in falls (2), Positive (2), Mixed (1), No effect (2)
Multifactorial interventions	6	83	Positive but inconclusive reduction in falls (4), Mixed (1), Unclear (1)
Multiple interventions	4	30	Positive but inconclusive reduction in falls (1), Mixed (3)
Medication	3	22	Positive but inconclusive reduction in falls (2), Inconsistent (1)
Hip protectors	3	13	Reduction in fracture rate (1), No effect (2)
Staff training	2	13	Positive but inconclusive reduction in falls (1), No effect (1)
Home assessment	2	11	Positive but inconclusive reduction in falls (1), No effect (1)
Assistive technology (vision, footwear, aids, fall alarm)	3	10	Significant reduction in falls (1), Mixed (1), No effect (1)
Education	4	9	Significant reduction in falls (1), Inconclusive (1), No effect (2)
Vitamin supplement (D, Calcium or both)	2	8	Significant reduction in falls (1), No effect (1)
Surgery	1	5	Positive but inconclusive reduction in falls (1)
Removal of physical restraint	1	5	Unclear effect on falls (1)
Psychological/Cognitive behavioural group	2	3	Significant reduction in falls (1), No effect (1)
Fluid or nutritional therapy	1	3	No effect on falls (1)
Monitoring patch	2	2	Reduction in falls (1), No effect (1)
Flooring	2	2	Reduction in fracture rate (1), No effect (1)
Health assessment	1	1	No effect on falls (1)
Aromatherapy patch	1	1	Positive but inconclusive reduction in falls (1)
Sunlight exposure	1	1	No effect on falls (1)

Table 3.3: Tabulation and synthesis of interventions from included reviews

3.4. Discussion

3.4.1. Summary of falls interventions

Interventions to prevent or reduce falls in healthy older adult populations are well-documented and well-evidenced [98]. Studies solely trialling interventions for adults with dementia and cognitive impairment are sparse in comparison. Only one review reported interventions trialled specifically in adults with cognitive impairment. Exercise and multifactorial interventions are most frequently reported for adults both with and without cognitive impairment, in community, residential care, and hospital settings. None of the reported interventions demonstrated a consistent, significant reduction in falls across all included reviews. Results varied between reviews and between settings. Generally, exercise demonstrated a positive impact in community populations with less effect in a care home or institutional setting. Multifactorial interventions provided more consistently positive results across all settings, but neither multifactorial nor multiple interventions provided any statistically significant effects on falls. Nineteen types of interventions were reported across all the included reviews, with most (n=13) having fewer than ten studies to support their findings.

3.4.2. Quality of reviews summary

This synthesis aimed to summarise reviews on falls interventions for adults with a cognitive impairment. The number of search results (n=200 at abstract level) identifies that there is considerable published material on falls prevention. However, high quality, homogeneous sample reviews involving interventions to reduce falls in adults with cognitive impairment are noticeably absent.

Many reviews were excluded from this overview due to a lack of systematic search or analysis method, their sample populations, or interventions which did not aim to effect or reduce falls. The quality of the included reviews varied considerably with a quality range score of between 4 to 11 (11 being the best score possible). Completion of sub-group analysis according to cognitive ability or level was impossible. Only two of the included reviews synthesised evidence from specific populations with dementia [186, 189]. The quality of the reviews must be considered in relation to findings presented. The three highest quality reviews [185, 186, 188] included the greatest number of intervention studies and reported statistically significant findings for some interventions. However, they were unable to analyse subgroups or specify a cognitively impaired population. The two lowest quality scoring reviews failed to provide clear conclusions from their syntheses [193, 194].

Considering the narrative nature of result reporting in the many of the reviews, it is difficult to draw conclusive or clinically-relevant recommendations. These conclusions reflect the paucity of published evidence of interventions involving adults with cognitive impairment.

3.4.3. Limitations

There are a number of limitations in this review. Firstly, the methodology of an umbrella review provided a broad tool to describe the evidence base, but this heterogeneity made pooling results impossible. Cross-reporting of studies was evident, particularly in such a specific population with limited number of published trials. An umbrella review method would also limit the inclusion of the most recently published material.

Secondly, every attempt was made to search and include all relevant material, but some reviews may not have been found and therefore not included. This review aimed to identify falls prevention interventions, but there are many proxy measures of falls (such as fractures), which were not included for reasons of reproducibility and manageability. For example, balance is associated with falls risk but reviews which specifically used this as an outcome were not included.

Thirdly, the definition of cognitive impairment varied between studies. Appropriate search terms were used but it is possible that not all relevant material was identified. Some reviews of other neurological diagnosis, such as stroke or Parkinson's disease, were identified. Despite these reviews yielding useful information regarding falls interventions for those populations, these were excluded to maintain some specificity to the conclusions.

Finally, categorisation of interventions varied (for example discrepancies in exercise classification) leading to differing results of meta-analyses and therefore differing conclusions. The term "exercise" is broad and encompasses different arrangements (for example, aerobic, resistance, balance training) which may have differing effects on falls risk [197]. Summarising interventions only used in participants with cognitive impairment was not possible due to the paucity of source material. Not all intervention outcome measures were suitable for meta-analysis and reviews produced both narrative and statistical results from their search, such as Cameron et al [186]. The diversity and variability of interventions within the falls prevention evidence-base is considerable. When collating review material, the endeavour of the research community to make each intervention novel and interesting to gain research funding becomes more evident, increasing the number of single intervention trials shown within this review. Surfing this wave of innovation in turn makes it difficult to synthesise results from homogeneous samples and interventions, and even more challenging to draw empirically-derived conclusions on effectiveness.

3.4.4. Applicability of findings

Firm clinical recommendations cannot be made from these results. Sub-group analysis conducted within one review [186] identified no difference in treatment effect according to cognitive scores. Considering the lack of evidence for falls interventions in adults with cognitive impairment, it has been suggested that standard interventions are used [98]. However, the differences in risk factors for falls in adults with cognitive impairment are well-documented [41, 42, 187, 198]. The number of trials investigating these individuals is increasing. Studies have recently and are continuously being published [99, 103-105].

3.4.5. Future work

All of the included reviews advocated the need for further, larger-scale trials involving adults with cognitive impairment. There are significant gaps in the evidence-base regarding interventions to reduce falls in these participants. The development of innovative, specific interventions to reduce falls in persons with cognitive impairment is required. Exercise as an intervention component to reduce falls is an encouraging and popular option according to this review. Dual-task training straddles both multicomponent and exercise classifications of interventions. A specific systematic review and synthesis regarding this intervention is required to explore its efficacy as a potential intervention in people with cognitive impairment.

The theoretical reasoning for *how* exercise might reduce falls in older adults with cognitive impairment should also be considered, particularly considering the initial development stages of dual-task training as an intervention, and falls intervention programmes in general. More detailed, quantitative reporting of the effects of these interventions and differences according to cognitive ability and setting (i.e. community, institutionalised) in the sample population would improve the synthesis of these studies into higher quality reviews. Stratification of intervention effects according to impairment severity, location, frequency, and intensity would also be a valuable progression of research in this area. However, this is reliant on recruitment of a sufficiently homogeneous population to gain sufficient power to determine efficacy.

3.5. Conclusions

Evidence for falls prevention interventions for adults with cognitive impairment is limited, varied, and provides no clear conclusions and limited clinical recommendations for treatment. Review materials in this area reflect the published research. In comparison to falls interventions for healthy older populations, both primary and synthesis studies are lacking in quality and number. Promising results have emerged but are hampered by heterogeneous sample populations and settings.

From the evidence in this review, clinical recommendations cannot be made. Clear reporting of quantitative findings of falls and cognitive ability of the sample should be encouraged in future work. Further detailed exploration of a sub-group of interventions is required to reach decisions regarding intervention content to reduce falls in older adults with cognitive impairment. Specificity in sample population is also required to overcome some of the methodological limitations identified in this review. These recommendations will be carried into the next two literature reviews.

Chapter 4. Interventions incorporating physical and cognitive elements to reduce falls risk in older adults with cognitive impairment: a meta-analysis

Summary

Exercise was identified as a promising intervention from the synthesis of literature reviews on falls interventions in older adults with cognitive impairment (Chapter 3). The hypothesis that older adults with cognitive impairment have difficulty dividing and allocating attention to prevent falls in challenging, dual-task circumstances has been previously outlined (Chapter 1). To reduce falls in this population, interventions could theoretically target and train both physical and cognitive ability. Combining and addressing cognitive components in falls rehabilitation is a novel and emerging area of health evidence. This chapter presents a literature review and meta-analysis to identify the effectiveness of combined cognitive and physical interventions on the risk of falls in cognitively impaired older adults. The main content of the chapter has been published [199] and is reproduced here with minimal adaptations.

A three-step search strategy was utilised in this review, including search of electronic databases: CENTRAL, JBISRIR, MEDLINE, EMBASE, AMED, CINAHL and PsychINFO. Eight studies were included which evaluated the effectiveness of multicomponent exercise programmes on falls-related outcomes including physical and cognitive activities, music-based group exercise and mind-body tai chi. Four studies reported effectiveness using number of falls, half of which

reported a significant difference between the groups, but pooling of results into meta-analysis was not possible due to difference in reporting of the outcome. Meta-analysis identified a statistically significant improvement in balance and gait speed following the intervention.

Multicomponent interventions incorporating both physical and cognitive components demonstrated positive effects on balance, functional mobility and gait speed when compared to a control, and had significantly better effect on balance and gait speed in populations with cognitive impairment at a mild stage. From this review clinical recommendations cannot be made but evidence within this area is emerging and the positive findings are encouraging. These results have been carried forward into the following chapters for both the method of feasibility testing and content of the intervention.

Publication: Booth V, Hood V, Kearney F. Interventions incorporating physical and cognitive elements to reduce falls risk in cognitively impaired older adults: a systematic review. JBI Database of Systematic Reviews and Implementation Reports. 2016; 1;14(5):110-35.

Booth V, Hood V, Kearney F. Interventions incorporating physical and cognitive elements to reduce falls risk in cognitively impaired older adults: a systematic review protocol. The JBI Database of Systematic Reviews and Implementation Reports. 2015;13(8):5-13.

4.1.1. Summary of findings table

Interventions Incorporating Physical and Cognitive exercises compared to Single Intervention or Usual Care for Reducing Falls Risk in Cognitively Impaired Older Adults

Bibliography: Interventions incorporating physical and cognitive elements to reduce falls risk in cognitively impaired older adults. JBISRIR [2015].

Outcomes	№ of participants (studies) Follow-up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Single Intervention or Usual Care	Risk difference with Interventions Incorporating Physical and Cognitive exercises
Falls (total number of reported falls) (Falls) follow up: range 1 months to 12 months	411 (4 RCTs) range 1 months to 12 months	⊕◯◯◯ VERY LOW [1 2]	-	not pooled	not_estimable
Berg Balance Scale (BBS) Scale from: 0 to 56	492 (4 RCTs)	⊕◯◯◯ VERY LOW [3 4 5 6]	-	The mean berg Balance Scale was **40.9** on BBS scale	MD **2.3 on BBS scale more** (1.78 more to 2.83 more)
Timed Up and Go (TUG): (seconds)	262 (3 RCTs)	⊕⊕⊕◯ MODERATE [5 7]	-	The mean timed Up and Go was **21.3** seconds	MD **1.09 seconds less** (1.57 less to 0.62 less)
Gait speed (m/s)	275 (3 RCTs)	⊕⊕◯◯ LOW [5 8]	-	The mean gait speed (m/s) was **1.096** m/s	MD **0.08 m/s more** (0.03 more to 0.12 more)

***The risk in the intervention group (and its 95% confidence interval) is based on the assumed risk in the comparison group and the relative effect of the intervention (and its 95% CI).**
CI: Confidence interval; RR: Risk ratio; OR: Odds ratio; BBS: berg balance scale; TUG: timed up and go test; RCT: randomised controlled trial; m/s: meters per second; MD: mean difference

GRADE Working Group grades of evidence
High quality: We are very confident that the true effect lies close to that of the estimate of the effect
Moderate quality: We are moderately confident in the effect estimate: The true effect is likely to be close to the estimate of the effect, but there is a possibility that it is substantially different
Low quality: Our confidence in the effect estimate is limited: The true effect may be substantially different from the estimate of the effect
Very low quality: We have very little confidence in the effect estimate: The true effect is likely to be substantially different from the estimate of effect

1. Mixed positive and negative findings within included studies
2. None of the included studies are powered for falls
3. Allocation concealment unclear in most studies
4. Attrition not recorded in most studies
5. Heterogeneity present across pooled results
6. None of the studies were powered for BBS
7. None of the studies were powered for TUG
8. Only one study adequately powered for gait speed outcome

4.2. Introduction

Falls frequently occur during walking or transferring [34]. Gait is controlled by a complex neural network of ascending information, cortical involvement, and descending control [47]. It has been demonstrated that adults with executive dysfunction have an altered gait pattern and are more at risk of falling [72, 200] (Chapter 2). Executive function refers to cognitive processes that orchestrate goal-directed activities and it is involved in allocating attention in competing tasks [200]. Activities such as walking whilst talking or performing another task (dual-tasking) involve executive function. To improve gait in a population with executive dysfunction such as seen in mild dementia, interventions could theoretically target and train both physical and cognitive ability.

Combined interventions (dual-task training and specific medications) have demonstrated positive results at improving executive function [64, 107]. Training the ability to maintain gait during multiple tasks is a viable hypothesis to reduce the rate of falls in a population with cognitive impairment [124, 201]. Repetition and practice of cognitive tasks combined with physical training could improve the efficiency of allocating attention during a task such as walking and talking [201]. Initial reports of animal studies have documented the cognitive benefits of combined physical and cognitive interventions (improved learning and memory abilities) [202]. Theoretically, combining physical and cognitive exercises enables benefits to be gained from both interventions [201]. It is these dual and combined interventions (i.e. exercise or physical activity, and cognitive rehabilitation or training) which this review aimed to capture.

Standard falls interventions applied to people with cognitive impairment do not reduce falls [33]. However, interventions such as exercise and multifactorial interventions were promising (Chapter 3). Combining and addressing cognitive components in standard falls prevention programmes is a novel and emerging area of health evidence. Literature is potentially to be found in a wide variety of disciplines and can be difficult to identify due to varying and non-standard search terms. A systematic search and meta-analysis of literature on combined cognitive and physical retraining in cognitively impaired populations in relation to falls has not been undertaken before. There has been a recent increase in the number of published studies investigating dual-tasks or combined physical and cognitive interventions [141, 203].

Previous systematic reviews have only focused on older persons [187, 204], cognitive outcomes [140, 205], or physical function [112, 201, 206]. At time of search (May 2016), no other systematic review had been undertaken to explore this combined intervention approach in older adults with cognitive impairment regarding fall outcomes. This review will contribute towards increasing understanding of previous cognitive and physical retraining concepts within the literature, providing a coherent direction for developing interventions to address areas of deficit in cognitively-impaired individuals which may reduce their risk of falling.

Considering the increasing amount of published studies in the field, a systematic review method is appropriate to consider whether combined cognitive and physical interventions have an effect on falls. Using meta-analysis methods will provide effect sizes of such interventions, and if not available or possible, direct future research [190]. The objective of this review was to identify the effectiveness of combined cognitive and physical interventions on the risk of falls in cognitively impaired older adults. This systematic review was guided by a published protocol with the JBI Database of Systematic Reviews and Implementation Reports (JBISRIR) [207].

4.3. Method

4.3.1. Inclusion criteria

4.3.1.1. Types of participants

Older persons who were 65 years or older were included. Studies in which the majority of participants were 65 years or older, as indicated by mean ages and standard deviations reported in the study, were eligible for inclusion. Participants who had been diagnosed or identified as having cognitive impairment were included.

The participants were characterised as having a cognitive impairment through:

1. Diagnosis of a dementia or cognitive impairment or other condition which directly results in reduced cognition.
2. Mini Mental State Examination (MMSE) score or other such global assessment of cognition, e.g. Montreal Cognitive Assessment (MoCA).

Participants were not limited by dementia diagnosis (i.e. Alzheimer's disease, vascular, MCI), but their cognitive impairment had to be acquired and progressive in nature. Studies with a population of older adults with an increased risk of falls were considered but were only included if more than 75% of the total sample had impaired cognition identified by the criteria above.

4.3.1.2. Types of intervention(s)

Publications were considered that described multifactorial or multiple interventions where both a physical and cognitive element was described. The aim of this review was to capture studies which had a combined physical and cognitive element in the intervention. However, studies which had separate physical and cognitive components, or where the components had been specifically implemented or tailored to the individual's cognitive level or impairment, were included. Studies were only included if this intent was explicitly described as a quality of the intervention or by the researcher's expert experience and opinion. Any physical intervention with the aim to reduce the number or risk of falls was included, such as, but not limited to, exercise, physiotherapy, activity and fitness components. The review included cognitive interventions, such as, but not limited to, dual-task training, cognitive rehabilitation, memory tasks, and verbal tasks. Delivery of the intervention did not limit inclusion of relevant studies into this review. Examples of delivery method include group, individual, or technology assisted (telephone, email, and internet). Studies were only included if they had a standard care or single-element comparator (such as physical only or cognitive only intervention).

4.3.1.3. Types of studies

RCTs, controlled clinical trials, and experimental studies in which randomisation was used were included. As these types of studies were found and included, other methods, such as comparative studies without randomisation, cohort and case-control studies, were not considered for inclusion. Studies were only included if they had repeated measures and compared an intervention against standard or no treatment.

4.3.1.4. Types of outcomes

Studies were included if they used an outcome measure related to falls risk. The outcome measures had to be measured before and after the intervention. Outcome measures related to falls risk included: specific falls risk measures (i.e. Physiological Profile Assessment), history and/or details of occurrence of falls (i.e. falls diaries), reliable clinical outcome measures (i.e. Timed Up and Go test [TUG], Berg Balance Scale [BBS], gait speed), or clinical measures which relate to incidence or risk of falls (i.e. postural sway, gait parameters). Outcome measures related to falls were included if the studies stated that the intervention was aiming to reduce falls.

4.3.2. Search strategy

The search strategy intended to find both published and unpublished studies and was conducted between June and July 2015. Only studies published in English were considered.

A three-step search strategy was utilised. An initial limited search of MEDLINE and CINAHL was undertaken followed by an analysis of the text words contained in the title and abstract, and of the index terms used to describe the article. A second search using all identified keywords and index terms was then undertaken across all included databases. The databases searched included: The Cochrane Central Register of Controlled Trials (CENTRAL) (The Cochrane Library, latest issue), The JBI Database of Systematic Reviews and Implementation Reports (JBISRIR), MEDLINE (1950 to July 2015), EMBASE (1980 to July 2015), AMED (1985 to July 2015), CINAHL (1982 to July 2015), and PsycINFO. Thirdly, the reference list of all identified reports and articles was searched for additional studies. The search for unpublished studies included an electronic search of trials registers: Current Controlled Trials and the National Institute of Health Clinical Trials Database.

Initial keywords used were: dementia, cognitive impairment, memory loss, exercise, rehabilitation, and accidental falls. An example of a search strategy is included in Appendix 12.

4.3.3. Data selection

Papers selected for retrieval were assessed by two independent researchers (VB and VH) for methodological validity prior to inclusion in the review using standardised critical appraisal instruments from the Joanna Briggs Institute Meta-Analysis of Statistical Assessment and Review Instrument (JBI-MAStARI) (Appendix 13). Any disagreements that arose between the researchers were resolved through discussion with the third researcher (FK).

4.3.4. Data collection

Quantitative data were extracted from papers included in the review using the standardised data extraction tool from JBI-MAStARI (Appendix 14). The data extracted included specific details about the interventions, populations, study methods, and outcomes of significance to the review question and objectives. Authors were contacted where appropriate data was not documented within the publication, to enable inclusion within the review.

4.3.5. Data synthesis

Quantitative studies were, where possible, pooled in statistical meta-analysis using Review Manager 5.3. All results were subject to double data entry. Effect sizes were expressed as odds ratio (for categorical data) and weighted-mean differences (for continuous data), and their 95% confidence intervals were calculated for analysis. Heterogeneity was assessed statistically using the standard Chi-square and identifying levels of heterogeneity determined according to the Cochrane Handbook [208]. Where statistical pooling was not possible the findings were presented in narrative form including tables and figures to aid in data presentation where appropriate.

Subgroup analysis according to level of cognitive impairment and patient population was conducted where possible. Cognitive impairment is not homogeneous, and it was anticipated that treatment suitability and effectiveness would vary depending on severity. Therefore, completing sub-group analysis of this nature provides information on the treatment's effectiveness dependent upon level of impairment, and assists in directing clinical recommendations. Participants were divided into mild, moderate, and severe groups using validated cut-offs for the cognitive test utilised in assessment (i.e. MMSE, MoCA). For example, cognitive impairment levels were defined by MMSE scores: mild=21-26, moderate=11-20, and severe=<10 [209].

Underlying diagnosis of sample population was used to categorize studies and pool results of similar conditions resulting in cognitive impairment. These categories included: mild cognitive impairment and the different types of dementia (i.e. Alzheimer's disease, vascular dementia).

4.4. Results

4.4.1. Description of studies

Of the 1852 articles identified, eight were included in the review [103, 106, 210-215] and 114 were excluded (reasons for exclusion are detailed in the Excluded Studies Table in Appendix 15). Figure 4.1 outlines the PRISMA diagram of articles during the retrieval process [216]. Study characteristics of the eight included articles are outlined in Table 4.1.

Four studies considered for inclusion were of the same trial reporting short-term results [217] and sub-group analysis [101, 141]. The researchers agreed that the study reporting the full data set of the study should be included [215].

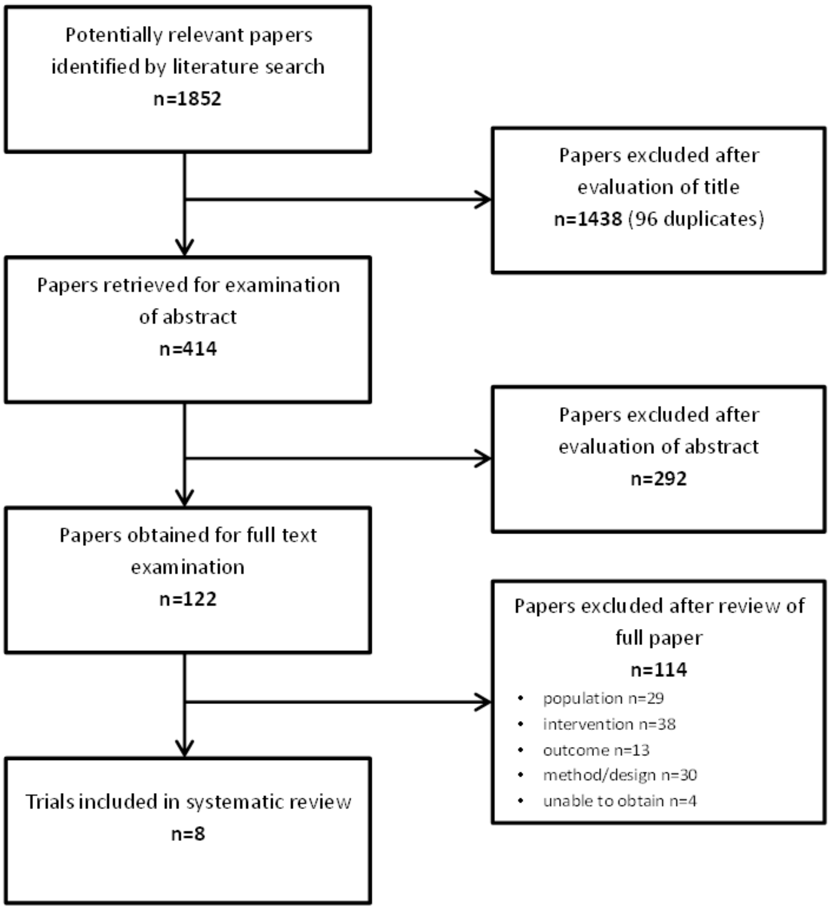


Figure 4.1: Flow diagram of study retrieval and selection for meta-analysis

The total number of participants across all studies was 1041. The mean age of the participants ranged from 70 [214] to 83 years old [215]. All the participants had a recognised cognitive impairment through diagnosis or cognitive screening test results. Three studies had participants with a diagnosis of dementia [210, 214, 215], one had participants with Alzheimer's disease [103], one had participants with amnesic MCI [212] and three recruited participants who were elderly but when assessed by a cognitive screening assessment would be classified as having cognitive impairment [106, 211, 213]. None of the participants in the included studies had severe cognitive impairment, all had either a mild [106, 211-213, 215] or moderate [103, 210, 214] classification.

The residential status of the participants was mixed within the included studies, with three studies having community-dwelling participants [103, 106, 212], three studies having institutionalised participants [210, 214, 215] and two studies including both categories of participants [211, 213]. Countries of origin included Brazil [210], India [211], Japan [212], China [213], Finland [103], Germany [215], Switzerland [106], and Korea [214].

All of the included studies were randomised controlled trials or controlled clinical trials with randomisation. Five studies had two intervention arms [106, 212-215], two had three arms [103, 210], and one had four intervention arms [211]. The length of the intervention ranged from 1 month [211] to 12 months [103, 213]. All but one of the studies required the intervention to be completed at least twice per week [106]. Most of the interventions included multicomponent exercise programmes with both physical and cognitive training elements described. One of the included studies was a tai chi intervention that described a physical and cognitive aim or benefit [213]. Four of the included studies had a motor or active control [211, 213-215] and four had usual care or no treatment as a control [103, 106, 210, 212]. Most of the interventions were completed within a group setting. One study included both group and individual therapy within their intervention [210]. One study had the same intervention being completed in different settings [103].

Most of the interventions had the primary aim of improving falls-related risk factors (such as gait, strength, and function). Two studies had the primary aim of reducing falls or falls risk [106, 211]. Four studies reported falls outcomes: total number of falls [103, 210, 212], incidence rate ratio of falls [103], number of participants with >1 and >2 falls [106, 215], fall rate per person [215], and time to first fall [106]. Outcome measurements associated with falls risk were reported in all the studies and included: Functional Reach Test [211], BBS [210, 211, 213, 214], Tinnetti [106], Short Physical Performance Battery [103], TUG [106, 210, 215], extended TUG [211], gait speed [106, 212, 215], and postural sway [214]. Two studies recorded a measurement of dual-task ability [106, 211] although they used different parameters.

Study	Setting	Level of Cognition	Participants	Outcomes of Interest	Length of Intervention	Intervention setting	Intervention
Christofoletti et al [210]	Brazil: Institution	Moderate	Grp 1: n=17, age 70.0 (1.8), MMSE 18.7 (1.7) Grp 2: n=17, age 72.9 (2.3), MMSE 12.7 (2.1) Grp 3: n=20, age 79.4 (2.0), MMSE 14.6 (1.2)	BBS, TUG	6 months	Group and 1:1	Grp 1: Interdisciplinary programme of PT with multicomponent ex, OT and PE (2hr x5pw) Grp 2: PT with multicomponent ex (1hr x3pw) Grp 3: Usual activity
D'Souza [211]	India: Community and Institution	Mild	Grp a: n=23, age 71.5 (5.1), MMSE 26.3 (1.9) Grp b: n=24, age 72.0 (3.4), MMSE 26.8 (1.8) Grp c: n=23, age 70.8 (4.3), MMSE 27.1 (1.9) Grp d: n=23, age 71.3 (4.3), MMSE 27.0 (2.1)	Falls, BBS, FICSIT-4, eTUG, FRT, LRT, DGI	1 month	Group	Grp a: PCT in ST condition (1hr x2-3pw for all) Grp b: PCT in DT condition with manual tasks Grp c: PCT in DT condition with manual-cognitive tasks Grp d: PCT in DT condition with manual-cognitive tasks in graded sensory
Doi et al [212]	Japan: Community	Mild	MEG: n=25, age75.3 (7.5), MMSE 26.8 (1.8) CG: n=25, age 76.8 (6.8), MMSE 26.6 (1.6)	Gait	6 months	Group	MEG: Multicomponent ex (90mins x2pw) CG: Health promotion educational classes (x2)
Lam et al [213]	China: Community and Institution	Mild	IG: n=171, age 77.2 (6.3), MMSE 24.7 (3.0) CG: n=218, age 78.3 (6.6), MMSE 24.3 (2.9)	BBS	12 months	Group	IG: Tai Chi (30mins x3pw) CG: Stretching and toning ex (unclear)
Pitkala et al [103]	Finland: Community	Moderate	HE: n=70, age 77.7 (5.4), MMSE 17.8 (6.6) GE: n=70, age 78.3 (5.1), MMSE 18.5 (6.3) CG: n=70, age 78.1 (5.3), MMSE 17.7 (6.2)	Falls, SPPB	12 months	Home/1:1 or Group	HE: Multicomponent ex (1hr x2pw) GE: Multicomponent ex (1hr x2pw) CG: Usual care
Trombetti et al [106]	Switzerland: Community	Mild	EI: n=66, age 75 (8), MMSE 26 (3) DI: n=68, age 76 (6), MMSE 26 (3)	Falls, Gait, TUG, sTinnetti,	6 months	Group	EI: Music-based multitask ex (1hr x1pw) DI: Usual care
Yoon et al [214]	Korea: Institution	Moderate	CAE: n=11, age 77.9 (7.5), MMSE 18.0 (1.5) CA: n=9, age 70.1 (12.2), MMSE 18.7 (1.2)	BBS, TUG,	3 months	Group	CAE: Cognitive activity (30mins x3pw) with multicomponent ex (20mins x3pw) and PT (30mins x5pw) CA: Cognitive activity (30mins x3pw) and PT (30mins x5pw)

Zieschang et al [215]	Germany: Community	Mild	IG: n=40, age 81.8 (6.7), MMSE 21.5 (3.0) CG: n=51, age 82.5 (6.9), MMSE 22.0 (3.3)	Falls, Gait, Tinetti POMA, TUG	3 months	Group	IG: Multicomponent ex (2hrs x2pw) CG: Motor placebo group training (1hr x2pw)

Legend: 1:1=individualised 1 therapist to 1 participant ratio, BBS=Berg Balance Scale, CA=cognitive activity only group, CAE=cognitive activity and exercise group,CG=control group, DGI=dynamic gait index, DI=delayed intervention group, DT=dual-task, DTC=dual-task cost, EI=early intervention group, Etug=expanded Timed Up and Go, ex=exercise, FICSIT-4=Frailty and Injuries: Cooperative Studies of Intervention Techniques-4, FRT=functional reach test, GE=Group exercise group, Grp=group, hr=hour, HE=home exercise group, IG=intervention group, LRT=lateral reach test, MEG=multicomponent exercise group, min=minutes, MMSE=Mini Mental State Examination, n=number of participants in group, OT=occupational therapy, PCT=postural control training, PE=physical education, PT=physiotherapy/physical therapy, pw=per week, SPPB=short physical performance battery test, ST=single-task, sTinetti=simplified tinetti test, Tinetti POMA=Tinetti Performance Orientated Mobility Assessment, TUG=Timed Up and Go.

Table 4.1: Characteristics of included studies

4.4.2. Methodological quality

One study fulfilled all the requirements for a high quality study [215] (Table 4.2). All studies measured outcomes consistently, completed appropriate statistical analysis and treated groups identically, other than for the stated intervention. One study, despite being described as an RCT, did not provide any detail of the randomisation process [212].

Study	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	TOTAL SCORE
Christofoletti [210]	Y	N	Y	U	Y	N	Y	Y	N	Y	6
D'Souza [211]	Y	N	U	N	N	Y	Y	Y	Y	Y	6
Doi [212]	U	N	U	N	U	Y	Y	Y	Y	Y	5
Lam [213]	Y	N	U	Y	Y	Y	Y	Y	Y	Y	8
Pitkala [103]	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	9
Trombetti [106]	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	9
Yoon [214]	Y	N	Y	N	U	Y	Y	Y	Y	Y	7
Zieschang [215]	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	10
%	88	13	63	50	63	88	100	100	88	100	Mean 7.5

Table 4.2: Methodological assessment scores of included studies

Seven studies were unable to blind participants to treatment group allocation [103, 106, 210-214]. The risk of performance bias from unconcealed intervention in the participants is high and needs consideration when comparing the outcomes from the different intervention arms. This is a recognised difficulty of using RCT design in complex intervention research. Three studies were unclear or unable to blind the outcome assessor [211, 212, 214]. Concealment of allocation was unclear in three studies [211-213].

All but one study had groups comparable at entry and measured outcomes in a reliable manner [210]. Half of the included studies completed intention-to-treat analysis [103, 106, 213, 215]. No study was excluded based on methodological quality but this was considered when looking at the strength of findings and meta-analysis results.

4.4.3. Results of quantitative research findings

4.4.3.1. Effectiveness of physical and cognitive interventions on falls

Four studies reported number of falls as an outcome (Table 4.3) [103, 106, 211, 215]. Due to difference in reporting of the measure, meta-analysis was not possible. For example, the number of falls was reported over different time frames and using different measures of central tendency, making pooling of results inconsistent.

Two studies reported significant between-group differences in the total number of falls [103, 106]. Pitkala et al [103] reported that both intervention groups (home and group exercise) experienced significantly fewer falls (p=0.005) in the 12 months of the intervention compared with a usual care group. Participants in the home exercise group experienced fewer falls than those in the group exercise (n=83 versus n=101) with corresponding lower incidence rate (IR=1.86 [1.51-2.26] versus 1.35 [1.07-1.67], p=0.005), indicating that an individualised approach had a greater effect on falls rate in this population of community-dwelling older adults with cognitive impairment, compared to a group exercise.

Trombetti et al [106] also demonstrated a significant between-group difference in the total number of falls from a music-based exercise group of community-dwelling participants (unadjusted incidence rate ratio=0.49 [0.27-0.91], p=0.005). As well as the total number of falls experienced within the 6 month intervention, Trombetti et al [106] reported significant differences between the groups when further subgroup analysis of repeat (≥1 falls experienced: relative risk=0.61 [0.39-0.96], p=0.03) and multiple (≥2 falls experienced: relative risk=0.19 [0.06-0.63], p=0.007) fallers was completed.

There was no statistical difference in total number of falls (measured by falls diary) between the groups in the 1 month intervention presented by D'Souza (p=0.24) [211]. Significant differences were reported by D'Souza [211] for within-group reduction of falls, however this outcome compares retrospective with prospective data collection and has considerably different time-frames for the collection of the number of falls (12 months versus 1 month). The quality of this study was weakened by lack of blinding for participants or assessor, no account for attrition, and unclear concealment of allocation to treatment group.

There was no statistical difference in total number of falls between the groups in the 12 month intervention presented by Zieschang et al (p=0.254) [215]. The falls outcomes reported by Zieschang et al [215] are at 12 month follow-up (9 months after the 3 month intervention) thereby providing information about the long-term rather than the immediate effects on falls rate (as with the other studies reporting falls outcomes). Neither Zieschang et al [215] nor D'Souza [211] reported incidence rates, incidence rate ratios, relative risk, or odds ratios regarding the number of falls in their publications. Both did use active controls as comparison [211, 215].

There was little consistency of results according to level of cognitive impairment. Both studies demonstrating significant between-group differences had participants with different levels of cognition, whereas both studies reporting non-significant findings included participants with mild impairment.

Study	Measurement	Results	Significant difference between groups	Effective
D'Souza [211]	Total number of falls in: previous 12mths; post intervention (90 days).	a) prev. n=24; post. n=2 b) prev. n=20; post. n=0 c) prev. n=26; post. n=2 d) prev. n=20; post. n=0	No. No significant difference between groups in median number of falls (x^2=4.17, *p*=0.24).	No. Significant difference from pre-post number of falls but different time scales for measurement (1yr vs 3mths).
Pitkala et al **[103]**	Total number of falls at the 12mth follow-up (immediately post-intervention).	HE) n=83, IR 1.35 (1.07-1.67) GE) n=101, IR 1.86 (1.51-2.26) CG) n=171, IR 3.07 (2.63-3.57)	Yes. Significant between group difference (*p*=0.005).	Yes. Both intervention groups had significantly fewer falls than the CG during the follow-up year.
Trombetti et al [106]	At the 6 mth follow-up (immediately post-intervention): Total number of falls; Number of participants with ≥1 fall; Number of participants with multiple ≥2 falls.	EI) n=24 (0.7); n=19 (28.8%); n=3 (4.6%) DI) n=54 (1.6); n=32 (47.1%); n=16 (23.5%)	Yes. Significant between group difference for; total number of falls (IRR 0.46, 95% CI 0.27-0.79, *p*=0.005), number of subjects experiencing ≥1 fall (RR 0.61, 95% CI 0.39-0.96, *p*=0.03), and multiple falls (RR 0.19, 95% CI 0.06-0.63, *p*=0.007).	Yes.
Zieschang et al [215]	At 12mth follow-up (9mths following end of 3mth intervention): Median number of falls; Number of non-fallers/single-fallers/multiple-fallers; Fall rate per person-year; Time-to-first-fall.	EI) median=1.5 (0-15); n=14/6/20; FR=2.1; 2 mths CG) median=1.0 (0-11); n=19/11/19; FR=2.02; 3 mths	No. No significant difference between groups for; median number of falls (*p*=0.254), number of fallers (*p*=0.481), or time-to-first-fall (*p*=0.922).	No. However, data is only presented for 12 mth follow-up assessment.

Legend: Key: mth=month, prev=pre-intervention measurement, post=post-intervention measurement, n=number, yr=year, HE=home exercise, IR=incidence rate (with 95% confidence intervals), GE=group exercise, CG=control group, EI=early intervention, DI=delayed intervention, IRR=incidence rate ratio, CI=confidence intervals, RR=relative risk, FR=falls rate per person-year

Table 4.3: Results and findings of falls outcomes

Study	Measurement	Results	Significant difference btw groups	Effective
	Berg Balance Scale (BBS)			
Christofoletti et al (190)	Mean BBS at: baseline; 6mths follow-up	Grp 1: 39.5 (1.9); 41.7 (2.4) Grp 2: 37.4 (2.0); 37.7 (2.8) Grp 3: 35.2 (2.6); 27.4 (3.2)	Yes. Statistical difference in both intervention groups (Grp 1 F=10.3, p<0.05; Grp 2 F=7.9, p<0.05) compared with the control.	Yes.
D'Souza [211]	Mean BBS at: baseline; 1mth follow-up; 3mth follow-up	Grp a: 44.6 (4.3); 50.0 (3.8); 48.8 (4.9) Grp b: 45.0 (4.8); 50.8 (4.6); 49.9 (5.1) Grp c: 46.1 (3.3); 51.4 (3.0); 51.1 (4.0) Grp d: 46.0 (4.8); 52.0 (4.2); 51.0 (4.3)	No. Statistical difference within-groups but no between intervention groups and control (F=0.45, p=0.82).	No.
Lam et al [213]	Mean BBS at: baseline; 12mth follow-up	IG: 52.4 (3.3); 53.4 (2.3) CG: 52.2 (3.1); 52.3 (3.4)	Yes. Significant group difference at 12mth (p=0.05 for ITT).	Yes. Intervention demonstrated difference both with ITT and completers only analysis
Yoon et al [214]	Mean BBS at: baseline; 3mth follow-up; mean difference	CAE: 35.3 (1.8); 38.0 (2.0); -2.7 (1.0) CA: 34.9 (4.6); 35.1 (4.4); -0.2 (2.4)	Yes. Significant difference between groups (p<0.05).	Yes.
	Timed Up and Go (TUG) (secs)			
Christofoletti et al [210]	Mean TUG at: baseline; 6mths follow-up	Grp 1: 13.7 (1.2); 12.9 (1.0) Grp 2: 22.3 (4.4); 22.1 (4.0) Grp 3: 30.6 (6.5); 35.6 (8.6)	Unclear. Statistical testing not reported for this outcome.	Unclear.
Trombetti et al [106]	Mean TUG at: baseline; change at 6mth follow-up	EI: 10.4 (2.8); -0.5 (1.6) DI: 10.8 (2.7); -0.2 (1.2)	Yes. At 6mth significant between-group difference (p=0.02).	Yes.

Zieschang et al [215]	Mean TUG at: baseline; 3mth follow-up; 6mth follow-up; 12mth follow-up	IG: 15.4 (7.6); 11.3 (4.8); 12.4 (4.9); 13.9 (6.1) CG: 18.1 (16.4); 17.8 (18.0); 17.2 (14.6); 27.1 (38.4)	Mixed. Yes immediately post-intervention (p=0.029). No at 6mth and 12mth follow-up (p=0.058, p=0.060).	Mixed. Yes for short-term. No for longer-term.
	Gait Speed (velocity, m/s)			
Doi et al [212]	Mean velocity at: baseline; 6mths follow-up; mean difference (CI)	MEG: 1.10 (-0.32); 1.38 (0.32); 0.28 (0.18-0.38) CG: 1.10 (0.20); 1.26 (0.21); 0.16 (0.10-0.22)	Yes. Significant difference for group x time effect (adjusted for sex as covariant) (F=6.269, p=0.037).	Yes.
Trombetti et al [106]	Mean velocity at: baseline; change at 6mth follow-up; change at 12mth follow-up	EI: 1.04 (0.19); 0.06(0.13); -0.03 (0.11) DI: 1.02 (0.19); 0.01 (0.13); 0.02 (0.13)	Yes. At 6mth significant between-group difference (p=0.03).	Yes. Further statistical testing not reported for 12mth.
Zieschang et al [215]	Mean velocity at: baseline; 3mth follow-up; 6mth follow-up; 12mth follow-up	IG: 0.9 (0.4); 1.2 (0.4); 1.1 (0.4); 1.0 (0.4) CG: 0.9 (0.3); 1.0 (0.3); 1.0 (0.3); 0.9 (0.4)	Yes. Significant group x time interaction at all time-points (p<0.001, p<0.001, p=0.020).	Yes.

Key: BBS=Berg Balance Scale, CA=cognitive activity only group, CAE=cognitive activity and exercise group, CG=control group, DI=delayed intervention, EI=early intervention, Grp=group, IG=intervention group, ITT=Intention to treat, m/s=metres per second, MEG=multicomponent exercise intervention, Mth=month, TUG=Timed Up and Go.

Table 4.4: Results and findings of outcomes related to falls

4.4.3.2. Effectiveness of interventions on falls related outcomes

Three outcomes associated with falls risk were consequently reported across the studies: BBS, TUG, and gait speed (as a single-task). Other falls-related outcomes were reported but only used in one study and include; Functional Reach Test [211], Tinnetti [106], Short Physical Performance Battery [103], extended TUG [211], dynamic gait index [211], and postural sway [214]. Table 4.4 presents the falls related outcome results.

Berg balance scale

Four studies used the BBS to measure balance ability [210, 211, 213, 214]. The BBS has a total score range from 0 (poor balance) to 56 (good balance) and a change of 3.3-8 points along the scale indicates a minimal clinically important difference (MCID) depending upon participants and initial BBS score [218, 219]. Three studies reported a statistically significant difference when the intervention groups were compared to the control [210, 213, 214]. Christofoletti et al [210] had noticeably different baseline BBS (see Table 4.4) and therefore the inclusion in meta-analysis needed to be carefully considered.

Despite using different structures of intervention (for example, group, individual, focus on music or movement), all of the included studies describe combining physical and cognitive components in their interventions and therefore were combined in meta-analysis. Two of the studies had equally structured interventions: both Christofoletti et al [210] and Yoon et al [214] incorporated multicomponent exercises as one part of an interdisciplinary programme involving physiotherapy and either occupational therapy or cognitive activities.

A group tai chi intervention was used in Lam et al [213] and was compared to a stretching and toning exercise program. All of the three studies reporting positive findings on BBS recorded outcomes immediately post-intervention program. D'Souza [211] was the only study to report no significant difference between intervention groups and the control.

Four studies [210, 211, 213, 214], using the most relevant intervention groups (Christofoletti et al [210] =group 1 versus group 3; D'Souza [211] =group C versus group A), were combined in meta-analysis (Figure 4.2) comparing the effects of multicomponent physical and cognitive interventions against a control on BBS. A fixed effects model was used due to the limited number of studies included. Overall, the studies were shown to have considerable heterogeneity (X^2=186.54, d.f.=3 , $p<0.001$, I^2=98%).

One potential cause of the heterogeneity was the different control groups used. When the studies are grouped according to nature of the control intervention (active control versus usual or no active control), only three studies were included in the BBS meta-analysis (Figure 4.3) and the studies are shown to be homogeneous (X^2= 2.31 d.f.=2 , $p=0.31$, I^2=14%). There was a significant difference in the change in balance ability (BBS) between the two groups post-intervention, with a greater increase in balance ability in the multicomponent physical and cognitive combined intervention when compared to an active control (weighted mean difference [WMD]=1.23 [0.69-1.77] Z=4.48 [$p<0.001$]).

Timed up and go

The TUG was reported in three of the included studies [106, 210, 215]. An MCID of 4.09 seconds has been identified in an Alzheimer's disease population [220]. Christofoletti et al [210] observed an improvement in TUG within the intervention group (and deterioration in TUG within the control) but as with their BBS outcome, there were noticeably different baseline abilities for the different groups (Table 4.4). Two studies reported a significant difference between the TUG scores immediately post-intervention (Trombetti et al [106] [p=0.02], Zieschang et al [215] [p=0.03]). However, Zieschang et al [215] identified that at the 6 and 12 month follow-up assessments, the difference between the groups diminished (6 month [effect size=0.04, p=0.058], 12 month [effect size 0.04, p=0.060]).

These three studies were combined in meta-analysis (Figure 4.4) comparing the effects of multicomponent physical and cognitive interventions against a control on TUG [106, 210, 215]. Overall, the studies were shown to have considerable heterogeneity (X^2=131.07, d.f.=2, p<0.001, I^2=98%). As with the BBS analysis, the controls were assessed as a potential source of heterogeneity, but in this case, the majority of studies [106, 210] had a non-active, usual care control, and when these were combined in meta-analysis the heterogeneity was increased (Figure 4.5) (X^2=126.81, d.f.=1, p<0.001, I^2=99%). The heterogeneity was too great to be combined and was potentially a result of the small number of studies included in the analysis (as demonstrated by the increase in heterogeneity when number of studies reduced) and the difference in method employed in the two pooled studies (group versus mixed supervision). However, both studies reported a cognitive and physical focus to their intervention, encouraging the pooling of results according to intervention nature, despite the differences in structure.

Gait speed

Three studies used gait speed as a measure of their multicomponent physical and cognitive interventions [106, 212, 215]. A change of 0.05-0.13 m/s in gait speed is considered a minimal clinically important difference (MCID) in older adults [221], and 0.09 m/s in Alzheimer's disease populations [220]. All three studies reported significant differences between groups following the experimental intervention when compared to a control. Zieschang et al [215] reported that the gait speed remained statistically different between the intervention and control groups at every follow-up assessment (immediately following 3mth intervention [effect size=0.31, p<0.001], 6mth follow-up [effect size=0.20, p<0.001], 12mth follow-up [effect size=0.08, p=0.020]).

Meta-analysis combined the three studies to compare the effects of multicomponent physical and cognitive interventions against a control on gait speed (Figure 4.6). Overall, the studies were shown to have moderate heterogeneity (X^2=3.55, d.f.=2, p=0.17, I^2=44%). There was a significant difference in the change in gait speed between the two groups post-intervention, with a greater increase in gait speed in the multicomponent physical and cognitive combined intervention (WMD=0.08 [0.03-0.12] Z=3.65 [p≤0.001]). The studies were deemed comparable in intervention nature and therefore suitable for meta-analysis, however the difference in comparator interventions could be a source of the moderate heterogeneity identified.

	Dual intervention			Control (all variations)				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
Christofoletti (2008)	41.7	2.4	17	27.4	3.2	20	8.4%	14.30 [12.49, 16.11]
D'Souza (2012)	51.1	4	23	48.8	4.9	23	4.1%	2.30 [-0.29, 4.89]
Lam (2012)	53.4	2.3	171	52.3	3.4	218	84.7%	1.10 [0.53, 1.67]
Yoon (2013)	38	2	11	35.1	4.4	9	2.8%	2.90 [-0.21, 6.01]
Total (95% CI)			**222**			**270**	**100.0%**	**2.30 [1.78, 2.83]**

Heterogeneity: Chi² = 186.54, df = 3 (P < 0.00001); I² = 98%
Test for overall effect: Z = 8.64 (P < 0.00001)

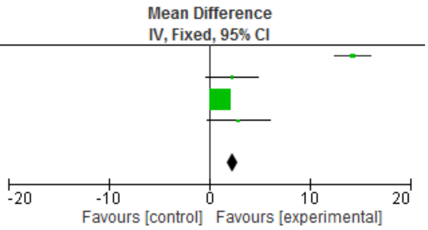


Figure 4.2: Forest plot of BBS (all controls)

Study or Subgroup	Dual intervention Mean	SD	Total	Physical control Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
D'Souza (2012)	51.1	4	23	48.8	3.2	23	6.6%	2.30 [0.21, 4.39]
Lam (2012)	53.4	2.3	171	52.3	3.4	218	90.3%	1.10 [0.53, 1.67]
Yoon (2013)	38	2	11	35.1	4.4	9	3.0%	2.90 [-0.21, 6.01]
Total (95% CI)			**205**			**250**	**100.0%**	**1.23 [0.69, 1.77]**

Heterogeneity: Chi² = 2.31, df = 2 (P = 0.31); I² = 14%
Test for overall effect: Z = 4.48 (P < 0.00001)

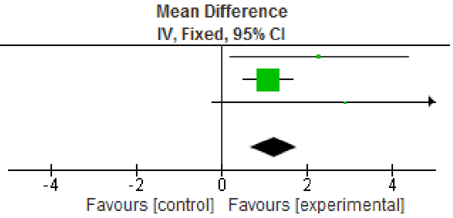


Figure 4.3: Forest plot of BBS (active control only)

Study or Subgroup	Dual intervention Mean [seconds]	SD [seconds]	Total	Control (all variations) Mean [seconds]	SD [seconds]	Total	Weight	Mean Difference IV, Fixed, 95% CI [seconds]
Christofoletti (2008)	12.9	1	17	35.6	8.6	20	1.6%	-22.70 [-26.50, -18.90]
Trombetti (2011)	9.9	1.6	66	10.6	1.2	68	97.6%	-0.70 [-1.18, -0.22]
Zieschang (2013)	11.3	4.8	40	17.8	18	51	0.8%	-6.50 [-11.66, -1.34]
Total (95% CI)			**123**			**139**	**100.0%**	**-1.09 [-1.57, -0.62]**

Heterogeneity: Chi² = 131.07, df = 2 (P < 0.00001); I² = 98%
Test for overall effect: Z = 4.51 (P < 0.00001)

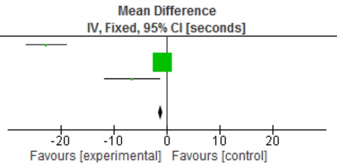


Figure 4.4: Forest plot of TUG (all controls)

Study or Subgroup	Experimental Mean	SD	Total	Control Mean	SD	Total	Weight	Mean Difference IV, Fixed, 95% CI
Christofoletti (2008)	12.9	1	17	35.6	8.6	20	1.6%	-22.70 [-26.50, -18.90]
Trombetti (2011)	9.9	1.6	66	10.6	1.2	68	98.4%	-0.70 [-1.18, -0.22]
Total (95% CI)			**83**			**88**	**100.0%**	**-1.05 [-1.52, -0.57]**

Heterogeneity: Chi² = 126.81, df = 1 (P < 0.00001); I² = 99%
Test for overall effect: Z = 4.30 (P < 0.0001)

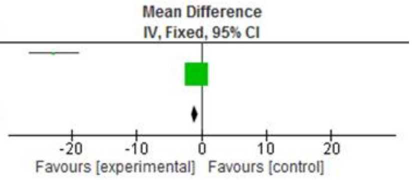


Figure 4.5: Forest plot of TUG (no active control only)

Study or Subgroup	Dual intervention Mean [m/s]	SD [m/s]	Total	Control (all variations) Mean [m/s]	SD [m/s]	Total	Weight	Mean Difference IV, Fixed, 95% CI [m/s]
Doi (2013)	1.38	0.3	25	1.26	0.2	25	8.2%	0.12 [-0.02, 0.26]
Trombetti (2011)	1.09	0.13	66	1.03	0.13	68	84.4%	0.06 [0.02, 0.10]
Zieschang (2013)	1.2	0.4	40	1	0.3	51	7.4%	0.20 [0.05, 0.35]
Total (95% CI)			**131**			**144**	**100.0%**	**0.08 [0.03, 0.12]**

Heterogeneity: Chi² = 3.55, df = 2 (P = 0.17); I² = 44%
Test for overall effect: Z = 3.65 (P = 0.0003)

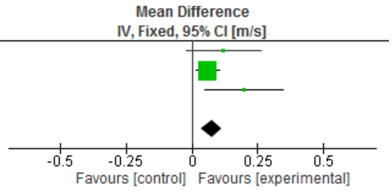


Figure 4.6: Forest plot of gait speed (all controls) fixed effects model

Other falls intermediate outcomes

Other balance outcomes associated with falls rate in the literature were reported in only one included study and therefore not suitable for meta-analysis. D'Souza et al [211] reported a significant difference between the groups for the Frailty and Injuries Cooperative Studies of Intervention Techniques for static balance (FICSIT-4) ($F [4.82,118.92]=2.78$, $p=0.02$) and the expanded Timed Up and Go (eTUG) in a manual-cognitive dual-task condition ($F [5.34,131.71]=4.13$, $p<0.01$). However, there was no significant difference found between groups for the modified Clinical Test for Sensory Interaction for Balance (mCTSIB) (p values not consistently reported), Functional Reach Test (FRT) ($p=1.51$), Lateral Reach Test (LRT) ($p=0.06$), Dynamic Gait Index (DGI) ($p=0.34$), extended TUG in single ($F [5.42,133.59]=0.97$, $p=0.44$), dual-manual ($F [0.55,134.85]=0.66$, $p=0.67$) or dual-cognitive task conditions ($F [5.19,127.96]=1.58$, $p=0.17$).

Pitkala et al [103] reported that there was no significant difference between groups at any time points for the Short Physical Performance Battery (SPPB) (3 months $p=0.34$, 6 months $p=0.86$, 12 months $p=0.90$ [values of mean change reported visually only]).

Both Zieschang et al [215] and Trombetti et al [106] used the Tinetti balance scale as an outcome but reported different versions (Zieschang=Performance Orientated Motor Assessment [POMA]; Trombetti=simplified). Both studies reported significant between-group difference immediately after the intervention (Trombetti et al [106] adjusted between group mean difference=-0.6 [-0.8,-0.3], $p<0.001$; Zieschang et al [215] effect size=0.19, $p<0.001$), and by Zieschang et al [215] at short (effect size=0.143, $p<0.001$) and long-term follow-up (effect size=0.094, $p=.008$).

4.4.3.3. Effectiveness of interventions according to severity of cognitive impairment

Five studies had participants with mild cognitive impairment [106, 211-213, 215] and three with moderate cognitive impairment [103, 210, 214] according to diagnosis or mean MMSE. Three studies did not specifically recruit participants with a cognitive impairment diagnosis but had a mean MMSE within the boundaries of mild cognitive impairment [106, 211, 213]. Table 4.5 demonstrates the number of studies with similar outcome measures according to cognitive impairment severity. There were enough studies to complete meta-analysis according to cognitive level for: BBS, TUG and gait speed within mild sub-group, and BBS for moderate sub-group.

Study	Intervention	Falls	BBS	TUG	Gait
Mild					
D'Souza [211]	Multicomponent ex	√	√		
Doi et al [212]	Multicomponent ex				√
Lam et al [213]	Tai Chi		√		
Trombetti et al [106]	Music-based ex	√		√	√
Zieschang et al [215]	Multicomponent ex	√		√	√
Moderate					
Christofoletti et al [210]	Multicomponent ex		√	√	
Pitkala et al [103]	Multicomponent ex	√			
Yoon et al [214]	Multicomponent ex		√		

Table 4.5: Interventions and outcome measures according to level of cognitive impairment

Mild sub-group

Sub-group analysis for multicomponent exercise programmes incorporating physical and cognitive elements was completed for BBS and TUG. The original meta-analysis for gait speed had studies with participants that only had cognitive impairment at a mild stage (Figure 4.6).

Two studies were combined for meta-analysis using the BBS outcome to report change in balance ability following the experimental intervention [211, 213]. Overall the studies were homogeneous (X^2=0.79, d.f.=1, p=0.37, I^2=0%). There was a significant difference in the change in balance ability (BBS) between the two groups post-intervention (Figure 4.7), with a greater increase in balance ability in the multicomponent physical and cognitive combined intervention when compared to the control (WMD=1.16 [0.60-1.71] Z=4.08 [p<0.001]).

Two studies were combined for meta-analysis (Figure 4.8) using TUG outcome to depict change in functional ability following the experimental intervention [106, 215]. Despite the two studies having different comparator interventions, the content and intent of the main intervention suggested meta-analysis is appropriate. Overall, the studies were considerably heterogeneous (X^2=4.81, d.f.=1, p=0.03, I^2=79%) and therefore the meta-analysis will not be considered to inform the recommendations from this review.

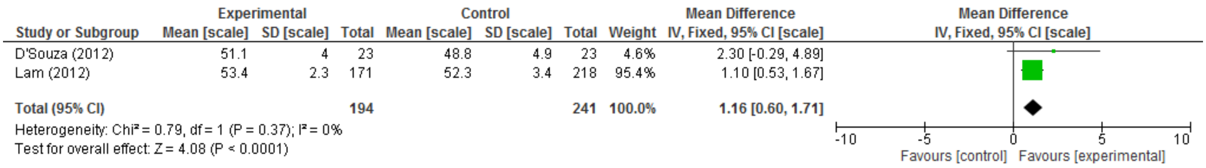


Figure 4.7: Forest plot of BBS in mild sub-group

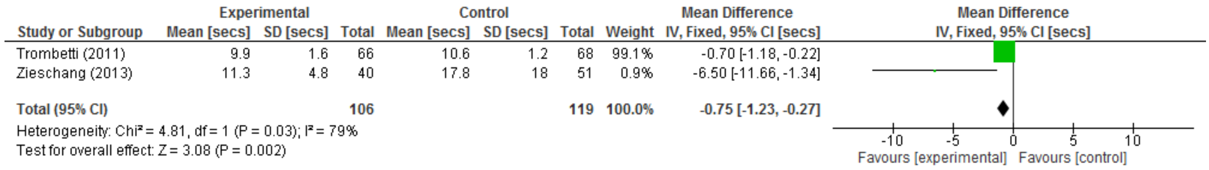


Figure 4.8: Forest plot of TUG in mild sub-group (fixed effects)

Moderate sub-group

Sub-group analysis for multicomponent exercise programmes incorporating physical and cognitive elements was completed only for the BBS. Two studies reporting BBS involved participants with cognitive impairment at a modertate stage [210, 214]. Overall there was considerable heterogeneity between these two studies (X^2=38.28, d.f.=1, p<0.001, I^2=97%) and therefore the meta-analysis will not be considered to inform the recommendations from this review (Figure 4.9).

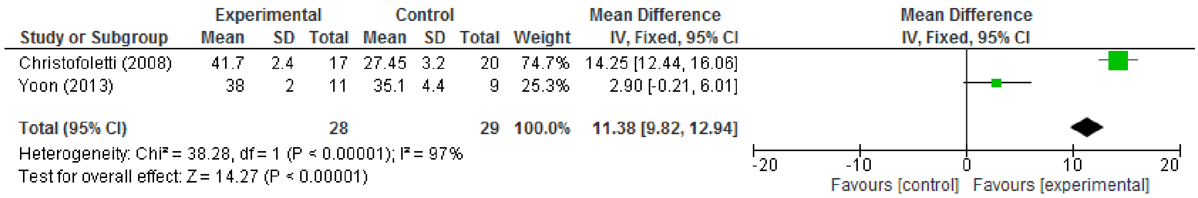


Figure 4.9: Forest plot of BBS in moderate sub-group

4.4.3.4. Effectiveness of interventions according to diagnosis of cognitive impairment

There was insufficient detail within the included studies to complete sub-group analysis for multicomponent exercise programmes incorporating physical and cognitive elements according to dementia diagnosis. Three studies did not disclose underlying conditions within their participant population [106, 211, 213], one study had only Alzheimer's disease participants [103], and one study had amnesic MCI participants [212]. Of the three studies that recruited participants with a dementia diagnosis, there was not enough detail within the publications to determine the type of dementia nor the percentage mix of types of dementia [210, 214, 215].

4.5. Discussion

4.5.1. Summary of main results

This systematic review is the first to determine the effectiveness of multicomponent exercises incorporating both physical and cognitive components to reduce falls and falls risk factors in older adults with cognitive impairment. Eight studies were included in the review. Most of the interventions incorporated physical and cognitive components as dual-task exercises which formed one aspect of a multicomponent exercise program. Two studies incorporated physical and cognitive components using other techniques: Tai chi and a music-based exercise class.

4.5.2. Overall completeness and applicability of evidence

Four studies reported effectiveness of the intervention on number of falls, half of which reported a significant difference between the groups. Meta-analysis was not possible with the falls outcome but balance, functional mobility, and gait parameters were pooled. Balance ability (BBS) was improved by 2.30 (/56) points (WMD) when compared to all control interventions and 1.23 points (WMD) when compared to active controls only. Sub-group analysis completed in populations with cognitive impairment at a mild stage reported 1.16 points (WMD). There was too much heterogeneity between the studies to complete a meta-analysis using the moderate sub-group results. None of the pooled WMD were close to the MCID score of 8 points [218], so despite the meta-analyses being statistically significant, the actual change to a participant's balance is not a noticeable change between the intervention groupings.

Despite attempting to control for confounding factors, there was considerable heterogeneity within the studies reporting functional mobility (TUG), and therefore all the main meta-analyses completed for this outcome could not be interpreted. In a sample of participants with cognitive impairment at a mild stage, -3.01 seconds WMD indicated a positive effect of the intervention compared to the control group, but did not reach statistical significance. However, this pooled result is close to the MCID cut-off previously reported in older adults with Alzheimer's dementia [220], indicating that the intervention may have a clinically significant impact on functional mobility.

Gait speed was the only falls related outcome that demonstrated a statistically significant difference between groups in all the individual studies when pooled in meta-analysis, producing 0.10 m/s WMD. All the studies that reported gait speed had participants at a mild stage, therefore no comparison could be done according to cognitive impairment severity. A change of 0.05-0.13 m/s in gait speed is considered a minimal clinically important difference in older adults [221] which is about the size of change in this analysis. All the studies using gait speed individually reported significant differences between the intervention groups, potentially indicating that gait speed is an outcome which is more sensitive to change in persons at a mild stage of cognitive impairment.

Overall, multicomponent interventions incorporating both physical and cognitive components demonstrated positive effects on balance, functional mobility, and gait speed when compared to a control. There were also significantly better effects on balance and gait speed in participants with cognitive impairment at a mild stage. All the suitable meta-analyses of the balance and gait speed secondary outcomes and sub-groups were statistically significant in favour of the experimental group. However, considerable heterogeneity between studies limited the number of meta-analyses completed and limited reporting of the moderate sub-group analysis. The number of included studies was small (range 2 to 4), making sub-group analysis difficult in some instances. The results of the meta-analyses must be considered carefully and in relation to the clinical significance and intervention characteristics.

4.5.3. Quality of the evidence

The methodological quality of the included studies was good, with one study gaining full quality rating and an overall mean score of 7.5 across all included studies. Many of the studies were limited by their design, unable to blind the participants or assessor to treatment allocation, and unable to account for or deal with attrition within the study analysis.

The considerable heterogeneity identified from the meta-analyses of some outcomes indicates that findings may be related to different populations, interventions, and outcomes. Despite reporting comparable groups at entry into the study, Christofoletti et al [210] had noticeably different baseline scores for both BBS and TUG, and as this was a key study of participants with moderate cognitive impairment, this potentially accounted for why the heterogeneity was large.

4.5.4. Potential bias in the review process

There were a number of limitations to this review. The variety of interventions in the included studies was a potential source for the heterogeneity not removed by sub-grouping studies according to control intervention. Despite all the interventions being described as incorporating physical and cognitive interventions, the actual intervention completed could be clinically different, e.g. tai chi in a group versus multicomponent exercise programme completed at home. The methodological differences in the included studies could account for the varying heterogeneity identified in the included studies.

It was the intention of this review to identify only those interventions where physical and cognitive interventions were combined, but wording of this topic area is not standardised and as such the inclusion criteria were broad to capture potentially relevant studies. At present there is no comprehensive definition of these multicomponent, dual-task interventions despite a well-explored and increasingly documented theoretical underpinning for such interventions [201]. As the intervention is multicomponent, it is difficult to fully identify which of the components triggers the mechanism or whether it is the combination of these components which provides the effect. To determine effectiveness, an intervention should be well-defined and standardised but in the complex pathology of falls within older adults, it is difficult to implement a standardised intervention when causative factors are often quite varied and patient-specific [41].

In this review there was considerable variation of intervention duration (range 1 to 12 months) but most were completed at least twice a week for at least 6 months. In the current economic climate, such long duration and high intensity interventions need to be considered carefully. However, in light of the unique challenges facing patients with cognitive impairment and the increasingly positive evidence from studies reducing falls risk factors, the time is ripe for a paradigm shift in how falls interventions are considered in this patient population.

The aims of the included studies were varied, with less than half of the studies having falls reduction as a main aim or outcome. Not only did this lead to different targets of the interventions (i.e. can you pool results from studies aiming to increase strength and from those aiming to improve the connection between mind and body?) but rendered it impossible to pool falls outcomes in meta-analysis. For example, only four studies reported the number of falls, all of which reported them in a different manner. Any meta-analysis is constrained by outcome choice and reporting within the included studies. This is evident within this review by completion of meta-analysis in only secondary measures related to falls risk. The consideration of validity and reliability of these measures within dementia populations was made prior to commencement of the review, particularly in view of the challenges in outcome measurement in people with dementia [222]. Despite the outcomes not being developed specifically for dementia populations, the BBS [223], TUG [220], and gait speed [224] have all demonstrated to be reliable and valid in this patient population.

It is possible that the search strategy did not identify all relevant papers. To counteract this, an information specialist assisted in developing the search strategy. Grey literature was included and authors contacted for further information when necessary. The review was completed with limited resources therefore articles not published in English language were excluded and time-frames provided for contacted authors to respond to information requests.

Despite limiting the participant population, the systematic review identified studies with differing degrees of cognitive impairment. Only three studies were classified as having participants with moderately severe cognitive impairment, four recruited participants specifically with dementia, one with AD, and one with amnesic MCI. This review used a well-referenced grading of MMSE to determine cognitive impairment levels [209] but there is debate and variance within the evidence base. The different patient populations may have different clinical presentations and causative factors for their falls or increased falls risk factors, therefore it would be simplistic to combine them as one participant group.

The eight studies included demonstrate that this is a developing area with all the included studies published within the previous seven years. A recent review noted the sparsity of well-designed studies in this new intervention paradigm [140]. There is a lack of rigorous randomised trials in older adults with dementia, and even more so in investigating the effects of falls prevention interventions and the role of dual-task interventions within them. This review specifically included trials that had used randomisation in concordance with using the highest level of evidence available [208]. It is noted that a larger number of studies could have been included if the criteria for study method were less rigorous [225, 226]. The author sought to pool results through meta-analysis where possible and would not have been able to do so if non-randomised or cohort studies were included.

4.5.5. Comparison with other reviews

This review adds to the developing evidence base on combined or dual-task based interventions, adding a different perspective to the conclusions of previous reviews on this intervention. Law et al [140] reported that interventions using this dual-task paradigm improved cognitive functioning in older adults with and without cognitive impairment, whereas the effects on physical functioning were more difficult to determine in the review by Pichierri et al [112]. There is overlap between the previous reviews and studies included within this review. By not including mixed population studies, this review has been able to derive more substantial conclusions based on the evidence available.

4.6. Conclusion

4.6.1. Implications for practice

Multicomponent interventions incorporating both physical and cognitive components have the potential to achieve greater improvements in balance, functional mobility, and gait speed when compared to usual care in older adults with cognitive impairment. Effectiveness of such an intervention on falls rate in older adults with cognitive impairment is inconclusive, although secondary measures of falls risk factors demonstrate positive trends. At this time, clinical recommendations cannot be made but evidence within this area is emerging and the positive findings from this review are encouraging.

4.6.2. Implications for future research

The evidence in relation to the effectiveness of multicomponent, dual-task based interventions in reducing the rate of falls is inconclusive but positive, considering the significant findings within the falls-related risk factor outcomes. The next stage of research should consider using all forms of evidence, such as qualitative and non-randomised pilot or feasibility studies, to aid the definition of intervention characteristics required for a successful falls intervention programme. Using research methods outside of the traditional or quantitative field may yield more contextual or theoretical detail than the traditional meta-analysis presented here. Progressing the theoretical model underpinning a falls intervention in older adults with mild dementia would aid specificity and efficacy of any future interventions, which can be progressed with further testing.

Future studies in this area should include rigorous reporting of falls rates as well as balance or functional outcomes. Active controls should be used to compare against the multicomponent interventions, potentially with only the combined physical and cognitive component being the difference. Trials need to be well-reported according to the CONSORT statement [227] with specific attention paid to the methods of randomisation, blinding of participants, allocators and assessors, and consideration of attrition rates within the statistical analysis. A number of studies were excluded from this review according to design and lack of randomisation. It is therefore a recommendation that further studies of this intervention are randomised controlled trial or clinical trials with randomisation to assign group allocation.

Considering the variety of a combined physical and cognitive intervention, particular attention should be paid to describing details according to guidance such as the TIDieR checklist [228]. A comprehensive definition of the intervention needs to be developed and published, allowing appropriate and accurate indexing of future studies within this field and ensuring studies whose intervention is intentionally multicomponent or dual-task based are correctly identified.

Finally, further studies into multicomponent interventions incorporating physical and cognitive components must be completed in diagnosis specific participant groups, particularly within dementia and Alzheimer's disease of well-defined mild and moderate cognitive impairment. Understanding the contextual details and different interactions dependent upon cognitive impairment severity requires further study.

4.6.3. Recommendations for feasibility study

Recommendations for the next stage of research study, a non-randomised feasibility study, are described (Table 4.6). A list of combined physical and cognitive exercises has been compiled (Appendix 16)

	Recommendations for feasibility study
1.	Falls rate and risk measurements should be included as well as balance and gait outcomes.
2.	Information to aid recruitment and retention for a larger randomised trial post-feasibility study should be collected.
3.	The intervention should be described according to the TIDierR checklist within any publications of the feasibility study.
4.	A select and specific patient population involving community-dwelling persons with cognitive impairment at a mild level should be recruited into the feasibility study to a) draw conclusions on homogeneity of the sample, and b) allow conclusions reached to be applicable to a specific patient population.
5.	Combined physical and cognitive intervention should be a main component of the intervention via dual-tasking exercises.

Table 4.6: Table of recommendations from meta-analysis

Chapter 5. Theoretical underpinning of an exercise-based falls prevention programme for older adults with cognitive impairment: a realist review

Summary

Evidence for falls prevention interventions for adults with cognitive impairment is varied and provides no clear findings and limited clinical recommendations for treatment. Both primary and synthesis studies are lacking in quality and number (Chapter 3). Promising results, such as multicomponent interventions incorporating both physical and cognitive exercise, are emerging but are as yet not fully evaluated (Chapter 4). Understanding the mechanisms involved in such interventions in this specific population will aid successful intervention development. The key benefit of realism is generalisability. The question "does it work?" (Chapter 4) is inadequate for complex interventions in clinically heterogeneous populations (severity, type of dementia, pattern of impairments, comorbidities, personal preference and abilities).

In this chapter a realist review method is employed to aid theoretical modelling, asking the question of why and for whom an exercise intervention may work, rather than just determining efficacy. The objectives of this realist review were: (i) to identify the underlying programme theory of exercise interventions targeted at those individuals who have cognitive impairment, and (ii) to explore how and why the interventions reduce falls in a community-dwelling population with cognitive impairment.

Six rough programme theories were tested against published literature found using a comprehensive search strategy. The process of data extraction, appraisal, and synthesis resulted in the development of an explanatory programme theory. Two components of the refined programme theory are presented within this chapter: physiological-responses and encouragement. Contextual details regarding the exercise interventions (such as dose, setting, and content) and level of cognitive impairment in the studies included are also described.

Clinically relevant recommendations from the programme theory are summarised and will be used to refine the intervention feasibility tested in subsequent chapters (Chapter 6).

Publication; Booth V, Harwood R, Hood V, Masud T, Logan P. Understanding the theoretical underpinning of the exercise component in a fall prevention programme for older adults with mild dementia: a realist review protocol. Systematic reviews. 2016;5(1):119.

Review registered with; PROSPERO CRD42015030169.

5.1. Introduction

5.1.1. Rationale for review

Falls prevention is a complex intervention that is well-evidenced in a healthy older adult population, but sparsely researched in cognitive impairment by comparison. The umbrella review within Chapter 3 describes the frequency and heterogeneity of exercise-based interventions in dementia populations [184]. There is a strong rationale for falls prevention in adults with cognitive impairment. Chapter 4 illustrates the potential for interventions, such as multicomponent physical and cognitive exercise, as well as the difficulties in synthesising the current evidence base.

Historically, research in older adults with cognitive impairment such as dementia has been controversial, raising complex ethical dilemmas [229]. Anecdotally this population has been associated with increased attrition and poor adherence to exercise programmes due to memory and executive problems, and co-morbidity. In the attempt to produce valid final results, older adults with cognitive impairment have been excluded, leading to a lack of quantity and quality evidence on falls interventions for this population [187]. Whilst it is reasonable to assume that some findings from research conducted in healthy older populations can be extrapolated to older adults with dementia, differences are likely and not all findings will be relevant. Older adults with mild dementia have specific impairments (such as altered attentional capacity) that may influence the effectiveness of an intervention developed for a different population.

Realist review is a methodology that adopts a different philosophical standpoint to accessing evidence than narrative or systematic evidence review. There are several reasons for choosing this method for investigations in this field. Firstly, a traditional systematic review focuses on the effectiveness of a particular intervention and whilst this is useful, there are currently not enough RCTs or quantitative studies in this patient population to determine the effectiveness of intervention programmes with any certainty. As demonstrated in Chapters 3 and 4, it is difficult to generate firm conclusions from the current evidence-base [184].

Secondly, at this early stage of intervention development and available evidence, the theoretical underpinning of an intervention should be considered [123]. It is likely that adherence, context, barriers and facilitators, and the social and physical environment are also important mediators of effectiveness, and a complete explanation must take all of these factors into account. Knowing what works for whom, how, and why will direct appropriate delivery of clinical interventions and the evolution of effective interventions. These are questions that a traditional systematic review does not answer. In his 2006 description of realist approach, Pawson outlined a critique of meta-analytical methods of the traditional systematic review, particularly in that by attempting to reduce bias from included studies "*the very features that explain how interventions work are eliminated from the reckoning*" ([230], p43).

Thirdly, there is substantial variability within dementia populations, such as the level of impairment (mild to severe), or diagnosis (Alzheimer's disease, vascular, mixed, Lewy body, frontotemporal dementia, etc.). Considering the limited literature available within this field, standard meta-analysis stratification is impossible and yields inconclusive results [185, 186, 188, 189]. A realist review allows consideration of different contextual influences.

Fourthly, some important studies in this area use methods that would not be included in a standard systematic review [231]. A realist review [232] allows the incorporation of detail from a range of literature with respect to the contextual factors and mechanisms of how an intervention reduces falls in a particular population. Realist enquiry has been recommended by the MRC within process evaluation [115] to allow consideration of context and theory generation within intervention development, specifically when studying complex interventions and patient populations [233].

A realist review explores how underlying mechanisms (M) might be 'triggered' in the context (C) of different intervention strategies to produce a reduction in falls, or other outcomes (O). Within realist enquiry CMO configurations (CMOc) are interlinked and dependent upon each other, creating chains of conceptual possibilities.

Mechanisms are further subdivided between resources and responses [234]. For example, a fall (O) could be prevented if an individual uses a walking stick ($M^{resource}$) to feel confident ($M^{response}$) when walking outside (C). This configuration is only relevant in the context of the individual walking outside, owning a walking stick, and having the response of feeling confident when holding a stick.

The aim of the realist review is "explanation building" [230], providing a "*contextualised understanding of how and why complex interventions achieve particular effects*" ([235], p2). Realist enquiry is increasingly used in the evaluation of complex interventions, as it can look at the wider context of the intervention, seeking to explain rather than judge if the intervention is effective, and investigating why, what the underlying mechanism is, and the necessary conditions for success. It does this through defining explicit descriptions and models, or 'programme theories', of how an intervention achieves the desired or observed outcomes. A full definition of all terms is provided in Appendix 17.

5.1.2. Objectives and research questions of the review

The objectives of the review were: (i) to identify the underlying programme theory of strength and balance exercise interventions targeted at individuals who have been identified as at risk of falling and who have cognitive impairment, and (ii) to explore how and why that intervention reduces falls in a community-dwelling population with cognitive impairment.

The research questions for the review were:

a) What strength and balance exercises have been used in mild dementia populations to reduce falls?
b) Why do those exercises reduce falls in that population?
c) In what context do those exercises reduce falls in that population and to what extent?

5.2. Methods

5.2.1. Study design

The design utilised five practical stages of the review process identified by Pawson et al [122]. This process was not linear and the researcher moved between stages to achieve "*theoretical saturation*" (when no further information or findings emerged against which to judge the programme theory) [232]. The stages of design were adapted to accommodate the resources and time available. These study stages were: i) articulating key rough programme theories to be explored, ii) searching for relevant evidence, iii) appraising the quality of evidence, iv) extracting the data, and v) synthesising evidence [122].

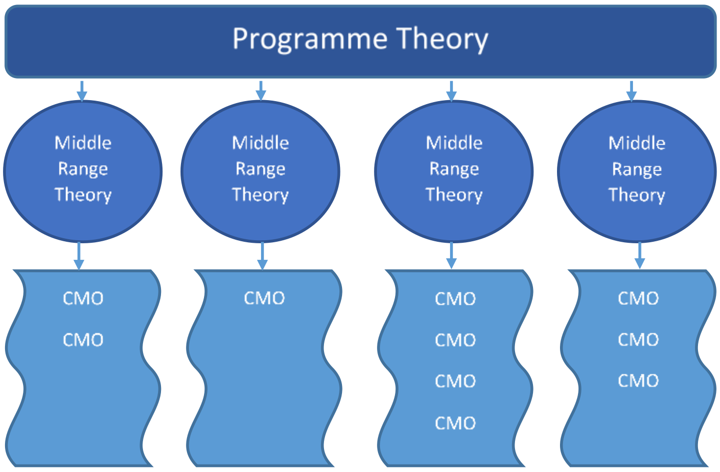


Figure 5.1: Diagram of the relationship between programme theory, middle range theory and context-mechanism-outcome (CMO) configurations

5.2.2. Articulation of key theories

Falls prevention is a complex intervention with many components that are introduced or employed according to individual patient characteristics. To clarify the scope of the review, the 'patient journey' was identified from case identification to discharge [97]. The underlying assumption was that through correct case identification and multi-disciplinary assessment, multifactorial interventions identify and address risk factors causing falls.

Initially, stages of the 'patient journey' were considered a sub-theory within an overall programme theory, containing possible CMO configurations relevant to that stage. The CMO configurations (CMOcs) were progressively refined and collated together to form middle range theories (MRT) that contributed to the overall rough programme theory in one stage of the patient journey: the strength and balance exercises (Figure 5.1). This was an iterative process based on prior knowledge of the literature in falls prevention [184] and previous clinical experience. Mental models [236] were mapped according to potential CMOcs.

These initial rough theories were discussed with key stakeholders in falls prevention, including a patient and public representative, geriatricians, researchers, and clinicians in the field. A stakeholder group involving these individuals was established. Consultation and discussion with this group was completed throughout this initial stage via a series of facilitated meetings and email discussion chains. Notes from the meetings were taken and the refinement process for the rough programme theories was documented in paper format to ensure transparency. The researcher was also guided by literature from exploratory internet-based searches. A dialogue was maintained with the stakeholder group throughout this initial stage to ensure the researcher maintained relevance and accuracy to clinical practice.

The initial process identified a rough programme theory including six MRTs to test against the literature (Appendix 18). During the review process, further MRTs were added or removed dependent upon the data.

5.2.3. Searching processes

To identify all relevant material, a two-phased literature search was conducted. The electronic search initially focused on exercise-based falls interventions in adults with mild dementia. To capture specific primary studies involving the intended population, key phrases and words specific to the rough programme theories to test and refine them were used.

The search strategy was:

1. An electronic search of databases: EMBASE, MEDLINE, CINAHL, the Cochrane Library, PsycINFO, and PEDRO. Keywords and MESH headings were refined during the initial SEARCH stage: *accidental falls, falls rehabilitation, exercise, dementia, cognitive impairment*. The search terms were adapted according to the database used.
2. Electronic "cited by" search using Google Scholar.
3. A hand search of the reference lists of included papers.
4. An electronic search of the grey literature: Ethos and Google Scholar.

The second search phase sought additional primary evidence that was specifically relevant to the testing and refinement of the rough programme theory or highlighted MRTs. The material was not restricted to older adults with dementia or cognitive impairment or falls so long as it informed a theory likely to be important for the development of the MRTs (for example material relating to people with Parkinson's disease, traumatic brain injury or learning disability, or to activity or behaviour change in people with dementia).

Additional searching was completed if more data were required to refine a particular aspect of the programme theory. The searching was both "*iterative and interactive*" [237] and the search terms evolved as the searches were undertaken. The search results were screened by the researcher (VB) who documented the number of articles retrieved during each search stage. EndNote reference management software was used to track electronic documents and references.

5.2.4. Source selection

Articles were considered for relevance based on an assessment of the "fit" to the research question. The titles and abstracts of retrieved studies were screened against pre-determined questions to ascertain the relevance of the material to the synthesis aims [238]. These were:

1. For screening article titles: Could this be about the strength and balance exercise component of falls rehabilitation in older adults with cognitive impairment in the community?
2. For screening article abstracts: Could this material provide useful information about completing the strength and balance exercise component of falls rehabilitation in older adults with cognitive impairment in the community?

The inclusion of material was not limited by document, article, or study type. Material was excluded if it was not published in English or did not involve community-based participants or interventions (such as those based on a hospital setting). Reasons for exclusion were documented. If the researcher was unsure about the inclusion of a document, then the second researcher (PL or RH) was used to aid decision making. Disagreements between inclusion and relevance of material was discussed with the stakeholder group.

Material that was considered irrelevant for full-text retrieval was kept until the end of the review process in case of any relevant material to inform programme theory development and testing from studies, which had initially been dismissed due to topic specificity, was required. For example, material that did not involve older adults but those with traumatic brain injury or learning disabilities that relate to a specific area of programme theory development was kept for inclusion during the second search phase if required.

The full-text for eligible studies was retrieved and assessed for quality and extraction of data by the researcher (VB).   The realist synthesis quality standards do not require screening, quality appraisal, or data extraction to be completed independently by two researchers. Unlike a traditional systematic review, the realist process allows for theory development to be influenced by the material identified [232]. However, to ensure that the researcher maintained focus and consistency of judgement, a random sample of 10% of the materials was selected and assessed by the stakeholder group with the remaining 90% completed by the researcher (VB).

5.2.5. Appraising the quality of evidence

Quality appraisal and data extraction were conducted simultaneously, but were distinct and separate processes. Relevance and rigour, two key requirements of a realist synthesis when considering the quality appraisal and extraction of data [237], were assessed.

"*A series of judgements*" ([237], p35) was made concerning the rigour of the material found and the relevance of that material to answering the aims of the synthesis. A combined data extraction sheet was developed for this purpose (Appendix 19). The rigour of the material had to be sufficient to be included in the review. This was judged by asking to what extent "*the methods used to generate the relevant data are credible and trustworthy*" ([237], p35).

Rather than a technical checklist to appraise rigour [121], the researcher considered the credibility and trustworthiness using these questions:

1. Is the material cohesive? Does it tell a comprehensive story or is there a juxtaposition of ideas or isolated statements?
2. What is the value of the evidence?
3. What is the material's position in relation to the programme theory and general topic area?

5.2.6. Data extraction

Data were extracted based on their relevance to the aims of the synthesis and the rough programme theory. Data were sought that substantiated, refined, or refuted the theories. Relevant material within documents was highlighted, labelled, and recorded on the data extraction sheet (Appendix 19). NVivo software was used to record and code the extracted data.

5.2.7. Analysis and synthesis process

A series of questions was asked of the extracted material to aid evidence synthesis. The data extraction sheet, adapted from previous realist reviews [239], outlined these questions (see Appendix 19), and included sections on:

1. Relevance.
2. Interpretation of meaning.

3. Judgements about CMO configurations (CMOcs).
4. Judgements about programme theory.
5. Rigour.
6. Population contextual information.

Extracted material was interpreted into context, mechanism, or outcome relevancy. The CMOcs from the extracted material were recorded and judgements regarding their configurations detailed. This allowed new CMOcs to be identified as well as comparison to the existing MRTs. It was then considered whether the material was trustworthy and rigorous enough to make changes to the rough programme theory or its CMOcs. Synthesis of the materials occurred in an iterative, complementary process.

As the researcher (VB) engaged with and extracted data, there was simultaneous development of reflections and conclusions, documented within NVivo as footnotes attached to the coded material. A process of reasoning occurred whilst the questions from the data extraction sheet were being asked [122]. This reasoning process has been used in other realist syntheses [240], and includes:

- Juxtaposition of sources of evidence (for example when evidence about implementation in one source brings insights into evidence about outcomes in another source).
- Reconciling of sources of evidence (when results differ in apparently similar circumstances, further investigation is appropriate in order to find explanations).
- Adjudication of sources of evidence (on the basis of methodological strengths or weaknesses).

- Consolidation of sources of evidence (when evidence about mechanisms and outcomes is complementary and enables a multi-faceted explanation to be built).
- Situating sources of evidence (when outcomes differ in particular contexts, an explanation can be constructed of how and why these outcomes occur differently).

Extracted, primary data were compared to the relevant MRTs (Appendix 18) to test and refine each pre-identified CMOc. The final programme theory was compiled using the context, mechanisms, and corresponding outcomes from the MRTs. Each included study was compared with the rough programme theories and with the relevant sections of text copied onto the data extraction sheet (Appendix 19).

The final MRTs were narratively described, using text, tables, and graphics. The results of the review are reported as a series of clinical, context-sensitive recommendations, for example, in such a context (C), "x" is likely to happen (O) because of "y" (M). The number and detail of recommendations were based on the data extracted and the final programme theory. The final programme theory and CMOc recommendations were narratively reported.

5.2.8. Changes to review process

The study design was delivered as specified in a published protocol [241]. However, some changes to the process were necessary due to a higher volume of material identified in the initial search. Therefore, once the documents had been selected according to title, they were categorised by title to increase the relevance and specificity, and reviewed in two waves.

Within the first wave, data extraction was limited to fifteen studies, to summarise and review the number of MRT's under consideration. Of the initial fifteen studies, most were experimental or literature review design, with quantitative-based outcomes and a strong focus on the *effect* of the exercise-based intervention. The physiological-response MRT was heavily populated and theoretical saturation was reached. However, there were limited data on "how" exercise influenced falls as an outcome. Therefore, within the second wave of data extraction and appraisal, only data that would specifically populate the outcome component of the physiological-response CMO were extracted.

Most of the included material featured secondary data (such as summaries of other published studies) that were relevant to this review. Another significant change to the data extraction process between the first and second wave was to give priority to primary data, and therefore this distinction in data was added to the extraction database. Snow-ball searching was stopped as relevant data were ascertained through the search.

The second wave involved data extraction and quality appraisal of an additional sixteen papers. No further data were gathered regarding the physiological-responses MRT unless: a) they expressly refuted the refined CMOcs and the MRT as a whole, or b) they contributed to a CMOc that explored "how" exercise reduced falls.

It became clear that qualitative studies were "conceptually richer" ("broader" and "thicker", see Chapter 5.3.2) than clinical trials and quantitative studies [242]. An example of this is illustrated by Hill et al [243] and Suttanon et al [244]. Both articles reported the same trial and intervention, however one was the study protocol [243] and the other qualitative results [244]. The difference between the depth and breadth of data was considerable. Therefore, to improve the potential of populating the other MRTs, a more specific iterative search was employed. A "cited-by" search was completed using Google Scholar for studies that had cited the Suttanon et al [244] paper. On investigation of these, a relevant systematic review was identified [245]. The reference list of this systematic review was then manually searched and three papers identified for consideration of inclusion and data extraction based on their titles. These three papers were chosen for their: i) focus on dementia or AD population, ii) qualitative methods, and iii) reporting experiences of completing an exercise or physical-activity intervention.

5.3. Findings

5.3.1. Document flow diagram

The initial database search identified 1954 papers for consideration (Figure 5.2). Sixty-one papers were identified for inclusion. Material was excluded for not including relevant participant population (n=12) and not being written in English (n=2) (Appendix 20). Sixteen papers from the initial search were not included as theoretical saturation had been reached. The iterative search identified a further four papers.

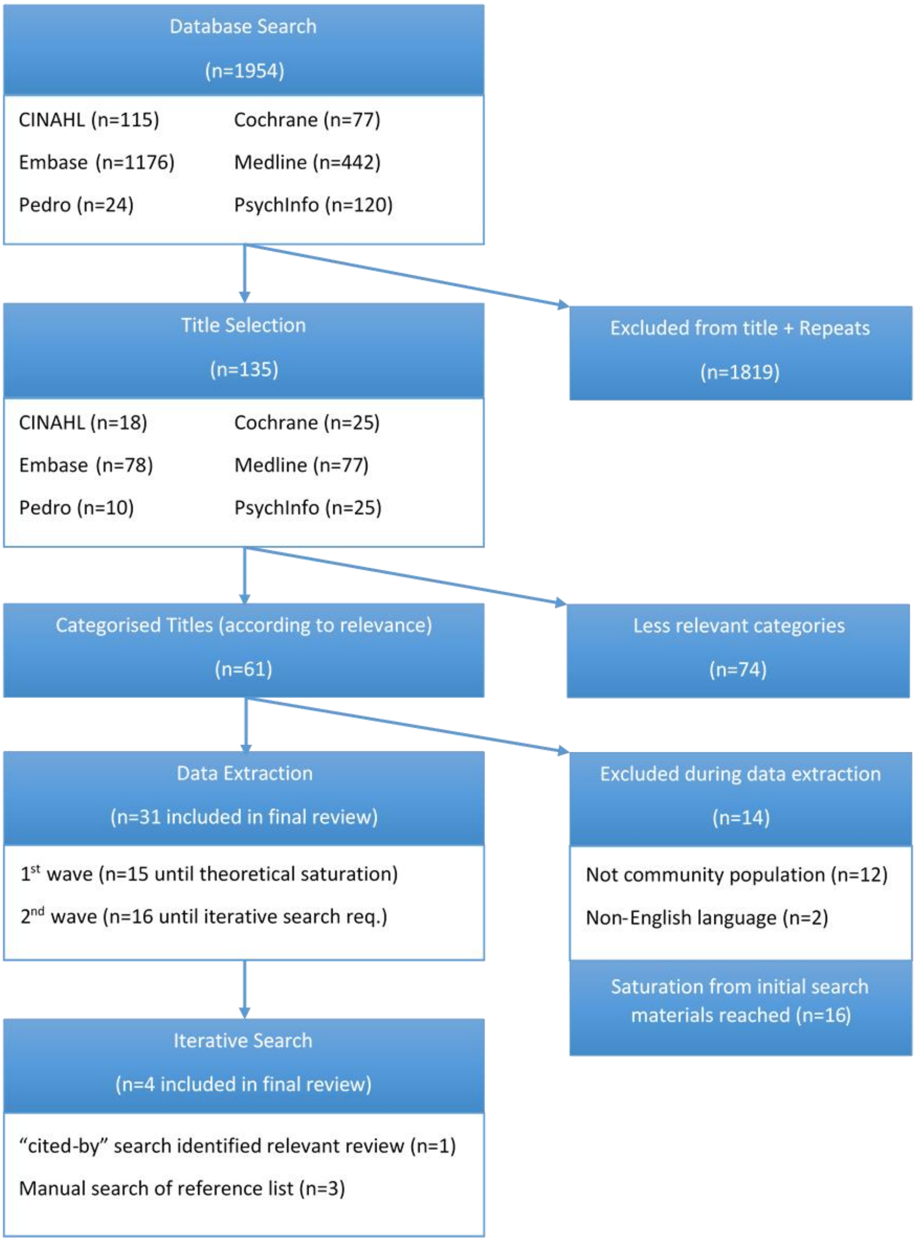


Figure 5.2: Flow diagram of documents in the realist review

5.3.2. Document characteristics

Thirty-five papers were included [103, 217, 243-275]. The papers varied in methodological design. All studies involved community-dwelling older adults with cognitive impairment. The characteristics of the contextual information, including the levels of cognitive impairment and the type, dose, and setting of the interventions, were summarised (Appendix 21) and described in the relevant findings section.

All of the material was characterised according to "conceptual richness" through breadth (broad or narrow) and depth (thick or thin) of data [242]. Classifying the breadth and depth of material has been used in previous realist reviews [242] and provided transparent reflection of the author's opinion on the material's importance and relevance. Material that was conceptually thin would theoretically add little detail or strength of argument to the programme theory refinement. On the other hand, deep and rich material provided enrichment of concepts. The breadth of material related to the number of theories discussed, refined or refuted, with narrow material being potentially focused on only one or two MRTs.

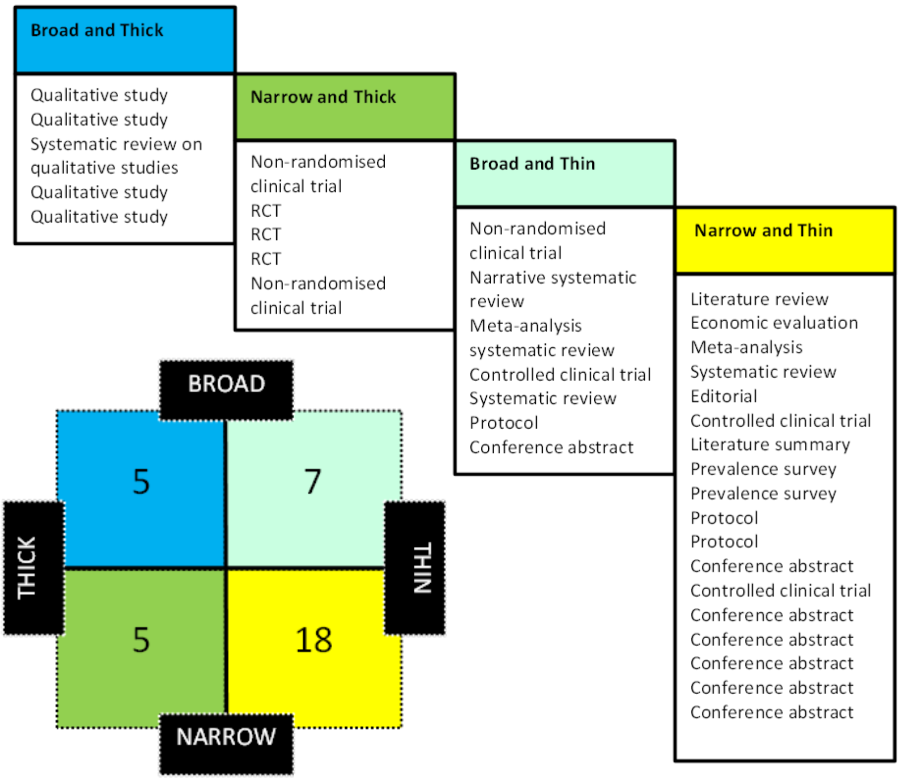


Figure 5.3: Diagram of breadth and depth of included material

Most of the papers from the initial search were narrow in breadth and thin in depth (n=18) (Figure 5.3). The iterative search specifically focused on qualitative study designs and yielded much deeper and broader data on the programme theories (Figure 5.3). All of the papers were quality appraised and all were critiqued according to cohesion, value, and position against other material and the rough programme theory (Appendix 22).

5.3.3. Contextual Characteristics

Data on contextual information about who (population), where (setting), and what (intervention) were reported in the included material were extracted, synthesised, and narratively described (Table 5.1, p180-184).

5.3.3.1. Who: Participants and level of cognitive impairment

An older adult (C^1) with mild to moderate dementia (C^2)

Participant data in included materials were sparse, reported as standard quantitative information (such as age, average cognitive scores, and diagnosis or medical condition), and provided limited information on context-specifics identified within the rough programme theory (such as previous experiences, beliefs, and identification or self-characterisation). Only two studies provided a more detailed description of their sample including previous exercise experience and activity levels [250, 251]. Most studies required a diagnosis of dementia or cognitive assessment score therefore every participant had an awareness of their condition.

Many studies included participants with a range of cognitive impairment levels, from mild to moderate, with only two featuring moderate or severe dementia [103, 217]. Generalising across cognitive levels is not appropriate [260]. The suggestion that improvements found from an intervention in one level of cognitive impairment may not be found in another [260] echoes findings from the meta-analysis ([199] Chapter 4). The included material suggested a "critical period" for improvement within the cognitive impairment continuum [256]. It was questioned if the same intervention and methods of delivery could or should be used in different levels of cognitive impairment [217]. There was conflicting information regarding participation and participant drop-out rates according to level of cognitive impairment [247, 271]. Potentially, another unidentified component or contextual detail (such as carer involvement) could dictate participation, rather than severity of impairment alone [275]. Overall, the participant's level of cognitive impairment was described as both a barrier and non-barrier to participation [245, 267].

5.3.3.2. Where: Setting

Interventions can be in either a home or group setting according to the preferences or wishes of the individual and their carer or spouse (C^3): a home setting might be preferable for those wanting individual support from the intervention staff, or a group setting might be preferable for those wanting carer respite or opportunities for social contact or engagement.

Two main intervention settings were featured: home or group. However, details were not consistently provided [257, 263] and when present were often sparse. Reports conflicted regarding which setting was preferable, home [244] or group

[103]. Characteristics of the different settings suited the preferences and wishes of the different individuals and their situations. For example, a group setting influenced habitual physical activity through travelling to the group [258, 260], potentially provided "respite" for carers [103] and provided an opportunity to socialise [244]. However, group activities may "*present challenging social situations*" ([267], p171), and it was highlighted as important that the structured activity is with others who understand dementia.

In comparison a home setting was viewed as pleasant [103], allowed flexibility around other daily routines, limited potential concentration loss, and involved having individual physiotherapist support [244]. Arguably these qualities are not home specific and could be provided in a setting outside the home. Generally, the papers were limited in describing the direct benefits of a participant's "home" as the setting. A hybrid solution of having different types of setting (home and group) and location (inside and outside) for the same intervention was suggested [244, 245].

5.3.3.3. What: Types of intervention

Interventions that are multicomponent combining physical (including strength/resistance, balance, endurance/mobility, aerobic) and cognitive exercises (C^4), at the correct intensity and level of progression (C^5), supported in the correct way by suitable staff and materials (interaction, communication and connection) (C^6), and with consideration for speed of initiation, length of intervention, encouragement of active lifestyle and enjoyment (C^7).

A range of interventions were featured including: physical therapy protocols (gerontological physical therapy) [255], resistance training [258], outdoor walking [250], and multicomponent programmes [273, 274] including cognitive interventions [256]. Some of the systematic reviews focused on "*physical activity*" rather than exercise per se [247, 267, 275]. Most interventions were multicomponent, featuring balancing and strengthening components. There is great variability within interventions of the same classification (Chapter 3) and the variety of interventions included in this review confirmed those findings. Discussions regarding which components of a multicomponent intervention provided the best outcome were sometimes included [247, 252]. Intensity and progression were important [246, 249, 271]. The influence of the intervention staff, including the interaction, communication, and connection, was considered a component and asset of the intervention [244, 267, 271]. The same can be said of the materials provided for the individual, particularly when the intervention was completed independently or with carers [244].

Particular recommendations were provided concerning the activities of the intervention, including that they should: be introduced slowly, have consideration for the maintenance or longevity of the intervention, and be focused on maintaining or encouraging active lifestyles and enjoyment [267]. Certain types of activity were more enjoyable for different individuals, as was the inclusion of certain types of exercise into the routine of daily life. Whilst the type of exercise was not directly mentioned in respect to building a routine, this is a logical interpretation from papers such as Malthouse and Fox [267], Cedervall et al [251], Pitkala et al [103], and van Alphen et al [245].

5.3.3.4. What: "Dose" of intervention

Intervention that is provided flexibly (C^{8}), for 6-12 months (C^{9}), 2-3 times a week (C^{10}), for minimum 15-20 minutes or whatever can be done to fit in with routine (C^{11}).

The "dose" of an intervention is a combination of frequency, duration, and intensity. A range of intervention doses were included: from 4 hours twice weekly for 12 months [103] to 45 minutes twice weekly for 8 weeks [271] (displayed in Appendix 21). Overall, the optimal dose for an exercise intervention for persons with cognitive impairment is important [253] but has not been defined [258] and is poorly understood [256]. The review papers highlighted this and presented heterogeneous outcome results. Shorter interventions were not effective at changing all measures of interest, such as gait [259]. A six month duration was acceptable for most participants [244], however 12 months was identified as being "sufficient" [103] and produced more conspicuous improvements when compared to 6 months [263].

The number of sessions per week were similar across all included papers and indicates that many interventions were conducted two or three times a week. Intervention sessions were between 30 and 150 minutes in length [217]. However, a brief 15 to 20 minute session length was acknowledged by participants as a valued characteristic and fitted "quite easily" into daily life [244]. The concept of "routine", both in content (such as a daily walk) and duration, was highlighted as being important [245, 250, 251, 267]. The dose and duration of an intervention being tailored to the individual cross-referenced an emergent theme of tailoring during data extraction. A flexible approach limited absences, particularly in consideration of the mood [267] or other health conditions [244], of the participant or their carer.

Six middle-range theories were originally proposed within the rough programme theory. During the review process this evolved into eleven middle-range theories. Two of the most populated and data rich middle-range theories, as well as the related context-specific data, are presented: physiological-responses and encouragement. The other MRTs are not discussed but are presented in diagrammatical format with example CMOcs (Figure 5.4).

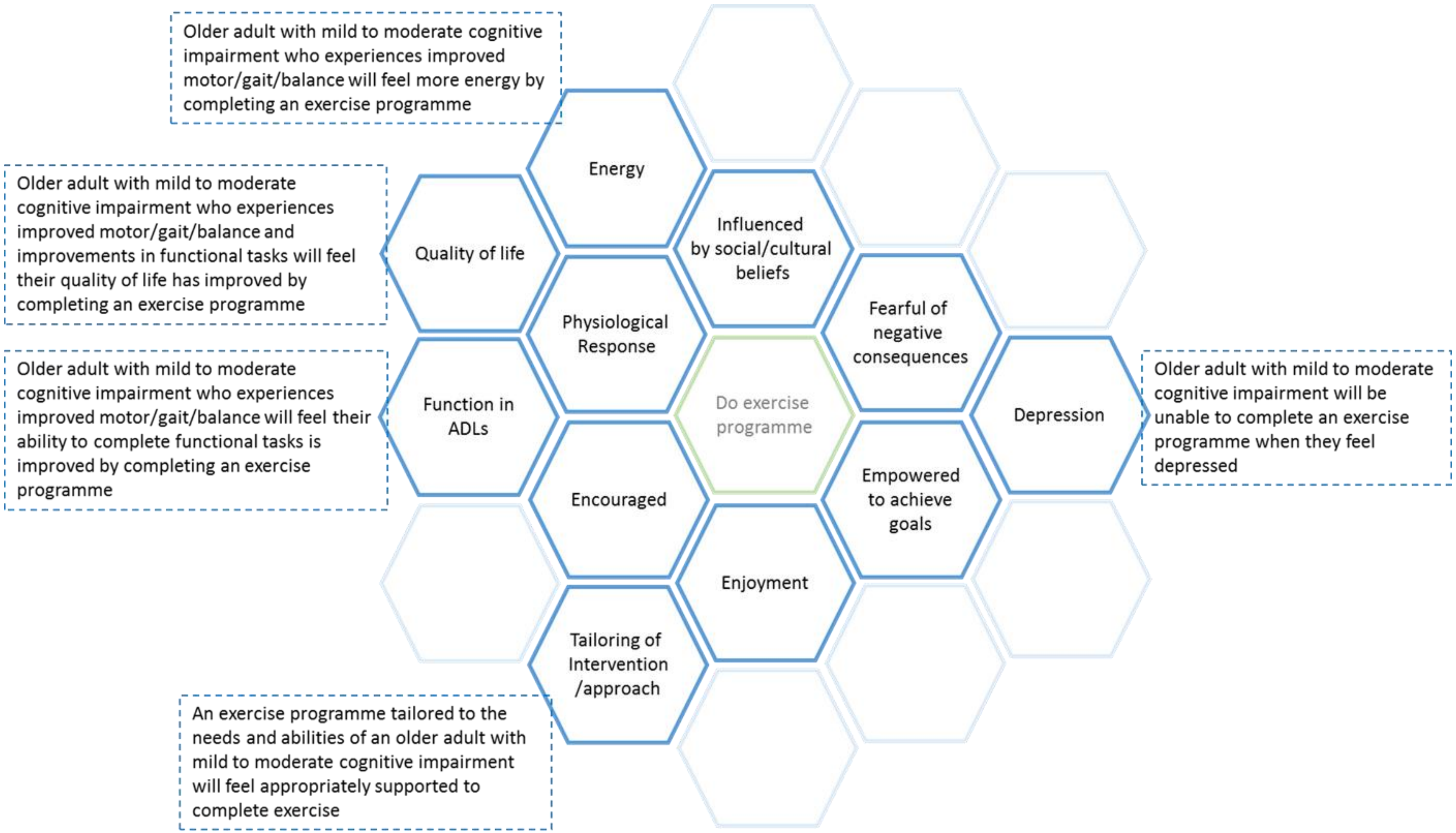


Figure 5.4: Evolved programme theory including emergent MRTs

5.3.4. Physiological-responses

The initial MRT for physiological-responses had five components: cognition, gait, motor, posture, and sensory. During the review process, a sixth component emerged: cardio-vascular. The following narrative describes the outcomes and how they influenced the MRTs and review process, before describing the mechanisms and contexts of each theory component.

5.3.4.1. Outcomes

The rough programme theory outcomes (improved physical ability and reduced risk of falls) were refined during the review process. A gap was identified regarding outcomes on falls risk. Most material described an intermediate outcome, such as improved motor function, rather than falls-specific outcomes. The material provided little explanation of movement between outcomes: *how* does improved motor function reduce the risk of falls and how do we get from outcome^1 to outcome^2? This discrepancy was highlighted when theoretical saturation was reached for physiological-responses MRT and the findings from the first wave of data extraction synthesised. Data related to the outcome of falls was prioritised in the second data extraction wave, with the aim to explore the mechanisms between outcome^1 (such as improved motor function) and outcome^2 (such as reduced risk of falls) in more detail.

5.3.4.2. Cognition response-mechanism

An older adult (C^1) with mild to moderate cognitive impairment (C^2) completing a combined physical and cognitive exercise programme ($M^{resource1}$) or resistance training ($M^{resource2}$) will: improve executive

functioning ($M^{response1}$); stimulate focused attention and sequential organisation of thought and self-control ($M^{response2}$); improve reserves of reasoning, attention and visual and spatial organisation ($M^{response3}$); increase insulin-like growth factor I (IGF-I) ($M^{response4}$); reduce serum homocysteine ($M^{response5}$); have neurogenic and angiogenic effects in hippocampi ($M^{response6}$); improve brain perfusion and increase supply of oxygen and energy substrates in the brain ($M^{response7}$); and/or improve procedural memory and learning systems ($M^{response8}$). This improves cognitive performance (O^1) or diminishes the anticipated decline in cognition (O^2).

Of the 25 papers relevant to cognitive response-mechanisms, twelve included primary data (direct results from their study or synthesis) [246, 250, 253, 254, 259, 261, 264, 265, 268, 269, 271, 272]. Most studies were positive about the influence of the exercise-based interventions on cognition, with only one reporting inconclusive results [253]. Two studies were pure resistance training programmes [254, 259] and two were multicomponent including cognitive stimulation [246, 261]. All of the studies reporting positive findings involved older adults with either mild or moderate dementia.

Overall, there was sparse information on "how" the cognitive-response reduced falls, with only two papers explicitly reporting a link [253, 269]. However, the findings did not support this addition into the CMOc. Most studies focused on the intermediate outcomes of improving [254] or diminishing the anticipated decline in cognition [261] through various responses. Cognitive-responses extracted are included within the CMOc (Table 5.1). The phrase "neural adaptation" by Hageman and Thomas [259] was vague and with poor definition, and was therefore not included within the CMOc.

The lack of data regarding cognitive-responses and falls outcomes is particularly relevant when considered against the theoretical framework previously proposed (Figure 1.3). The relationship between dual-task ability and falls may not have been explicit due to the literature search strategy. However, this does support both the need to model how cognition influences falls risk (Chapter 2) and to study specific interventions further (Chapter 6).

5.3.4.3. Gait response-mechanism

An older adult (C^1) with mild to moderate cognitive impairment (C^2) completing a combined physical and cognitive exercise programme ($M^{resource1}$) or resistance training ($M^{resource2}$) will have faster gait speed ($M^{response1}$), longer strides ($M^{response2}$), and a decreased number of steps ($M^{response3}$), which improves their gait (O^1).

An older adult (C^1) with cognitive impairment (C^2) and improved gait (C^3) will have better or normalised quality gait pattern ($M^{response4}$) which reduces their risk of falls (O^2).

Fourteen studies produced primary data on the gait response-mechanism [217, 246, 247, 250, 251, 253, 254, 259-262, 269, 270, 272]. A mixture of interventions was included: resistance [254, 259] and multicomponent [246, 247, 260, 261]. All the data supporting the CMOc were from mild to moderate dementia populations. Data from one study did not support the CMOc [217] and was the only study to include people with moderate to severe dementia.

Most studies demonstrated a positive effect on gait parameters involving mechanisms including: faster gait speed [247, 259, 261], longer strides [261], and a decreased number of steps [246]. Overall this improves gait pattern

[254, 260]. Two studies reported inconclusive responses [217, 253], however both were syntheses from a relatively long time ago (2006 and 2007). Despite many studies mentioning falls, few provided mechanisms on how gait-responses reduce falls [250, 262, 269, 270, 272]. A range of physical activity levels in people with dementia were described in one study, and highlighted that those who were more physically active (often labelled as "wanderers") were more exposed to risk and therefore fell more often [262]. Theoretically it is not the "amount" of walking that physical activity or exercise achieves, but the "quality" of the walking pattern which defines associated risk. These findings correspond with research from outside the review materials, where more walking provides more exposure to risk of falls [276]. Improving quality [272], control [270], and stability [251, 269] are response-mechanisms which link improved gait pattern and ability to exposure and risk of falls [262, 276].

5.3.4.4. Motor response-mechanism

An older adult (C^1) with mild to moderate cognitive impairment (C^2) completing a combined physical and cognitive exercise programme ($M^{resource1}$) or resistance training ($M^{resource2}$) will have: greater lower limb strength (knee extension and flexion) ($M^{response1}$); greater flexibility ($M^{response2}$); improved recruitment and synchronisation of motor units ($M^{response3}$); positive impacts on grip strength and fine motor coordination ($M^{response4}$); maintained agility ($M^{response5}$); and/or improved endurance ($M^{response6}$). This improves their motor function (O^1) or diminishes the anticipated decline in motor function (O^2), improves functional capacity (O^3), and maintains ability of manual skills (O^4).

Thirteen studies contributed primary data to the motor response-mechanism [103, 217, 246, 247, 253, 258, 260-262, 264, 265, 270, 271]. The interventions were either multicomponent [246, 247, 260, 261] or resistance training [247, 258], with Christofoletti et al [253] labelling their intervention as a "motor intervention".

Reported outcomes were mainly related to improvements in function [246, 247, 260], maintenance [258], or minimised motor or physical decline [253, 261] rather than falls risk. Strength was a common motor response-mechanism [246, 247, 258, 260] with others including: greater flexibility [246], improved recruitment and synchronisation of motor units [258], positive impacts on grip strength (as indicator of overall muscle strength), fine motor coordination and refinement of visual acuity [258], maintenance of agility [258, 261], and improved endurance [247]. One study contradicted the CMOc [217] reporting only a limited number of studies that demonstrated improvements in motor aspects from their synthesis. As with gait, "control" as a secondary response-mechanism is subtly indicated in the motor CMOc through secondary data interpretations [264, 270].

There was considerable cross-over between physiological-responses, such as motor and gait. However, it was suggested that improvement in one physiological component did not necessarily translate across them all. Pitkala et al [103] identified that in one of their intervention groups there was improvement in muscle strength (O^1) but not in gait (or function). This suggests that specificity of training is required. Unfortunately, the data were not substantial enough to influence the CMOc for the motor response-mechanism.

5.3.4.5. Postural response-mechanism

An older adult (C^1) with mild to moderate cognitive impairment (C^2) completing a combined physical and cognitive exercise programme ($M^{resource1}$) or aerobic training ($M^{resource2}$) will have: less body-sway ($M^{response1}$), improved postural control ($M^{response2}$), improved balance-related functions ($M^{response3}$), improved dynamic balance ($M^{response4}$), better management of active ankle and hip strategies ($M^{response5}$), and enhanced postural muscle control capacity ($M^{response6}$). This improves (O^1) or maintains (O^2) their balance.

An older adult (C^1) with mild to moderate cognitive impairment (C^2) who can maintain their balance (C^3) will be protected ($M^{response7}$) against an increased risk of falls (O^3).

Data on postural response-mechanisms were extracted from eight papers [246, 247, 254, 260, 261, 263, 264, 269]. All the interventions involved either multicomponent [246, 247, 260, 261] or aerobic-based [254] exercises. Resistance training did not trigger the postural response-mechanism [254]. All the studies featured mild to moderate dementia samples. The responses extracted included: less body-sway [246], improved postural control [246], improvement in balance-related functions [260], improved dynamic balance [260], better management of active ankle and hip strategies [264], and enhanced postural muscle control capacity [263]. Outcomes included improvements in balance and posture [247, 254] or maintenance of ability [261].

Despite reporting no association between balance ability and falls in their study population, Pedroso et al [269] described the multifactorial nature of falls as explanation for their findings, indicating that the "context" of the individual and the situation might have a greater role in the mechanisms for reducing falls than the physiological-responses. Whilst these data were contradictory to the initial stage of the CMOc, it did prompt a secondary CMOc that has been included. The interpretation is, that in the context of an older adult with cognitive impairment being able to maintain their balance, there is an element of protection against future and further falls risk [269].

5.3.4.6. Sensory response-mechanism

Sensory response-mechanisms suggested within the rough programme theory were not supported by the included studies. No data were extracted supporting or contradicting these mechanisms, therefore, this component is not included in the refined physiological-responses MRT.

5.3.4.7. Cardiovascular response-mechanism

Cardiovascular response-mechanisms (relating to the heart or blood vessels) emerged during the review process from three studies [248, 254, 269]. Extracted data were from secondary sources (such as summaries of other literature). The results were conflicting, neither supporting nor refuting the addition of cardiovascular responses into the programme theory. Therefore, these data did not assist in refining the programme theory.

Summary of the physiological-responses MRT

Exercise-based interventions, including combined and single concept programmes, triggered several physiological-responses within older adults with mild to moderate cognitive impairment. Gait and postural response-mechanisms were associated with influencing falls outcomes through improvements in control of movement and maintenance of abilities. Many aspects of the rough programme theory were congruent with the included studies, with one emergent component (cardiovascular) and only one component (sensory) “silent” of evidence.

Many of the components were interlinked, with data covering more than one response-mechanism, blending interpretations together. Clarifying and unpicking the potential relationships was open to interpretation and all CMOcs were therefore modest in their certainty. Data were particularly sparse for developing CMOcs from intermediate to secondary outcomes. A considerable amount of secondary data was extracted from included studies. Wherever possible, primary data from the included material were used to influence the CMOcs.

5.3.5. Encouragement

The encouragement MRT was the second most populated theory following physiological-responses. Data were extracted from 22 of the 35 review documents [103, 217, 244-247, 249-253, 257, 258, 260-262, 265, 267, 271, 273, 275]. During data extraction and synthesis, it became apparent that there were two mechanisms operating: a) perceived benefit and b) support.

5.3.5.1. Perceived benefit

An older adult (C^1), with dementia (C^2), with the belief that exercise is advantageous (C^3) or a positive attitude to exercise (C^4), will perceive

the benefit ($M^{response1}$) of completing (O^1) an exercise intervention ($M^{resource}$).

An older adult (C^1), with dementia (C^2), with either a carer or themselves having previous experience of being active and participating in exercise (C^5), and with a perception that exercise is beneficial (C^6), will feel encouraged ($M^{response2}$) to complete (O^1) an exercise intervention ($M^{resource}$).

The perception or feeling of benefit was an emergent concept [244, 245, 247, 250, 251, 262, 267] and could be interpreted as either a response-mechanism or context. The perception or realisation of the benefits of exercise could be a feeling or response-mechanism generated by the supporting staff and their qualities as a resource, resulting in the older adult with cognitive impairment feeling, perceiving, or recognising exercise as beneficial.

Interpretation of Suttanon et al [244] suggests the perception of benefit could be a response-mechanism that is operating when the person with cognitive impairment has "*prior experience of being active, participating in exercises, and perceiving benefits of general exercise*" ([244], p1180). These context features are relevant for both the participant and carer [244]. Understanding an individual's previous experience of exercise and their perceptions regarding it can allow tailoring of approaches [244].

However, it could also be construed from Suttanon et al [244] that a perception or realisation of the benefits of exercise may be a characteristic or feature of the person with cognitive impairment or their carer, and therefore is a context component. In reality, this is both context and response-mechanism, moving within the CMOc depending upon the individual and other context components.

Reinforcement by physiological-responses

An older adult (C^1), with dementia (C^2), who has the ability to comprehend (C^7) and who does identify physical or functional changes (C^8) will perceive the benefit ($M^{response1}$) from completing (O^1) an exercise intervention ($M^{resource}$).

Recognition of improvements or changes in physiological-responses reinforce an individual's perception of benefit. When improvements are made and recognised, for example in function or physical ability, there is an improvement in participation [247]. Identification of benefit is important for both participation and the maintenance of an intervention [250, 251]. Huger et al [262] identified that persons with cognitive impairment can "*suffer from multiple problems*", which could include lack of comprehension of the benefits of training. This would influence ability to identify benefits from completing exercise. Whilst this statement seems particularly negative towards participants, it could be interpreted as a context component for certain individuals, rather than a general characteristic of all older adults with cognitive impairment.

Reinforcement by external supporter

An older adult (C^1), with dementia (C^2), who has an external supporter who either understands the benefits of exercise, or who can prompt regarding the benefits of exercise, or who enables the person with dementia to compare themselves with others (C^9), will perceive benefit ($M^{response1}$) from completing (O^1) an exercise intervention ($M^{resource}$).

Both the older adult with dementia and the carer are involved in the perception of benefit response-mechanism [250]. Synergy is required between the carer's understanding, support, and ability to address barriers to exercise, and the participant's comprehension [245, 250]. An emergent context was the perception of exercise health benefits for others, which produced the support and encouragement which prompted participation. For example, an individual walking his dog demonstrates an external source as a prompt and reinforcement of the health benefits of engaging in physical activity [250]. The feeling of encouragement could also come from being able to compare themselves with others that have the same diagnosis, but only in the context where the older adult with dementia was doing well [251].

Benefit versus risk?

An older adult (C^1) with dementia (C^2) who has a carer who perceives that the benefit for the person with dementia doing exercise outweighs the risk of doing exercise or the burden of extra care duties (C^{10}) will provide support ($M^{response3}$) for the participation (O^1) in an exercise programme ($M^{resource1}$) or routine physical activity ($M^{resource2}$).

The carer's perception and belief in the benefit of exercise must outweigh the risk, care burden, or adaption required to complete the exercise [250, 267]. Negative connotations to exercising (reminder of inability to do previously enjoyable activities or potential deterioration), adaptions, or changes to routines or daily lives that are required to support the physical activity are destructive to the perception of benefit for both the person providing the support and the person with dementia [250]. Concern regarding risks involved is a context component that is particularly relevant when the person providing support to exercise is a spouse, relative, or carer. Concern can be both facilitator and barrier to engagement in exercise, such as concern about not staying mobile and healthy versus concern about getting lost or falling [267].

Types of benefit

An older adult (C^{1}) with dementia (C^{2}) who has a carer who perceives benefit on mood (C^{11}), behaviour (C^{12}), weight (C^{13}), flexibility (C^{14}), ageing (C^{15}), and enjoyment of everyday life (C^{16}) for that older adult doing exercise (C^{17}) will provide support ($M^{response3}$) for the participation (O^{1}) in an exercise programme ($M^{resource1}$) or routine physical activity ($M^{resource2}$).

Benefits perceived from completing exercise were not limited to health outcomes. Benefits reported included: mood [250, 267], behaviour, quality of everyday life [250], weight, flexibility, and ageing [267]. A contentious benefit was an attempt to re-establish previous activities or the "person" that came before the dementia diagnosis or progression of cognitive impairment [250]. Cedervall and Aberg [250] reported this perception as coming from the person providing the support. The consideration of how exercise might influence dementia or benefit falls risk was not directly reported [267].

5.3.5.2. Support

Support was a frequently reported concept and identifiable both directly [249-251] and indirectly [247] throughout extracted material. The support could be provided through supervision [252, 262], practical measures [250], supportive strategies such as making or maintaining routines [251] or through emotional support [251, 262].

There were many references to people providing the support. Examples extracted from the review material include: students [247, 249], carers [244, 245, 249, 267, 275], family members [275], physiotherapists [103, 244, 249], occupational therapists [249], trained personnel [252, 262, 265], dogs or animals [250], spouses or significant others [250, 251], community and fitness centres [265], healthcare providers [273], and society in general [267].

How support was given was varied and included: telephone or mobile phone [250], talking during an intervention session [247], supervision and prompts by professionals during intervention session [244, 249], carers encouraging participation between intervention sessions [249], making practical arrangements [250], or providing assistance [251].

Role of the professional

An older adult (C^1) with dementia (C^2) who is supervised by trained personnel ($M^{resource1}$) who give clear and repeated instructions (C^3), who optimally progress the exercises (C^4), who provide the amount of supervision required by that individual and their needs (C^5), and who understand the needs of persons with dementia (C^6) will feel supported ($M^{response1}$) to complete (O^1) an exercise programme ($M^{resource2}$).

An older adult (C^1) with dementia (C^2) who is being supported ($M^{response1}$) by a professional person ($M^{resource1}$) who can time-manage (C^7); who is knowledgeable (C^8); who is firm but encouraging (C^9); who is kind, friendly, or supportive (C^{10}); who understands dementia (C^{11}); and who can develop a rapport with the individual (C^{12}), will do an exercise programme (O^1).

Supervision was discussed as a component of support [252]. In particular, supervision by trained personnel "*met the special needs of persons with cognitive impairment*" ([252], p153) by giving clear and repeated instructions, optimally progressing the programme, and providing the amount of supervision required depending upon their ability to understand and learn new information [252].

Huger et al [262] also credited training instructors with providing more than just formal support during an intervention. The health professional or intervention staff were influential in both the commencement, participation and maintenance of exercise [244]. Key characteristics of the professional person included: time management (not being intrusive or disruptive, and being prompt with sessions and support provided), and being knowledgeable and firm, but also encouraging, understanding, kind, friendly, and supportive [244]. An ability to "*understand my problem*" ([267], p172) was also identified as key, particularly in regards to dementia. This facilitated rapport development between supporter and person with dementia, which included a relationship built on personal information [271] and trust [245].

Role of the carer

An older adult (C^{1}) with dementia (C^{2}), who has a carer (C^{13}) who perceives a benefit from the older adult doing exercise (C^{14}), and who can provide transport (C^{15}), a positive attitude (C^{16}), practical considerations (C^{17}), supportive strategies (C^{18}), and/or assistance (C^{19}), will feel supported ($M^{\text{response1}}$) to complete (O^{1}) an exercise programme ($M^{\text{resource1}}$) or routine physical activity ($M^{\text{resource2}}$).

An older adult (C^{1}) with more severe dementia (C^{20}) will require more support ($M^{\text{response1}}$) to successfully participate (O) in exercise programme ($M^{\text{resource1}}$) or routine physical activity ($M^{\text{resource2}}$).

An older adult (C^{1}) with dementia or AD (C^{2}) who has a carer (C^{13}) who receives information (C^{21}) and on-going support (C^{22}) from the therapist or intervention staff ($M^{\text{resource1}}$) to enable them to support ($M^{\text{response1}}$) the participation or completion of an exercise programme of the person with dementia (O^{1}).

Carers were a frequently discussed and important component in terms of the support they provided [275]. The role of the carer was described by Malthouse and Fox [267] as "*facilitators to activity*" and "*gate-keepers*". Malthouse and Fox [267] used this term in reference to the avoidance of stressful or negative situations but also incorporated the provision of transport to intervention sessions [246, 261], promoting a positive attitude [257], organising the practical arrangements needed to complete exercise [250], and employing specific strategies [251] and additional assistance [275] that were specific to an older adult with dementia and their situation. There were many ways in which the carers provided support.

Carers also counteracted the "*loss of initiation and motivation*" that is a characteristic of AD [245]. The promotion of exercise either in the practical or emotional sense implies an underlying assumption or perception that the activity is beneficial for the individual or themselves as a carer. There were limited data that carers received encouragement, benefit, or reduced distress from providing support for the person with cognitive impairment [103, 253], although the complex nature of this relationship was illustrated with contradictory data [103, 245, 267, 275].

Carers provided varying levels of support that were tailored to the individual and their carer [244, 250]. Carer involvement was integral to programme delivery in one study [244]. The carer and their support was more influential the more severe the cognitive impairment and may account for why persons with severe dementia were still able to engage in interventions [275]. However, it was highlighted how complex the support component is, particular as cognitive impairment progresses [275]. Van Alphen et al [245] suggest that because persons with dementia require care and support, they are more influenced by support as a variable in an intervention. The carers themselves also require support, with information identified as a resource-mechanism to enable the support to take place. Carers require information from the professionals or intervention staff to enable their support of the person with dementia [244, 245].

Role of a group setting

An older adult (C^{1}) with dementia (C^{2}) who wants to exercise in a group (C^{23}), will feel supported ($M^{response1}$) to complete (O^{1}) a group exercise programme ($M^{resouce1}$) or group physical activity ($M^{resource2}$).

Support was also provided in interventions delivered as groups, from both the trained staff running the sessions and social aspect [258, 261]. Individuals within the group were contributing components, particularly with regards to understanding the issues and experiences of someone with dementia [245, 267]. Undertaking exercise with others was a context feature and reinforced the conflicting information regarding which setting, home or group, is more advantageous.

Positive results from the social aspect of a group intervention were reported by some studies directly [244] and indirectly [217]. However, this was not consistent across all material within the review [258]. Differences in participation and outcomes could be explained by the personality and preferences of the individuals. Some individuals will have had a strong opinion on attending groups of people with dementia and this in itself will have influenced their participation [103, 244, 260]. Tailoring the setting of the intervention is an interesting consideration for future research studies and would address the individual preferences.

Society and societal attitudes were suggested as having positive and negative influences on physical activity [267]. The influence of social and cultural expectations and beliefs was proposed within the rough programme theory and, whilst not explored within these findings, has overlap with the findings on encouragement. Malthouse and Fox [267] indirectly describes other societal forms of support, such as day and leisure centres. Even when describing the bigger societal picture, Malthouse and Fox [267] referenced "*understanding*", strengthening the earlier discussion on the characteristics of the source of the support response-mechanism.

Lack of support

An older adult (C^{1}) with dementia (C^{2}) who has a poorer ability to understand and learn new information (C^{24}), who has not exercised previously (C^{25}), who has ill-health (C^{26}), or who has regular holidays (C^{27}), will not access the required support needed to exercise ($M^{resource1}$) and therefore will not feel supported ($M^{response1}$) to complete an exercise programme(O^{1}).

Lack of support resulted in poor adherence or participation in exercise [249], conversely reinforcing support as a response-mechanism. Other reasons identified by Burton et al [249] for poor participation included lack of previous exercise experience, ill-health, and holidays. All of these context features provide arguments for tailoring an exercise-based programme. Lack of support has also been attributed to poor effectiveness within trials of certain interventions [217] and as a barrier to physical activity [245].

Summary of encouragement MRT

Exercise-based interventions and physical activity were resources utilised in a variety of contextual situations to engage the encouragement MRT within older adults with mild to moderate cognitive impairment to achieve a multitude of benefits. A perception of benefit encouraged participation in exercise and is a context component for both the individual and their supporter or "*gate-keeper*". Support was identified from a number of sources and methods in which contextual details were relevant for their success in that role. There was considerable overlap between CMOcs in the encouragement MRT and other theories both emergent from and from within the rough programme theory.

Programme Theory Component	CMOc	Reference
Context	An older adult ($\mathbf{C}^{1}$) with mild to moderate dementia ($\mathbf{C}^{2}$).	**Context (C) number:** 1. All 2. Andrade [246]; Blankevoort [247]; Boyle [248]; Burton [249]; Cedervall [250]; Cedervall [251]; Chan [252]; Davis [254]; de Oliveira [255]; Frederiksen [257]; Garuffi [258]; Hauer [260]; Hernandez [261]; Huger [262]; Jeon [263]; Leandri [264]; Liu-Ambrose [265]; Malthouse [267]; Makizako [266]; Park [268]; Pedroso [269]; Pitkala [270]; Pitkala [103]; Ries [271]; Shimada [274]; Shimada [273]; Stubbs [275]; Suttanon [244]; van Alphen [245]
	Either a home or group setting according to the preferences or wishes of the individual and their carer or spouse ($\mathbf{C}^{3}$): a home setting might be preferable for those wanting individual support from the intervention staff, or a group setting might be preferable for those wanting carer respite or opportunities for social contact or engagement.	**Context (C) number:** 3. Suttanon [244]; Pitkala [103]; Garuffi [258]; Hauer [260]; Malthouse [267]; van Alphen [245]
	Interventions that are multicomponent combining physical (including strength/resistance, balance, endurance/mobility, aerobic) and cognitive exercises ($\mathbf{C}^{4}$), at the correct intensity and level of progression ($\mathbf{C}^{5}$), supported in the correct way by suitable staff and materials (interaction, communication and connection) ($\mathbf{C}^{6}$), and with consideration for speed of initiation, length of intervention, encouragement of active lifestyle and enjoyment ($\mathbf{C}^{7}$).	**Context (C) number:** 4. Shimada [274]; Shimada [273]; Erickson [256]; Blankevoort [247]; Chan [252] 5. Andrade [246]; Burton [249]; Ries [271] 6. Ries [271]; Suttanon [244]; Malthouse [267] 7. Malthouse [267]; van Alphen [245]
	Intervention that is provided flexibly ($\mathbf{C}^{8}$), for 6-12 months ($\mathbf{C}^{9}$), 2-3 times a week ($\mathbf{C}^{10}$), for 15-20 minutes or whatever can be done to fit in with routine ($\mathbf{C}^{11}$).	**Context (C) number:** 8. Malthouse [267]; Suttanon [244] 9. Suttanon [244]; Pitkala [103]; Jeon [263] 10. Park [268]; Jeon [263]; Hauer [177]; Pitkala [103]; Liu-Ambrose [265]; Hernandez [261]; Shimada [274]; Shimada [273]; Makizako [266]; Hauer [260]; Garuffi [258]; Huger [262]; Frederiksen [257]; Hageman [259]; Ries [271] 11. Hauer [217]; Cedervall [250]; Cedervall [251]; Malthouse [267]; van Alphen [245]; Suttanon [244]

Physiological responses	**Cognition**	An older adult ($\mathbf{C}^1$) with mild to moderate cognitive impairment ($\mathbf{C}^2$) completing a combined physical and cognitive exercise programme ($\mathbf{M}^{resource1}$) or resistance training ($\mathbf{M}^{resource2}$) will: improve executive functioning ($\mathbf{M}^{response1}$); stimulate focused attention and sequential organisation of thought and self-control ($\mathbf{M}^{response2}$); improve reserves of reasoning, attention and visual and spatial organisation ($\mathbf{M}^{response3}$); increase insulin-like growth factor I (IGF-I) ($\mathbf{M}^{response4}$); reduce serum homocysteine ($\mathbf{M}^{response5}$); have neurogenic and angiogenic effects in hippocampi ($\mathbf{M}^{response6}$); improve brain perfusion and increase supply of oxygen and energy substrates in the brain ($\mathbf{M}^{response7}$); and/or improve procedural memory and learning systems ($\mathbf{M}^{response8}$). This improves cognitive performance ($\mathbf{O}^1$) or diminishes the anticipated decline in cognition ($\mathbf{O}^2$).	**Mechanism-Response ($\mathbf{M}^{response}$) number:** 1. Andrade [246] 2. Andrade [246] 3. Cedervall [250]; Davis [254] 4. Liu-Ambrose [265] 5. Liu-Ambrose [265] 6. Park [268]; Leandri [264] 7. Pedroso [269] 8. Ries [271] **Outcome (O) number:** 1. Davis [254] 2. Davis [254]; Hernandez [261]
	Gait	An older adult ($\mathbf{C}^1$) with mild to moderate cognitive impairment ($\mathbf{C}^2$) completing a combined physical and cognitive exercise programme ($\mathbf{M}^{resource1}$) or resistance training ($\mathbf{M}^{resource2}$) will have faster gait speed ($\mathbf{M}^{response1}$), longer strides ($\mathbf{M}^{response2}$), and a decreased number of steps ($\mathbf{M}^{response3}$), which improves their gait ($\mathbf{O}^1$). An older adult ($\mathbf{C}^1$) with cognitive impairment ($\mathbf{C}^2$) and improved gait ($\mathbf{C}^3$) will have better or normalised quality gait pattern ($\mathbf{M}^{response4}$) which reduces their risk of falls ($\mathbf{O}^2$).	**Mechanism-Response ($\mathbf{M}^{response}$) number:** 1. Hageman [259]; Hernandez [261]; Blankevoort [247] 2. Hernandez [261] 3. Andrade [246] 4. Huger [262]; Pedroso [269]; Pitkala [270]; Sageat [272]; Cedervall [250]; Cedervall [251] **Outcome (O) number:** 1. Hauer [260]; Davies [254] 2. Huger [262]; Pedroso [269]; Pitkala [270]; Sageat [272]; Cedervall [250]; Cedervall [251]
	Motor	An older adult ($\mathbf{C}^1$) with mild to moderate cognitive impairment ($\mathbf{C}^2$) completing a combined physical and cognitive exercise programme ($\mathbf{M}^{resource1}$) or resistance training ($\mathbf{M}^{resource2}$) will have: greater lower limb strength (knee extension and flexion) ($\mathbf{M}^{response1}$); greater flexibility ($\mathbf{M}^{response2}$); improved recruitment and synchronisation of motor units ($\mathbf{M}^{response3}$); positive impacts on grip strength and fine motor coordination ($\mathbf{M}^{response4}$); maintained agility ($\mathbf{M}^{response5}$); and/or improved endurance ($\mathbf{M}^{response6}$). This improves their motor function ($\mathbf{O}^1$) or diminishes the anticipated decline in motor function ($\mathbf{O}^2$), improves functional capacity ($\mathbf{O}^3$), and maintains ability of manual skills ($\mathbf{O}^4$).	**Mechanism-Response ($\mathbf{M}^{response}$) number:** Chapter 1. Andrade [246]; Garuffi [258]; Blankevoort [247]; Hauer [260] Chapter 2. Andrade [246] Chapter 3. Garuffi [258] Chapter 4. Garuffi [258] Chapter 5. Garuffi [258]; Hernandez [261] Chapter 6. Blankevoort [247] **Outcome (O) number:** 1. Andrade [246]; Blankevoort [247]; Hauer [260]; Liu-Ambrose [265] 2. Hernandez [261]; Christofoletti [253] 3. Pitkala [270]; Pitkala [103] 4. Garuffi [258]; Ries [271]

	Postural	An older adult ($\mathbf{C}^{1}$) with mild to moderate cognitive impairment ($\mathbf{C}^{2}$) completing a combined physical and cognitive exercise programme ($\mathbf{M}^{\text{resource1}}$) or aerobic training ($\mathbf{M}^{\text{resource2}}$) will have: less body-sway ($\mathbf{M}^{\text{response1}}$), improved postural control ($\mathbf{M}^{\text{response2}}$), improved balance-related functions ($\mathbf{M}^{\text{response3}}$), improved dynamic balance ($\mathbf{M}^{\text{response4}}$), better management of active ankle and hip strategies ($\mathbf{M}^{\text{response5}}$), and enhanced postural muscle control capacity ($\mathbf{M}^{\text{response6}}$). This improves ($\mathbf{O}^{1}$) or maintains ($\mathbf{O}^{2}$) their balance. An older adult ($\mathbf{C}^{1}$) with mild to moderate cognitive impairment ($\mathbf{C}^{2}$) who can maintain their balance ($\mathbf{C}^{3}$) will be protected ($\mathbf{M}^{\text{response7}}$) against an increased risk of falls ($\mathbf{O}^{3}$).	**Mechanism-Response ($\mathbf{M}^{\text{response}}$) number:** 1. Andrade [246] 2. Andrade [246] 3. Hauer [260] 4. Hauer [260] 5. Leandri [264] 6. Jeon [263] 7. Pedroso [269] **Outcome (O) number:** 1. Blankevoort [247]; Davis [254] 2. Hernandez [261] 3. Pedroso [269]
	Vascular	n/a	**Data not informative**: Davis [254]; Boyle [248]; Pedroso [269]
Encouraged	**Perception of benefit**	An older adult ($\mathbf{C}^{1}$), with dementia ($\mathbf{C}^{2}$), with the belief that exercise is advantageous ($\mathbf{C}^{3}$) or a positive attitude to exercise ($\mathbf{C}^{4}$), will perceive the benefit ($\mathbf{M}^{\text{response1}}$) of completing ($\mathbf{O}^{1}$) an exercise intervention ($\mathbf{M}^{\text{resource}}$). An older adult ($\mathbf{C}^{1}$), with dementia ($\mathbf{C}^{2}$), with either a carer or themselves having previous experience of being active and participating in exercise ($\mathbf{C}^{5}$), and with a perception that exercise is beneficial ($\mathbf{C}^{6}$), will feel encouraged ($\mathbf{M}^{\text{response2}}$) to complete ($\mathbf{O}^{1}$) an exercise intervention ($\mathbf{M}^{\text{resource}}$).	**Context (C) number:** 1. All 2. All 3. Suttanon [244]) Cedervall [250]; Malthouse [267] 4. Suttanon [244]; Cedervall [250]; Malthouse [267] 5. Suttanon [244]; Cedervall [250]; Malthouse [267] 6. Suttanon [244]; Cedervall [250]; Malthouse [267] **Mechanism-Response ($\mathbf{M}^{\text{response}}$) number:** 1. Suttanon [244] 2. Suttanon [244]; Cedervall [250]; Malthouse [267]
		An older adult ($\mathbf{C}^{1}$), with dementia ($\mathbf{C}^{2}$), who has the ability to comprehend ($\mathbf{C}^{7}$) and who does identify physical or functional changes ($\mathbf{C}^{8}$) will perceive the benefit ($\mathbf{M}^{\text{response1}}$) from completing ($\mathbf{O}^{1}$) an exercise intervention ($\mathbf{M}^{\text{resource}}$).	**Context (C) number:** 7. Huger [262] 8. Blankevoort [247]; Cedervall [250]; Cedervall [251]
		An older adult ($\mathbf{C}^{1}$), with dementia ($\mathbf{C}^{2}$), who has an external supporter who either understands the benefits of exercise, or who can prompt regarding the benefits of exercise, or who enables the person with dementia to compare themselves with others ($\mathbf{C}^{9}$), will perceive benefit ($\mathbf{M}^{\text{response1}}$) from completing ($\mathbf{O}^{1}$) an exercise intervention ($\mathbf{M}^{\text{resource}}$).	**Context (C) number:** 9. Cedervall [250]; Cedervall [251]; Van Alphen [245]

	An older adult ($\mathbf{C}^{1}$) with dementia ($\mathbf{C}^{2}$) who has a carer who perceives that the benefit for the person with dementia doing exercise outweighs the risk of doing exercise or the burden of extra care duties ($\mathbf{C}^{10}$) will provide support ($\mathbf{M}^{response3}$) for the participation ($\mathbf{O}^{1}$) in an exercise programme ($\mathbf{M}^{resource1}$) or routine physical activity ($\mathbf{M}^{resource2}$).	**Context (C) number:** 10. Cedervall [250]; Malthouse [267] **Mechanism-Response ($\mathbf{M}^{response}$) number:** 3. Cedervall [250]; Malthouse [267]
	An older adult ($\mathbf{C}^{1}$) with dementia ($\mathbf{C}^{2}$) who has a carer who perceives the benefit on mood ($\mathbf{C}^{11}$), behaviour ($\mathbf{C}^{12}$), weight ($\mathbf{C}^{13}$), flexibility ($\mathbf{C}^{14}$), ageing ($\mathbf{C}^{15}$), and enjoyment of everyday life ($\mathbf{C}^{16}$) from that older adult doing exercise ($\mathbf{C}^{17}$) will provide support ($\mathbf{M}^{response3}$) for the participation ($\mathbf{O}^{1}$) in an exercise programme ($\mathbf{M}^{resource1}$) or routine physical activity ($\mathbf{M}^{resource2}$).	**Context (C) number:** 11. Cedervall [250]; Malthouse [267] 12. Cedervall [250] 13. Malthouse [267] 14. Malthouse [267] 15. Malthouse [267] 16. Cedervall [250] 17. Cedervall [250]; Malthouse [267]
Support	An older adult ($\mathbf{C}^{1}$) with dementia ($\mathbf{C}^{2}$) who is supervised by trained personnel ($\mathbf{M}^{resource1}$) who give clear and repeated instructions ($\mathbf{C}^{3}$), who optimally progress the exercises ($\mathbf{C}^{4}$), who provide the amount of supervision required by that individual and their needs ($\mathbf{C}^{5}$), and who understand the needs of persons with dementia ($\mathbf{C}^{6}$) will feel supported ($\mathbf{M}^{response1}$) to complete ($\mathbf{O}^{1}$) an exercise programme ($\mathbf{M}^{resource2}$). An older adult ($\mathbf{C}^{1}$) with dementia ($\mathbf{C}^{2}$) who is being supported ($\mathbf{M}^{response1}$) by a professional person ($\mathbf{M}^{resource1}$) who can time-manage ($\mathbf{C}^{7}$); who is knowledgeable ($\mathbf{C}^{8}$); who is firm but encouraging ($\mathbf{C}^{9}$); who is kind, friendly, or supportive ($\mathbf{C}^{10}$); who understands dementia ($\mathbf{C}^{11}$); and who can develop a rapport with the individual ($\mathbf{C}^{12}$), will do an exercise programme ($\mathbf{O}^{1}$).	**Context (C) number:** 1. All 2. All 3. Chan [252] 4. Chan [252] 5. Chan [252] 6. Malthouse [267]; Ries [271]; van Alphen [245] 7. Suttanon [244] 8. Suttanon [244] 9. Suttanon [244] 10. Suttanon [244] 11. Malthouse [267] 12. Ries [271]; van Alphen [245] **Mechanism-Response ($\mathbf{M}^{response}$) number:** 1. Cedervall [250]; Cedervall, [251]; Burton [249]; Blankevoort [247]; Chan [252]; Huger [262]; Stubbs [275]; Suttanon [244]; Malthouse [267]; van Alphen [245]; Pitkala [103]; Liu-Ambrose [265]; Shimada [273]; Frederiksen [257]; Andrade [246]; Hernandez [261]; Hauer [217]; Garuffi [258]

	An older adult ($\mathbf{C}^{1}$) with dementia ($\mathbf{C}^{2}$), who has a carer ($\mathbf{C}^{13}$) that perceives a benefit from the older adult doing exercise ($\mathbf{C}^{14}$), and who can provide transport ($\mathbf{C}^{15}$), a positive attitude ($\mathbf{C}^{16}$), practical considerations ($\mathbf{C}^{17}$), supportive strategies ($\mathbf{C}^{18}$), and/or assistance ($\mathbf{C}^{19}$), will feel supported ($\mathbf{M}^{\mathbf{response1}}$) to complete ($\mathbf{O}^{1}$) an exercise programme ($\mathbf{M}^{\mathbf{resource1}}$) or routine physical activity ($\mathbf{M}^{\mathbf{resource2}}$). An older adult ($\mathbf{C}^{1}$) with more severe dementia ($\mathbf{C}^{20}$) will require more support ($\mathbf{M}^{\mathbf{response1}}$) to successfully participate (**O**) in exercise programme ($\mathbf{M}^{\mathbf{resource1}}$) or routine physical activity ($\mathbf{M}^{\mathbf{resource2}}$). An older adult ($\mathbf{C}^{1}$) with dementia or AD ($\mathbf{C}^{2}$) who has a carer ($\mathbf{C}^{13}$) that receives information ($\mathbf{C}^{21}$) and on-going support ($\mathbf{C}^{22}$) from the therapist or staff ($\mathbf{M}^{\mathbf{resource1}}$) to enable them to support ($\mathbf{M}^{\mathbf{response1}}$) the participation or completion of an exercise programme of the person with dementia ($\mathbf{O}^{1}$).	**Context (C) number:** 13. Burton [249]; Stubbs [275]; Suttanon [244]; Malthouse [267]; van Alphen [245]; Pitkala [103]; Christofoletti [253] 14. Suttanon [244]; Cedervall [250]; Malthouse [267] 15. Andrade [246]; Hernandez [261] 16. Frederiksen [257] 17. Cedervall [250] 18. Cedervall [251] 19. Stubbs [275] 20. Stubbs [275] 21. Suttanon [244]; van Alphen [245] 22. Suttanon [244]; van Alphen [245]
	An older adult ($\mathbf{C}^{1}$) with dementia ($\mathbf{C}^{2}$) who wants to exercise in a group ($\mathbf{C}^{23}$), will feel supported ($\mathbf{M}^{\mathbf{response1}}$) to complete ($\mathbf{O}^{1}$) a group exercise programme ($\mathbf{M}^{\mathbf{resouce1}}$) or group physical activity ($\mathbf{M}^{\mathbf{resource2}}$).	**Context (C) number:** 23. Hauer [260]; Suttanon [244]; Pitkala [103]
	An older adult ($\mathbf{C}^{1}$) with dementia ($\mathbf{C}^{2}$) who has a poorer ability to understand and learn new information ($\mathbf{C}^{24}$), who has not exercised previously ($\mathbf{C}^{25}$), who has ill health ($\mathbf{C}^{26}$), or who has regular holidays ($\mathbf{C}^{27}$), will not access the required support needed to exercise ($\mathbf{M}^{\mathbf{resource1}}$) and therefore will not feel supported ($\mathbf{M}^{\mathbf{response1}}$) to complete an exercise programme($\mathbf{O}^{1}$).	**Context (C) number:** 24. Burton [249]; 25. Burton [249]; 26. Burton [249]; 27. Burton [249]; **Mechanism-Response ($\mathbf{M}^{\mathbf{response}}$) number:** 1. Hauer [217]; van Alphen [245]

Table 5.1: Summary table of all CMOcs and associated references

5.4. Discussion

5.4.1. Summary of findings

The initial rough programme theory comprising of six MRTs evolved into eleven MRTs during data extraction and synthesis. Two of these MRT are elaborated and evidenced as findings in this chapter: encouragement and physiological-responses (Table 5.1). Evidence supported the provisional definition of the physiological-responses mechanisms, confirming that older persons with mild to moderate dementia can experience physiological response-mechanisms involving cognitive, gait, motor, and postural processes from completing exercise. Contextual information regarding the type of exercise and populations involved was gathered. Evidence suggested that improvements in gait and postural ability can positively influence falls risk through mechanisms involving improved control, although there was limited material linking cognitive and motor responses to falls outcomes.

Encouragement was a well-populated and evidenced MRT that was refined within this review. Perception of benefit was an initial mechanism which became a context for the secondary mechanism of support. When an older person with mild to moderate dementia has the perception that exercise will be beneficial they will use this mechanism to complete an exercise programme. Support was an emergent mechanism that required a "*gate-keeper*", such as a therapist or carer, who shared the person's perception of exercise as beneficial to enable access to exercise programmes. Evidence also reinforced that a lack of access to support had a detrimental effect on adherence and participation in exercise.

5.4.2. Strengths and limitations

This is the first realist literature review within falls prevention research so it is important to highlight the strengths and limitations. The main strength of this review is the implementation of realist rationale, which was well suited to the research question. Consideration of the mechanisms underpinning exercise-based interventions allowed development and extrapolation of the theoretical rationale. Exploring and documenting context components allowed individualisation.

Methods of realist enquiry encourage transparency, particularly regarding influence of the researcher on the interpretation of material. Whilst this may be considered to produce the potential for bias from a traditional systematic review method, the researcher is acknowledged in this review and has assisted in the theory development and interpretations. As an experienced physiotherapist working with both older people and in falls prevention, there was potential for detailed recognition of underlying or "*hidden*" mechanisms and understanding of the CMOcs. The stakeholder group ensured consistency and transparency of decision-making.

Realist methodology worked well to uncover the encouragement mechanisms underpinning an exercise-based intervention. However, the benefits were not so evident in the physiological-responses MRT. It is questionable if the results presented would differ from those of a traditional systematic review. The focus therefore should have been on the MRTs that traditional methods would not have been able to elaborate upon.

The dearth of published information on linking one outcome (such as improved motor function) to another (such as reduced falls risk) could be from an assumption of background knowledge taught to therapists in basic training and therefore not required to be stated within a research paper. Text books and teaching material might have produced more data on the relationship between outcomes.

The focus and scope of the review were limited by time and resources. The review is only one chapter and was therefore constrained to be focused and relevant to the aforementioned direction and aims (Chapter 1.3). This could have hampered the depth of the review. Only two of the eleven MRTs were elaborated upon within the findings. The physiological-responses and encouragement MRTs were included due to the volume of data accumulated in those theories. These were also considered valuable components to aid intervention development for the next study.

The review could be described as focused on a micro (interpersonal) level of programme theories [277]. The MRTs and overall programme theory did not consider meso (such as institutional) or macro (such as government and policy) levels of social structure [277]. The review also did not include any grand sociological theories (such as Activity theory [278]). Previous realist researchers have used theoretical frameworks to structure their search strategies and data analysis to ensure all components or levels were considered within their reviews [277, 279]. Whilst this limitation is acknowledged, the specificity and subsequent recommendations of this review are a considerable strength.

The review was limited by the quality and content of the evidence in the included materials. The literature found from the initial search did not feature the detail of theoretical reasoning required to adequately test and define all MRTs. Research into falls interventions is heavily weighted towards quantitative methods with publications following a rigid reporting structure. Calls for greater detail in publications regarding intervention reporting (such as the TiDier guidelines [228]) may produce more context or resource information. However, it became evident during data interpretation that information regarding the participants and their influencing characteristics were sparsely discussed. Having materials that were heavily quantitative in nature assisted in determining associations, specifically in the physiological-responses MRT. However, a traditional systematic review method would have drawn similar conclusions. Including different study methods in the same synthesis allowed the inclusion of both quantitative data for inferences and qualitative material for interpretation and opinion. Potentially the material could have been ordered according to depth and breadth with related exclusion criteria (Figure 5.3).

Lack of material or "silence" within some of the MRTs (such as fearful of negative consequences) is a limitation. Silence may suggest the MRT is not supported and therefore not valuable as a component of the programme theory. However, areas of silence could also highlight topics for further investigation or that the literature search was insufficient. With unlimited time and resources, areas of silence could be further explored, drawing material from other fields of research.

In this way it is conceivable that relevant material was not included within the review. Indeed some studies that have been previously described in preceding chapters were not found in the initial search. An iterative search to include other relevant materials was not completed in view of the limited time and resources. Snowball-searching was not completed in the review. The first search categorised material according to relevance and it is conceivable that looking closer at the concentric circles of relevant material would yield different results to those presented.

All of the materials included in the review described participants who had either completed regular physical-activity or the exercise-based intervention under study. Therefore, the context for these participants is that they were, or recently had been, completing exercise. This is an important consideration when the context is specific to the engagement of the mechanisms. Potentially data from only one perspective is produced (of someone already completing exercise). Very little information is provided on those who withdrew during the intervention studies or who did not start at all, and there is potentially useful data in considering that perspective to refine the MRTs.

A strength of this review is the consideration of mechanisms and contexts in a field that has not articulated this aspect before. The review provides a greater level of understanding of the underpinning mechanisms at play within an exercise-based intervention. Whilst not exhaustive, the findings do indicate valuable information on how the intervention could reduce falls in older adults with cognitive impairment, and will be used to direct the content and delivery of the intervention tested within the next study. Context components required for the response-mechanisms to operate provide understanding on what features are needed in a future intervention, enabling more accurate tailoring to this population.

Realist review uses a wide range of evidence (observation, experiment, interview, opinion, interpretation, or reflection) to inform, evidence, support, or contradict models or hypotheses (CMOcs) which is more subtle than in usual reviews, but which is potentially more useful for practitioners dealing with individuals who have various characteristics and circumstances. Whilst the certainty about causal relations and lack of bias is less than traditional systematic reviews, there are checks and rigour (such as triangulation), and both generalisability and coverage are improved for complex interventions in complex situations.

5.4.3. Future research directions

Future research following this review needs to consider the areas of silence within the data extracted through tailored searches into other or new research fields. The interpretation and summarising of the other MRTs not presented also need completing. This review is one step towards answering the research question, rather than a conclusive summary.

Throughout the review process the researcher identified how the findings would direct the next stage of a realist evaluation. It is clear how the work in this review could be used to: a) direct questioning within participant and carer interviews, b) aid outcome measure decision-making, and c) refine the delivery and contextual map required to ensure an intervention is tested in the most efficient manner. A future realist evaluation could also target people with cognitive impairment who do not participate in regular physical activity or exercise. This would provide a direction to the programme theory underpinning exercise and potentially produce recommendations that would identify both positive and negative CMOcs.

Exploring "*how*" exercise reduces falls is associated with adherence and facilitators-barriers. One cannot experience response-mechanisms of exercise until one participates in exercise. Future studies should consider this co-dependent relationship.

Future research should also focus on the discrepancies identified within this review. It was apparent in the interpretation of data that there were different stages of participation in exercise and the initial rough programme theory was too simplistic in its original outcome. There are multiple potential MRTs that are applicable at different stages of a person with cognitive impairment participating in exercise (from the initiation of exercise, to the maintenance, and then to routine practice). This review reinforced previously identified differences in terminology for exercise, ranging from very specific programmes of resistance training to general physical activity. Future research could look at these components to make specific recommendations for clinical practice.

5.4.4. Comparison with existing literature

There are currently a handful of other realist reviews being completed within the dementia population [280-284]. Realist reviews and evaluations have been increasingly used within health to aid explanation of the complexities of health systems and complex interventions [285-289].

At present, there are no realist evaluations or reviews that are focused around falls. This review is the first as far as the researcher is aware, however there have been some looking at similar exercise or activity-based interventions. A realist evaluation and synthesis of data for community-based physical activity programmes in socially vulnerable groups [290] has considerable overlap with the findings from this review. Whilst dementia or cognitive impairment were not their target population, the CMOcs presented by Herens et al [290] to enhance active lifestyles using their group intervention also feature mechanisms involving the "*actor*" or group leader. However, the intervention evaluated was multisite and therefore leads to methodological issues regarding specificity and generic contextual factors [290]. This is also relevant to this realist review, where the variety of interventions included within the material could lead to only generic mechanisms or context components.

Similarities in the mechanisms of this review can also be drawn against Clark et al [291] whose evaluation of a cardiac rehabilitation programme produced both social and body-focused mechanisms (similar to the physiological responses

MRT). Clark et al [291] identified that these mechanisms were only triggered when the rehabilitation was completed within a "*safe*" context. This dynamic of "*safety*" is an understandable context in participants with heart disease following a sudden event and was not elicited from the materials in this review, highlighting how the underlying health condition will change CMOcs and the overarching programme theory. However, ensuring safety and avoiding risk are constant themes when discussing activity in persons with cognitive impairment, and the link with the carer's perspective of weighing-up the risks of physical activity is clearly related to safety considerations.

Probably the most similar realist review with respect to participant and intervention setting is a review by Pearson et al [242] on intermediate care. Involvement of the service user and their carer was deemed the "pivotal" component of their conceptual framework and reflected the findings from this review regarding the role of the carer as a supporter or "gate-keeper". Pearson et al [242] refined this component, suggesting how this mechanism fed into service delivery to ensure the intermediate care intervention was effective.

5.5. Conclusion and recommendations

Falls are an "outcome" experienced by older adults with mild to moderate cognitive impairment. Exercise-based interventions are a resource which, in the right circumstances or contexts, can assist in positively influencing both short-term and intermediate outcomes experienced by older adults with cognitive impairment. The circumstances and underlying mechanisms are important in ensuring success for the intervention, the individual, and their support network. Traditional systematic reviews report a dearth of evidence for falls interventions for this population (Chapter 3). However, this realist review demonstrated that evidence from different methodological perspectives can elicit greater understanding of the underpinning mechanisms operating and necessary conditions for success. This synthesis of evidence provides a valuable addition to the evidence-base surrounding the exercise components of falls intervention programmes for older adults with cognitive impairment at a mild stage. Clinically-relevant recommendations for improving the care of people with dementia are provided (Table 5.2).

Topic	Recommendation
Who	Older adults with mild to moderate cognitive impairment.
	If a person with dementia has the belief that exercise is advantageous, a positive attitude to exercise, the ability to understand the benefits of exercise or is able to identify the physical or functional changes from doing exercise, then they will perceive the benefit of doing exercise.
	If a person with dementia perceives the benefit, they will participate in exercise-based intervention.
What	Multicomponent exercise-based intervention that: • combines physical (including strength/resistance, balance, endurance/mobility, aerobic) and cognitive exercises, • is appropriately intensive and progressive, • is supported by suitable staff (who can interact, communicate and connect) and materials, • considers speed of initiation, length of intervention, encouragement of active lifestyle and enjoyment, • is delivered in a flexible manner for at least 15-20 minutes (or whatever can become or fit in with routine) 2-3 times a week for 6-12 months, • can be delivered at home (for those wanting or needing 1:1 support from the intervention staff) or in a group (for those wanting carer respite, increase in habitual physical activity or socialising aspects).
Circumstances	Support can provide encouragement for completing an exercise-based intervention.
	Sources of support can include but are not exclusively supplied by trained intervention staff, carer, spouse, or family member.
	If support is being provided by trained intervention staff, then they should have professional competence including: • time-management, • knowledgeable, • firm but encouraging, • kind, friendly and supportive, • understanding of the issues experienced by persons with dementia, • rapport development.
	Trained intervention staff supporting an intervention should: • provide clear and repeated instructions, • optimally progress the exercises, • provide the amount of supervision required by that individual and their needs, • understand the needs of persons with dementia.
	If support is being provided by a carer, then the intervention should provide information and on-going support to enable them to continue.
	Carers supporting an intervention should: • perceive and understand the benefit of the person with dementia doing exercise, • provide transport or consider practical arrangements for access to the intervention, • have a positive attitude, • implement supportive strategies and/or assistance in the manner required by the person with dementia.

	If the carer or the supporter's perception of the benefits of doing exercise outweighs the risk, concern, or burden of extra care duties, then the intervention will be encouraged.
	Benefits of exercise perceived by the carer or supporter for the person with dementia include; mood, behaviour, weight, flexibility, ageing, and enjoyment of everyday life.

Table 5.1: Clinically relevant recommendations from the realist review

Chapter 6. Investigation of an intervention to prevent falls in older adults with mild dementia: a feasibility study

Summary

Older adults with mild dementia are at a high risk of falls and experience a high dual-task cost (Chapter 2). At present, there are few proven intervention programmes specifically designed to reduce falls in older adults with cognitive impairment [103]. Exercise (Chapter 3) and dual-task training (Chapter 4) have demonstrated positive results influencing falls risk and gait, particularly for those at mild stage of cognitive impairment. Consideration of the mechanisms underpinning how these interventions might reduce falls has demonstrated that a person's perceptions, their level of cognitive impairment, and the support they receive to complete exercise is influential (Chapter 5). The study presented in this chapter is the culmination of preliminary work, synthesised into an intervention programme that was tested for feasibility.

A non-randomised feasibility study tested the components and acceptability of a 6-week combined physical (strength and balance), and cognitive (dual-task training) exercise-based falls prevention intervention. Outcome measures collected pre- and post-intervention and field notes completed by the research therapist were collected. Ten adults (median age 84, range 69 to 89; 50% women) with mild dementia (median MoCA 21, range 16 to 26) were recruited. Adherence to the sessions was high. Mean differences between pre- and post-intervention assessment demonstrated improvement in falls risk, balance, and gait. Variable improvements in dual-task cost were found.

Thematic analysis of field notes produced two major topics including sixteen themes and a list of clinically-relevant recommendations for the content, delivery, and supervision of this intervention for an adequately powered, and randomised study. In conclusion, a combined physical and cognitive exercise-based intervention programme was deliverable, feasible, and acceptable to older adults with mild dementia.

Publication: Booth V, Logan P, Masud T, Harwood R, and Hood V. A feasibility study of a tailored physical and cognitive exercise intervention to reduce falls in older adults with mild dementia. *European Geriatric Medicine* (2016) Supplement 1(7), S142-S143*.*

6.1. Introduction

6.1.1. Scientific background and explanation of rationale

Older adults with cognitive impairment are at increased risk of falls. The cross-sectional data outlined in Chapter 2 supports previously published material to clearly indicate that these people are falling, are at increased risk of future falls, and have alterations to their gait pattern and balance ability [67, 198]. Older adults with mild dementia also have an increased dual-task cost: a higher than expected cost to their walking pattern when asked to do two tasks at once (Chapter 2).

There is a clear rationale for training an older adult's ability to complete two tasks at once. By including this exercise component into a traditional multi-component falls intervention programme, an older adult will have a better ability to do two things at once. Dual-tasking is inevitable during everyday life. When attention is correctly allocated to posture, or the attentional reserve to maintain an upright balance while walking or standing is preserved, the risk of falls reduces.

Dual-task training or multicomponent interventions have been trialed previously in older adults with cognitive impairment [141, 215]. Similar studies have demonstrated positive findings on falls [99], function [103], gait [101, 292], and dual-task performance [141]. Meta-analysis has established the impact of these interventions on physical outcomes including the number of falls, balance, and gait parameters (Chapter 4). Dual-task, multicomponent interventions significantly improved balance and gait speed in older adults with mild dementia (Chapter 4). However, the studies were small in number, with limited sample sizes, and classified as feasibility or pilot design.

Although promising studies using falls risk as an outcome are emerging [293], more dual-task training intervention studies are required which focus on falls as the main outcome of interest. How dual-task training fits within a falls intervention programme also needs exploring in order to determine its feasibility and its practical application in individuals with mild dementia.

It is unsurprising that substantive conclusions could not be made regarding the efficacy of dual-task training in this population considering the stage of development of these interventions. However, the work previously described presents encouraging findings. The process of intervention development and testing should begin as depicted within the MRC framework for the development of complex interventions [123, 294].

> *"Evaluations are often undermined by problems of acceptability, compliance, delivery of the intervention, recruitment and retention, smaller-than-expected effect sizes, and so on, that could be anticipated by thorough piloting."*
> *([294], p10)*

6.1.2. Research question

The following study tested the concept of whether dual-task training exercises can be completed by older adults with mild dementia. The aim, therefore, was to conduct a non-randomised pre-post study exploring the design and feasibility of a novel approach to fall prevention for older people with mild dementia living in the community. The specific research aims were:

1. To develop an intervention that combines physical and cognitive rehabilitation, based on the synthesis of current best evidence.

2. To test the acceptability and feasibility of a combined physical and cognitive rehabilitation programme in older adults with mild dementia.
3. To inform and test the practicality of delivering a combined physical and cognitive exercise programme in two settings (group- or home-based sessions).
4. To refine the content of the combined physical and cognitive exercise programme and its participant-facing documentation.
5. To determine the usefulness and limitations of the outcome measures, especially dual-task cost, gait, balance, and falls risk assessments.
6. To inform the recruitment, consent, and retention rates of older adults with mild dementia from a community NHS setting.

6.2. Intervention development

6.2.1. Process

The intervention used in this study was developed during a 2-year process. Information was used from multiple sources including: researcher and study management group core knowledge and clinical experience; cross-sectional survey (Chapter 2); systematic literature reviews (Chapter 3-5); liaison with experienced nationally and internationally recognised researchers in the field; workshops with experienced clinicians working in dementia, falls and related fields; interviews with people with mild dementia and their carers; and discussions with patient and public involvement (PPI) representatives (Figure 6.1). The study management group discussed progress and consisted of academic and clinical supervisors, the PPI representative, and the researcher. The study management group featured a range of expertise including: two consultant geriatricians, two clinical academics, two physiotherapists, an occupational therapist with a special interest in falls, and a PPI representative.

Synthesis of findings and information occurred through the process of designing and compiling the protocol and training programme for the following feasibility study (Appendix 23). The intervention development process has been grouped according to the MRC guidelines on development and evaluation of complex interventions: evidence, theory, and modeling [294].

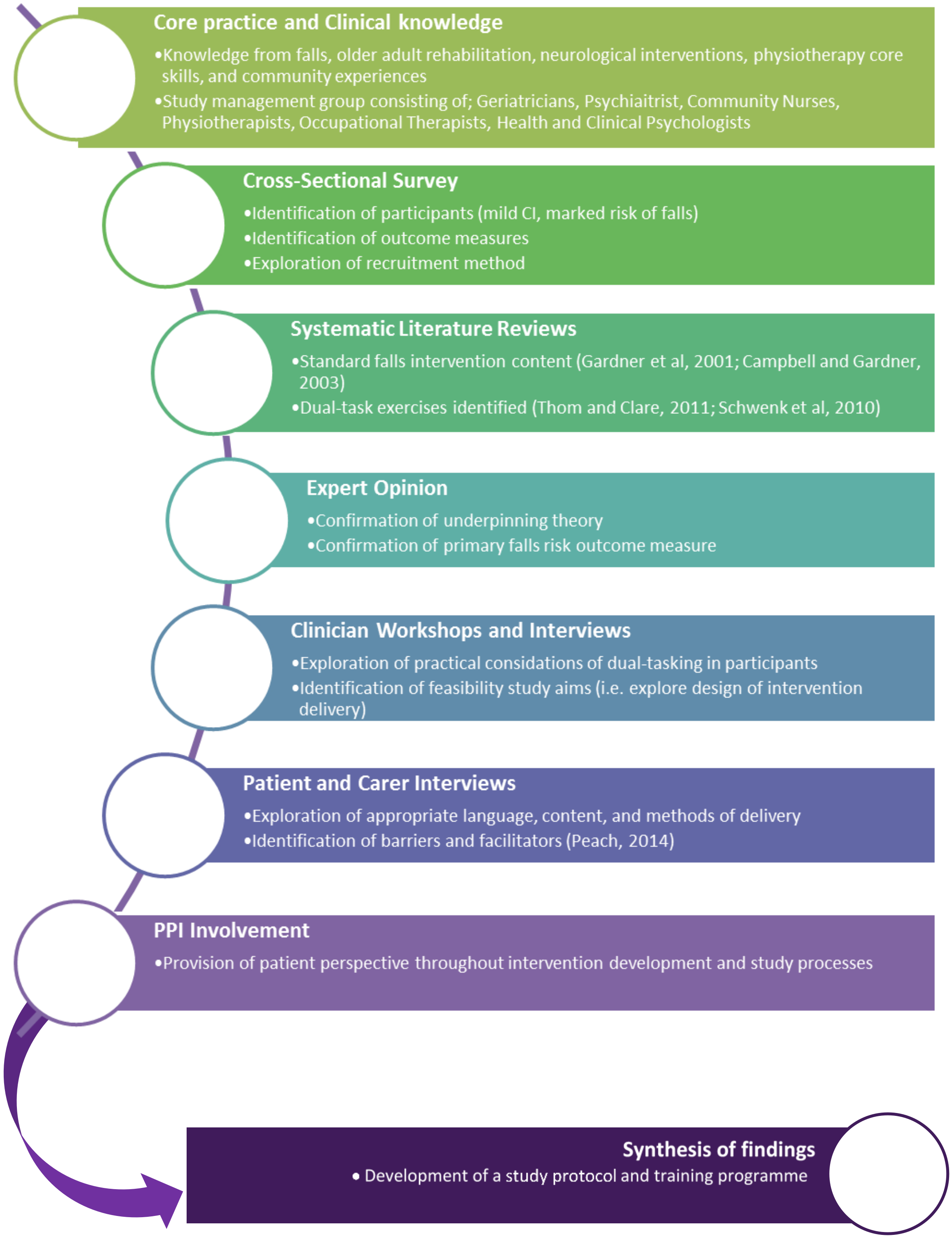


Figure 6.1: Intervention development diagram

6.2.1.1. Evidence

Three literature reviews were completed to identify potential intervention content. A broad umbrella review of current falls interventions trialled in persons with cognitive impairment indicated the potential for exercise to be effective in these individuals (Chapter 3; [184]). A more detailed and specific dual-task training or combined physical and cognitive interventions meta-analysis was then completed to determine effectiveness (Chapter 4; [199]). Following these reviews, a list of dual-task exercises was derived (Appendix 16), and discussion in the management group refined the content into the exercises which would be delivered (Appendix 23).

Participants of interest were clearly demarcated from the systematic reviews, focusing on older adults with mild dementia that encompasses different diagnoses. Synthesis of the evidence determined that those with a mild impairment were found to benefit from dual-task and exercise interventions. The reviews corroborated information on the participants gathered during the cross-sectional survey. The cross-sectional survey was completed using a variety of outcome measures to record falls risk, gait, and balance in older adults with mild dementia (Chapter 2). The survey identified outcomes which could be used to measure change in these participants, as well as confirming that the target population was at risk of falls, has gait and balance disturbances, and had an increased cost to their physical ability when dual-tasking. Discussion within the study management group narrowed the number of outcomes used in future studies.

6.2.1.2. Theory

The third review, a realist synthesis, identified mechanisms underpinning exercise-based interventions and necessary conditions for success (Chapter 5; [241]). Practical components of the intervention were identified such as involvement of the participant's carer, consideration of therapist characteristics, and methods of delivery. The main theoretical underpinning and rationale for exercise-based interventions in these participants was developed. Mechanisms involving cognition, motor, postural, and gait physiological-responses were derived from the literature on exercise. Support and understanding benefits from participation were also identified as mechanisms which are important for participation.

Theoretical assumptions regarding dual-task training were supported through the meta-analysis in Chapter 4. Discussions with experts in the field confirmed these findings and developed the rationale for combining physical and cognitive exercises. These discussions occurred during meetings at national conferences with acclaimed researchers: Professor Stephen Lord and Dr Jacqui Close at the British Geriatrics Society Autumn meeting in Manchester (2014), and Professor Reto Kessig at the East Midlands Trent Falls Symposium in Nottingham (2015).

Information on barriers and facilitators to falls prevention interventions for persons with mild dementia were derived from interviews conducted by researchers from the wider research group [295]. Thematic analysis of the interviews ascertained that not all participants in this study considered themselves as at risk of falling. These individuals could see the benefit of doing exercise but did not necessarily associate this with reducing the risk of future falls. The findings from Peach et al [295] aligned with many aspects of the realist review, such as a perception of benefit that might not directly relate to falls is required by these individuals in order to participate.

6.2.1.3. Modelling

Experienced researchers and clinicians in the field of falls prevention and dementia were approached to discuss their opinions on both intervention content and measures of outcome. These experts were identified through the experience of the steering group and invited to attend through email correspondence. Two workshops of 20-25 people were held (October and November 2013) to explore views on dual-task training in persons with dementia and discuss practical considerations of intervention delivery. Considering the requirements of clinicians, these workshops were held in the middle of the working week, at mid-day, with lunch provided, and they included an element of education and teaching as well as discussion. Small groups used display boards and post-it notes to document key-points, which were later typed and summarised by the researcher.

Findings corresponded with the cross-sectional survey results and provided advice on methods of delivery. For example, the workshops identified that this patient population were experiencing falls and difficulties with physical outcomes such as gait and balance. Clinical advice focused on compensatory techniques such as dual-task avoidance and issuing walking aids. Providing pictorial documentation was also advocated from the workshops to aid intervention delivery.

Information from these workshops, results from similar studies within the literature, and expert opinion were taken and discussed with the study management group. Separate meetings were regularly held with the PPI representative to discuss the project as a whole, study findings, direction of the research, and overall applicability to persons with dementia and their families. Discussions with the study management group and the PPI representative occurred throughout the feasibility study time-period. A number of modelling decisions were made before the study protocol was written, such as exploring the method of intervention delivery in the feasibility study. However, a number of decisions were made during or after the programme period, such as changing from exercise-band to variable cuff-weights, and conducting thematic analysis of the clinician notes.

6.2.1.4. Synthesis

Key findings derived from this process of intervention development are summarised in Table 6.1 according to the categories of the TIDieR checklist [228]. Findings were synthesised through the process of writing the feasibility study protocol and producing the intervention programme (Appendix 23). Synthesis was facilitated by the study management group and the PPI representative during a series of meetings and email discussions. Any discrepancies in findings were debated and decisions were prioritised according to practicality, ability of the researcher, and funding constraints.

MRC Development Component	Research Component	Summary of Findings (in relation to TIDieR components)
Evidence / Modelling	Cross-sectional survey (Chapter 2)	• Participants (older adults with mild CI) • Outcome measurements (falls risk, gait parameters including DTC, balance) • Recruitment – strategy (memory clinics)
Evidence / Theory	Falls interventions umbrella review (Chapter 3)	• Rationale – Research in field • Standard physical components (strength and balance/OTAGO exercises)
Evidence / Theory	Dual-task interventions meta-analysis (Chapter 4)	• Participants (older adults with mild CI) • Rationale – combined physical and cognitive exercise • Content (dual-task exercises) • Outcome measurements (number of falls, gait speed, balance)
Theory / Modelling	Realist review (Chapter 5)	• Rationale – exercise in mild dementia • Methods of delivery (support mechanisms, setting: home or group) • Requirements for intervention provider (registered, knowledgeable, supportive)
Theory / Modelling	Expert opinion	• Rationale – combined physical and cognitive exercise • Tailoring and modifications (implementation of components)
Theory / Evidence	Patient-carer interview study [295]	• Rationale – exercise in mild dementia • Tailoring and modifications • Content (goal-orientated)
Modelling / Theory	Clinician-expert workshops	• Rationale – combined physical and cognitive exercise • Methods of delivery (home and group) • Content (dual-task exercises) • Materials (use of individual folders, wording on participant material, use of pictures)
Modelling / Theory	PPI meetings	• Rationale – research in field, exercise in mild dementia, combined physical and cognitive exercise • Materials (wording on participant material, use of pictures) • Procedures (flexibility)
Modelling / Theory	Core knowledge and clinical experience	• Rationale (all) • Standard physical components (strength and balance/OTAGO exercises) • Requirements for intervention provider

Legend: Evidence=material related to evidence component of MRC guidelines, Theory=material related to theory component of MRC guidelines, Modelling=material related to modelling component of MRC guidelines.

Table 6.1: Summary of findings from intervention development process (pre-feasibility study)

6.2.2. Content

6.2.2.1. Description and rationale

The intervention was a combined physical (strength and balance exercises) and cognitive (dual-task) training programme, tailored and adapted to older adults with cognitive impairment. The rationale for the intervention has been described (Chapter 6.1 and Chapter 1.1). Standardised and well-evidenced strength and balance exercises [296] were used to address lower limb weakness and postural instability commonly found in older adults. Dual-task training was employed to train the individual's ability to divide, reallocate, or prioritise attention [141, 201]. Methods of delivery were explored to determine strategies specific to individuals with cognitive impairment to assist them in completing an exercise-based training programme [100]. A multicomponent intervention was utilised that addressed standard risk factors for falls in older adults, with an additional consideration of specific issues related to cognitive impairment.

6.2.2.2. Tailoring and progression

Tailoring to the individual was achieved through goal setting with the participant and their carer. During the pre-assessment visit, the participants were guided to set relevant goals to achieve during the study period [297]. Using the measurements recorded in the assessment, the researcher prescribed the training programme according to ability. As an aim of the study was to develop the intervention, the researcher providing the intervention had the standard falls prevention physical strength and balance exercises [296] in addition to dual-task training exercises, derived from the previous systematic review of the literature (Chapter 4; [199]). However, the researcher chose what was appropriate to the individual and details regarding the actual number of exercises prescribed was collected for analysis. The programme was tailored and modified during the initial sessions of the intervention based on abilities, comorbidities, interests, and goals of the individual participant.

Throughout the intervention sessions, the exercises were progressed to maintain an achievable challenge for the individual participant according to the American College of Sports Medicine guidelines [298]. Progression was achieved through: increasing the number of repetitions or time completing each exercise; the resistance for the strength exercises (exercise-band or variable-cuff-weights); reducing base of support for the balance exercises (for example removing touch support or narrowing base of support); and increasing the difficulty of the dual-task component.

How the exercises were progressed was outlined prior to the intervention starting in a series of tables depicting the different levels of difficulty that the research therapists could prescribe (Appendix 23). Exercises were progressed when the participant was able to: complete 8-10 repetitions of an exercise, achieve the time-limit required for the balance exercise, or complete the dual-task cognitive component accurately. The decision to progress was made jointly between researcher and participant.

Intensity of the sessions was guided by the individual's presentation during each session. Self-perceived effort levels using a visual analogue scale (0=no effort/breathing unchanged, to 10=maximal effort/completely out of breath) were recorded at the end of each session to assist progression and intensity decision making, and to encourage reflection by the participants on the exercises just completed.

6.2.2.3. Intervention provider

The researchers providing the intervention varied during the study and included: two qualified physiotherapists (one physiotherapy lecturer with >10 years' experience, one senior physiotherapist with 9 years' experience), one research nurse, and student physiotherapists. The research nurse was an experienced researcher (>10 years' experience in research with older people) who was taught the exercises prior to commencement of the initial phase. The research nurse was only involved in delivering the intervention for the initial participants seen in the home setting and fulfilled the role of an unregistered support staff member who did not prescribe or progress the exercises. The students that supported the group setting were from the University of Nottingham, School of Physiotherapy, and fulfilled the role of an unregistered support staff member.

6.2.2.4. Modifications

Modifications were made during the study. The most significant is the change from group to home setting for the sessions. Initially the intervention was trialled in a group setting. Feedback from the participants and the study steering group identified a need to trial the intervention at home.

Documentation of clinical notes after each intervention session varied during the study. The purpose of the clinical notes was to encourage communication between the researchers and to document events during the training programme. For the group setting, these notes were electronic and stored on the University of Nottingham's shared drive to which all researchers had access. Initially, in the home setting, notes were hand-written and included within the participant's folder as different researchers were completing the intervention with the participants on different sessions. As the study progressed, this was changed back to electronic notes that were stored on the University of Nottingham's shared drive. The research nurse was also asked to complete the clinical notes following each intervention during their involvement in the home setting.

Documentation of the session content was completed by the participant with assistance from the researchers, on paper exercise sheets situated in each participant's folder. However, the onus put on the participant to complete the exercise sheets varied according to participant and situation. This documentation was used in conjunction with the researcher's clinical notes to record adherence, modifications, and tailoring of the intervention to the individual participants. The number of researchers providing the intervention varied during the course of the study, reducing from four researchers to one. Methods of resistance for the strengthening exercises were provided using two different types of equipment: exercise-band and variable cuff-weights. Fidelity was not specifically recorded in this feasibility study.

6.2.2.5. Intervention materials and procedure

The intervention was conducted in a group and home setting. Materials used were the training programme and various types of equipment, which varied slightly according to the setting. The training programme was provided through paper copies of the exercises and stored in individual folders for each participant. How, where, and by whom the intervention was delivered, and what equipment was used were described according to setting.

Group setting

In the group setting, the equipment used included: static bike, treadmill, aerobics step, exercise-band, balance cushions, parallel bars, balls, and variable-cuff-weights. The intervention procedure was similar in each session: group warm-up involving a walking activity (such as walking in a circle whilst completing a group dual-task); individually-set balance, strength, cardiovascular and dual-task exercises done in circuits; group cool-down involving a dual-task activity such as targeted throwing; and documentation of the session with hot drink. The session format could be modified by the researcher depending on the number of participants and supporting staff present, the focus of the dual-tasks, and individual abilities of the participants on the day.

The group sessions were held in the Human Performance Laboratory at the University of Nottingham. In each session there was always one research therapist present and occasionally an unregistered student physiotherapist. The participant to researcher ratio varied within this setting from three to one, to one to one depending upon unregistered support staff presence. The sessions were held at the same time, on the same day, and in the same location. There was always a two-day interval between sessions. All session dates were provided to the participants at the start of the study. Pre-booked taxis transported participants to and from sessions. The programme consisted of 12 sessions, for 90 minutes, twice a week, for 6 weeks. Carers or family members were allowed to attend and join in if they or the participant wished, but just observing the sessions was discouraged.

Home setting

In the home setting, the equipment used included: exercise-band, variable-cuff-weights, household items such as a cup or glass, a ball, and steps or stairs within the home. The intervention procedure was similar in each session: feedback from the participant regarding previous session or daily activities; individually set balance, strength, and dual-task exercises; continuous walking inside or outside the home; and documentation of the session. The participant to researcher ratio was always one to one during this setting.

Initially, all session dates were provided to the participants at the start of the study and wherever possible these sessions were kept fixed. As the study progressed, this was adapted to arrange the dates for the next session on a day-by-day basis. Where possible the sessions were held at the same time, on the same day, and in the same location, but the researcher was flexible in order to provide the training session around the participant, their daily life, and their pre-arranged engagements. An interval of one or two days was maintained between sessions wherever possible. The programme consisted of 12 sessions, for 90 minutes, twice a week, for 6 weeks. Carers or family members were allowed to attend and join in if they or the participant wished but, as with the group setting, just observing the sessions was discouraged.

6.3. Methods

6.3.1. Study design

A pre-post, non-randomised feasibility study measured change in intermediate outcomes related to falls (balance, strength, gait and dual-task cost) following the multicomponent exercise programme. Outcomes were recorded immediately before and after the 6-week programme by the researcher. The recruitment strategy involved two different time points to allow for the iterative development of the programme and comparison of two different settings for intervention delivery: small-group and home-based (Figure 6.2). Ethical approval was sought and gained from the University of Nottingham and West Midlands - South Birmingham NHS Research Ethics Committee (REC reference 15/WM/0412) (Appendix 24).

6.3.2. Participants

Participants were recruited from Nottinghamshire Healthcare NHS Foundation Trust Memory Assessment Services. Initial screening was completed by the service staff who judged capacity to consent and highlighted potential participants to the researchers to gain informed consent. All participants were able to provide written informed consent. Participants were included if: they were over 65 years old, they were a resident of Nottingham City or Nottinghamshire County, and they had a mild cognitive impairment identified from a cognitive screen such as MMSE range 21-26 or MoCA range 15-25.

Participants were excluded if: they lacked mental capacity to consent to participate, they declined to consent, they were unable to speak or understand good English, they had an MMSE score affected by visual or hearing impairment, they had any physical disabilities or uncorrected sensory impairment that prevented the undertaking of tests such as being unable to see or hold a pen, or they were unable to walk without human help.

6.3.3. Assessment

The procedures for completing recruitment, pre-, and post-assessments were identical throughout the study. Once the participant had given consent, the assessment visit was arranged at a time convenient to the participant. Transport was provided, via taxi, for the participant and carer or family member to and from the assessment session. The assessment sessions were 120 minutes in duration, were composed of ten outcome measures, and were completed by two researchers using standardised documentation (Appendix 2).

Following the 6-week period, a post-intervention assessment was arranged with the participant and carer or family member. This was a repeat of the pre-intervention assessment with only one change: at the end of the assessment the participant was given a verbal report of their progress with positive changes highlighted and a review of their initial goals. Participants were provided with fresh copies of the exercises specific to their level of ability at the last intervention session. Participants and their carers were encouraged to continue with key exercises if they wished but it was explained that their involvement and commitment to the study had finished. The option to demonstrate the exercises to carers or family members was offered to all participants.

6.3.4. Measurements

Outcomes were recorded pre- and post-intervention by the researcher. The primary outcome was falls risk using the Physiological Profile Assessment (PPA) [40]. The PPA is a composite of five physiological aspects of balance completed by the research therapist, calculated into a risk ratio via a computer programme that compares the measurements to a normative, age-matched sample.

Secondary outcomes were:

- Number of falls (weekly prospective diaries completed by the participant).
- Balance outcomes (Berg Balance Scale [133], Timed Up and Go [162] completed by the research therapist).
- Gait parameters (in single and dual-task conditions) for: velocity, step-length, step-time, step-width, step-length variability, step-time variability completed using the GAITRite (Appendix 2).
- Fear of falling (Falls Efficacy Scale – international [161]) completed by the participant.
- Anxiety and depression (Hospital Anxiety and Depression Score [160]) completed by the participant.
- Compliance (% of sessions attended and length of intervention sessions).

The feasibility study aimed to test the implementation of the intervention and not to determine statistical significance or estimating parameters, therefore a formal sample size calculation was not appropriate. There was no comparison group, randomisation, or blinding of researchers, participants, or assessors. Sample size was determined according to feasibility for the researcher and following advice from the study management group. A sample size of ten participants was deemed sufficient to meet the primary aim of the study.

6.3.5. Intervention

The intervention has been described previously (Chapter 6.2.2) and is presented according to recommended guidelines (Table 6.2).

TIDieR checklist item				Intervention item and brief description
1.	**Name**			Combined physical (strength and balance) and cognitive (dual-task) exercise-based falls prevention intervention.
2.	**Why**		Rationale	Older adults with mild dementia have high risk of falls due to: i) inability to allocate cognitive resources appropriately resulting in high DTC, ii) alterations to gait pattern, iii) standard falls risk factors associated with age and comorbidities.
			Theory	Adding dual-task training (as a consideration for influencing the impact of executive dysfunction) will enhance the standard strength and balance exercises to reduce the risk of falls in older adults with mild dementia.
			Goal	To conduct a non-randomised pre-post feasibility study exploring the design and feasibility of a novel approach to fall prevention for older people with cognitive impairment living in the community.
	What	**3.**	**Materials**	Exercises were printed on paper and collated together in a folder situated with the participant. The exercises included: • Standard strength and balance exercises (Otago programme). • Dual-task exercises collected during dual-task intervention literature review (Chapter 4.5.3). Equipment for intervention sessions included: static bike, treadmill, aerobics step, exercise-band, balance cushions, parallel bars, balls, variable-cuff-weights, household items such as a cup or glass, and steps or stairs within the home.
		4.	**Procedures**	Intervention session procedure for each setting: • Group: group warm-up involving a walking activity (such as walking in a circle whilst completing a group dual-task); individually-set balance, strength, cardiovascular and dual-task exercises done in circuits; group cool-down involving a dual-task activity such as targeted throwing; documentation of the session with hot drink. • Home: feedback from the participant regarding previous session or daily activities; individually set balance, strength, and dual-task exercises; continuous walking inside or outside the home; documentation of the session.
5.	**Who**			Intervention provider varied according to setting and time: • Group: two research physiotherapists and one student physiotherapist. • Home (start): two research physiotherapists and one research nurse. • Home (end): one research physiotherapists (VB). The research physiotherapists were both qualified and experienced in exercise, falls, and older persons. The research nurse was an experienced researcher in older persons who was taught the intervention programme by the qualified researchers. The student physiotherapists were from the University of Nottingham, School of Physiotherapy. Both the research nurse and student physiotherapists fulfilled the role of an unregistered support staff member.
6.	**How**			The intervention was delivered face-to-face, in either a group or home setting:

			• Group: small, circuit-based group with 3 participants, 1 research physiotherapist and 1 unregistered support staff. • Home: individualised with 1 participant and 1 research physiotherapist. Carers or family members were invited to attend sessions.
7.	**Where**		The intervention was completed within two different settings: • Group: Human Performance Laboratory, University of Nottingham. • Home: participants own residence.
8.	**When**		12 sessions, completed twice as week, for 6-weeks. Each session lasting up to 90 minutes (60 minutes activity). Where possible the day and time were maintained, and incorporated at least one day break between sessions.
9.	**Tailoring**		The programme was tailored according to abilities, comorbidities, interests and goals of the individual participant. These were established during the initial session of the intervention and monitored by the research physiotherapist. The programme was progressed to maintain an achievable challenge for the individual participant. Progression was achieved through: • Increasing the number of repetitions or time completing each exercise. • The resistance for the strength exercises (exercise-band in the initial phase and the variable-cuff-weights in the second phase). • Reducing base of support for the balance exercises (for example removing touch support or narrowing base of support). • Increasing the difficulty of the dual-task component.
10.	**Modifications**		Four modifications occurred: • Exercise-band use for resistance was stopped and variable cuff-weights introduced for all participants in the home setting. • Intervention providers reduced to only one research physiotherapist in the home setting. • Intervention delivery was purposively flexible during second half of the home setting participants. • Clinical notes were initially written electronically, then hand-written in the participant's intervention folder, before changing back to electronic.
	How well	**11. Planned**	Intervention adherence was measured by: • Number of sessions attended. • Number of exercises completed (standard vs dual-task).
		12. Actual	Measurement of adherence was achieved: • 84% of sessions were attended (total=101/120, mean=10). • Mean number of exercises completed were 16 (±3.7, range 9-21), 45% of which were dual-task (mean=8 ±3.5, during 6th session).

Table 6.2: Intervention description according to TIDieR guidelines [228]

6.3.6. Field notes

Clinical notes were written by the researcher conducting the intervention after each session. These notes were descriptive, clinically-focused, practical observations intended to document the intervention sessions events from the researcher's perspective. The notes were written in a standard format: subjective comments, observations, analysis, and plan [299]. Three researchers participated in writing the clinical notes and they constituted a method of communication between team members regarding the sessions. Both electronic and hand-written notes were trialled within the study (see section 6.2.4). Following completion of the study, all clinical notes were transcribed into Word and uploaded into NVivo10 according to location of the study (group or home setting).

6.3.7. Analysis

Descriptive analysis was completed on the outcomes by comparing pre- and post-intervention scores. There was no interim analysis, although falls diaries and adverse events were continuously monitored to consider the safety of continuing the study. The mean differences between the pre- and post-intervention scores were calculated and reported as mean values with 95% confidence interval (CI). Analysis of the outcome data was completed using StataSE 13.

Thematic analysis was used to explore the field notes [300]. All the documents were repeatedly read, and important or recurrent elements that emerged were coded into two main categories: content of the intervention and practical considerations for implementing the intervention. This process was completed by the researcher (VB) who developed themes within these categories. Once the themes were clear, they were narratively described including excerpts from the text.

The narrative transcript and draft interpretations were then discussed by the study management group before a final narration of the themes and overall interpretation was agreed upon. Interpretation of the themes was then divided and refined into Evidence Statements and Recommendations by the researcher, before agreement through discussion was reached by all members of the study management group. The results and discussion of each theme is presented together within the Results section.

6.4. Results

6.4.1. Recruitment

The participant flow is documented in Figure 6.2. Recruitment occurred between 2013 and 2016. During active recruitment, two participants per week were enlisted (via researcher attending two Memory Assessment clinic sessions per week). Twelve patients were approached by the care team who informed them of the study. Two withdrew before giving informed consent (n=1 due to health reasons, n=1 did not wish to take part). All ten consented participants completed the programme and all assessments.

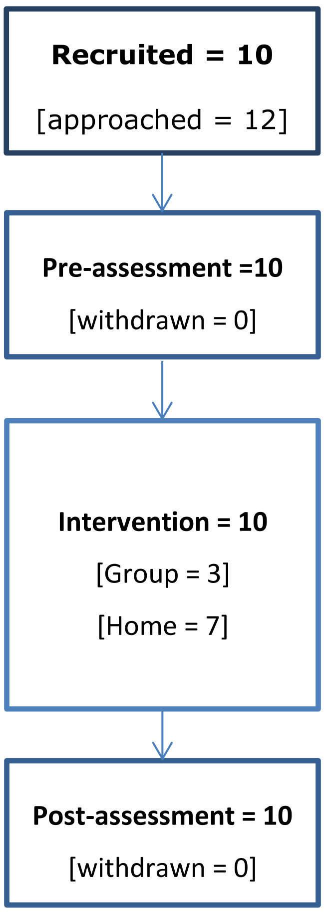


Figure 6.2: Flow diagram of feasibility study participants

6.4.2. Numbers analysed

Ten participants were recruited into the study and completed the intervention programme and assessments required. Participants completed the intervention in either a group (n=3) or home (n=7) setting according to the stage of the study when recruited. Pre- and post-intervention assessments were completed by the researchers within the allocated time frame and for all consented participants. Baseline data and outcomes were all collected during the assessment sessions.

6.4.3. Baseline data

All participants had mild dementia (MoCA median=21; range 16 to 26) (Table 6.3). Half of the participants recruited were women (n=5), and most lived with others (n=6) in a house or two-floored accommodation (n=7). Half of the participants reported having fallen at least once in the previous six months, with a median of 4 falls experienced by those who are falling (range 0 to 30).

Baseline characteristics	Median (range)
Gender (n, % women)	5 (50%)
Age (years)	84 (69-89)
Number of medications*	7 (1-18)
Number of co-morbidities*$	4 (2-6)
Living situation:	
Lives alone (n, %)	4 (40%)
Lives with spouse or family (n, %)	6 (60%)
Accommodation type:	
House (n, %)	7 (70%)
Bungalow (n, %)	3 (30%)
Mobility aid used (n, %)	5 (50%)
Number of falls in past 6 months	4 (0-30)
Falls in past year:	
No falls (n, %)	5 (50%)
1 fall (n, %)	2 (20%)
2 or more falls (n, %)	3 (30%)
MoCA^	21 (16-26)

Legend: n=number; *from initial phase data only (n=6), $excluding underlying diagnosis for cognitive impairment, MoCA=Montreal Cognitive Assessment, ^MoCA score direction 30=highest 0=lowest

Table 6.3: Table displaying baseline participant characteristics

6.4.4. Field note findings

Field notes were written for nine participants. The number of entries per participant ranged from 8 to 14 (11 mean entries) with the amount of written information varying from 1 to 42 lines per entry. Data from the field notes were coded into sixteen themes and grouped in two categories; content and practical considerations. Figure 6.3 depicts themes and categories. There was considerable cross-referencing between themes, with many recommendations originating from and relatable to more than one theme. The evidence related to each theme is presented within Appendix 25. The findings related to each theme are described narratively.

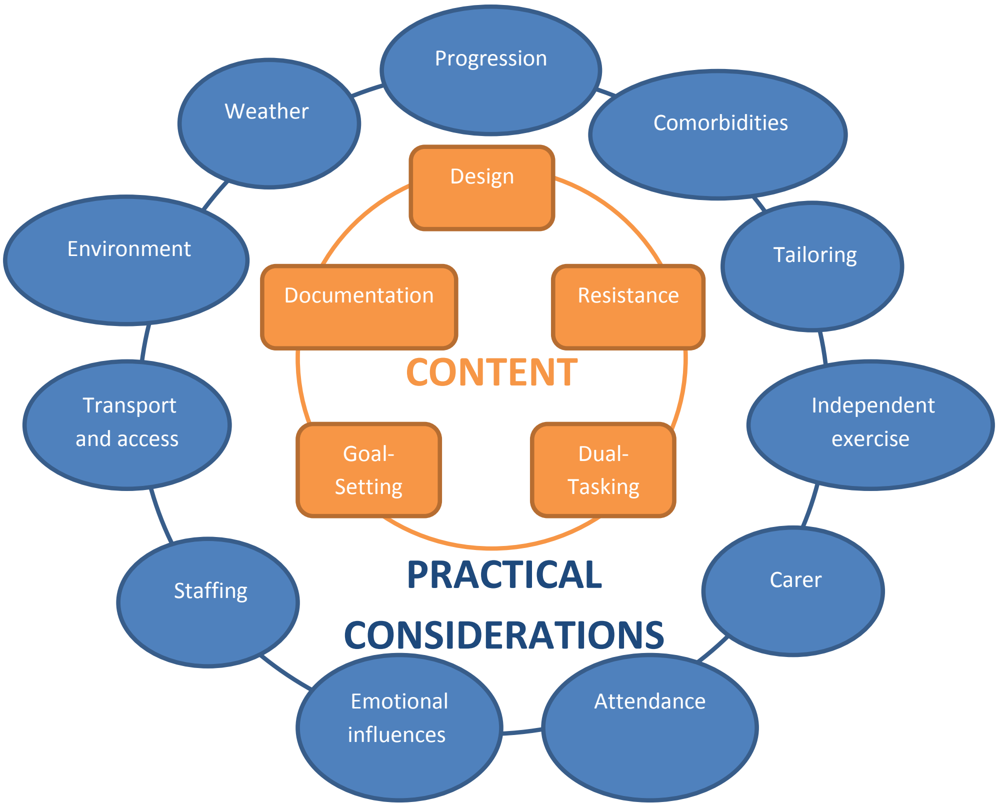


Figure 6.3: Diagram of themes from field note analysis

6.4.4.1. Content

Types of dual-tasking exercises used

The dual-task exercises chosen for the participants were an important and frequently discussed theme within the researcher notes. A variety of dual-task exercises were completed by participants which extended beyond those originally proposed (Appendix 26). Despite a number of dual-task exercises only being completed within a group setting, all cognitive processes challenged were transferrable to a different activity. For example, working memory was tested during a game to remember commands or during a shopping list task. Hypothetically, the underlying process challenged during the dual-task training is transferrable to any setting and links with the design theme. The field notes correspond with the study documentation, indicating dual-task training did not commence immediately. Participants were amenable to the dual-task exercises, did not report a preference for the different types, and did not have any suggestions of tasks or activities that they wanted to complete. This therefore indicates that the dual-tasks were prescribed at the correct level for the participant.

Dual-task training was completed within balance and cardiovascular exercises. Future studies should consider increasing the proportion by incorporating dual-task into strength exercises. This would be suitable for both the more fit and more frail participants depending upon supportive position (such as standing or sitting), and is relevant to the comorbidities theme. During dual-task training, task prioritisation needs attention from the person supporting the intervention. Task prioritisation was documented in one participant. Consideration of task prioritisation should be included within staff training materials to recognise and tailor to the individual's abilities and goals.

Documentation

Participants needed assistance with documentation in each setting. As the study programme progressed, some participants required less assistance with documentation but all required prompts, particularly for the date. The documentation process and assistance required could be considered a reminder to participants of their cognitive impairment. In the group setting, where comparisons of ability are inevitable, there was a positive sense of unity and empathy. Documentation has connotations of both emotional influences and staffing, in particular the skill and training of the staff supervising the sessions (link with staff theme).

> *"16007 forgot to bring blue folder with him – during completing the exercise sheets for today's session he requested that I not draw attention to the fact he had forgotten it." (Group; VB)*

The information that participants were required to document was quite detailed (date, level of exercise, repetitions, dual-task addition), potentially increasing the level of assistance required. When emphasised by the therapist, some participants developed a sense of ownership over some documentation components (such as completing the weekly activity diary). The documentation was also a memory prompt, reminding participants of their programme schedule. Both study documentation and a participant's individual methods (such as using diaries and wall calendars) were utilised and adapted according to need (link with tailoring theme).

Design

The study incorporated two settings: group and home. Group participants made no assertions, positive or negative, regarding the circuit-based structure of the session. However, the researchers reported that participants required one to one supervision to complete the exercises accurately, at the beginning of the programme in some cases and continuously in others. The group structure altered according to the staff-participant ratio. When fewer staff were present, alterations were required to maintain participant safety, and the ability to tailor the exercises, particularly the dual-task training, was compromised.

> *"…it was difficult to get all participants to dual task at an appropriate level. Some exercises were too hard for one of them and would slow [the] group DT down..." (Group; VB)*

> *"16007 finished exercises quicker than the others and had tendency to drift away from the group, kicking a football or paying attention to another aspect of the room." (Group; VB)*

A home setting ensured consistent one to one supervision and enabled consistent tailoring and safety. Session structure varied during the study. For example, the exercise order could reduce the transfer frequency of the variable-cuff weights from limb to limb. The structure was acceptable to participants, did not cause increased post-exercise muscle symptoms, and potentially reduced non-active time within the sessions (links to resistance theme).

Resistance

The same balance and strengthening exercises were used throughout the study. However, two different methods of resistance were utilised: exercise-bands and variable-cuff weights. These methods were frequently discussed within the researcher notes with some valuable recommendations identified. An exercise-band was used in both group and home settings but was reportedly difficult to use with all prescribed exercises. Using an exercise-band required extra instructions to ensure safety and efficacy that were not needed with the variable-cuff weights.

The ability to vary the weight allowed the same set to be used, with different resistance, depending upon the participant and their ability that session. The weight was easier to ascertain with the cuffs compared to the exercise-band, where colour was used to depict resistance. How the resistance was provided is an important consideration, particularly in view of the progression element required for the strengthening exercises (see progression theme), as well as the ease of use for this patient population.

Goal-setting

Goal-setting had a dual purpose in the study: as a measure of outcome and as a method to assist the researcher in prescribing the intervention. There was limited documentation within the field notes regarding this aspect. However, goal-setting was an achievable task with this patient population as it was completed by the majority of the participants.

6.4.4.2. Practical considerations

Progression of the exercises

Progression was frequently commented upon in the field notes. The exercises were progressed in a number of ways (Appendix 27). Exercises consistently started at a lower level before progressing at an individually appropriate rate. Progression of dual-task training was trialled in both task components, but only one component at a time was progressed, and only once completed without errors. Progression was limited in the group setting, particularly considering the individual and differing levels of physical and cognitive ability (link with dual-task theme). Group session structure was adapted to accommodate this wherever possible.

Progression was important to ensure the correct level of challenge was achieved. Hypothetically, too high a level of challenge may be frustrating, but too low a level reduces the benefit of the exercise. Effort ratings guided the researcher but were reliant on the participant being self-aware. The field notes demonstrated an element of variation regarding the amount of progression occurring within the sessions. Not every exercise was progressed in each session. Some sessions documented that fewer exercises were completed or the exercises done were at a reduced level to accommodate the participant on that day (link to comorbidities and tailoring theme).

Improvement was demonstrated through progression of an exercise being noted by participants, carers, and researcher. However, it was often difficult to measure the progression identified in the cognitive components of the dual-tasking. Carer involvement in the sessions provided an opportunity for feedback on progress and could have an impact on motivation to do the exercises independently either outside the sessions or once the study had finished (link to independent exercise theme).

Consideration of comorbidities

The influence and impact of comorbidities was a common theme within the field notes. Older adults with mild dementia experience a range of other medical conditions (Table 6.3). Despite this, each participant was able to complete the study programme.

Tailoring the intervention and approach was intrinsically linked to adapting to comorbidities. The participants used different methods to manage them. Both the participant and the therapist had a joint role in managing the symptoms and judging the appropriateness of continuing with caution, adapting or abandoning an exercise during an intervention session. This decision was made by determining the difference between a new symptom and something which the participant experiences regularly. Changes to routine, extended or exacerbated symptoms, pain medication use, symptoms at different time of day, or unusual activities were all identified as indicators.

Generally, comorbidities had a greater effect in the initial programme stages when the participant was completing something new. This further supports previous findings on progressing gradually, starting at a manageable level for the participant before increasing the level of challenge (link to progression theme), and rapport building with staff (link to staff theme). The supervising staff member needed the skill and experience to make judgements (link to staff theme).

Tailoring of the exercises to the individual

Tailoring is an underpinning principle of the intervention and was widely spoken about in the field notes. Tailoring was a mechanism for ensuring that a standardised intervention could be completed by a variety of participants, with different circumstances and abilities. The theme is intrinsically linked to other themes within content and practical considerations. An example of this was the strong cross-over between tailoring and comorbidities in that the exercises were adapted, omitted, or given an alternative if comorbidities limited the participant's ability to complete a specific exercise.

Tailoring was also utilised to accommodate the effects of other daily activities upon the participant and to ensure a full session was accomplished, rather than omitting exercises. Tailoring was completed in both settings. A circuit-based group design accommodated individual differences in ability (link to design theme). As within the comorbidities theme, the skill and ability of supervising staff to tailor the exercises on a session-by-session basis was required (link to staff theme).

Independent completion of exercises

It was not a prerequisite of participation that exercise sessions be completed independently (away from the scheduled programme), but some participants were identified in the field notes as wanting to continue the exercises themselves and requested information to accomplish this. Most of the participants did not complete any independent exercise. The reasons for this were not asked or documented in the field notes. However, it was implied that two participants enjoyed the sessions or found a sense of achievement, and both suggested independent exercise. Carer involvement was utilised by one participant in preparation to continue the intervention independently (link with carer theme).

The intervention folder was consistently given to participants following programme completion to ensure all had the information necessary to continue. As such, completing the exercises independently was linked to the documentation theme, demonstrating the importance of the programme materials.

Influence and involvement of the carer

There was a variety of carer involvement in the study. One carer attended and participated in most group sessions. Most participants did not have any carers involved in the implementation or completion of the study sessions. Carers involved were mainly family members, such as a wife or daughter. Many carers were only involved by attending the initial and final outcome assessments, irrespective of intervention setting. One carer adopted a supportive role, facilitating the participant to complete the exercises independently once the intervention programme had finished.

The support provided might not be overt to the programme staff but was present in the background or outside the session. The carer also influenced the access the participant had to the exercises and programme. For example, one participant lived with their relatives who facilitated access to the programme by unlocking the door, arranging, and reminding the participant of the timetabled sessions.

The potential for increasing carer burden was high considering the variety and levels of support the participants' relatives provided during the intervention period. The carer theme was linked to many other themes in this analysis, specifically attendance and tailoring. Theoretically there could be a relationship between the number and extent of the influence of medical conditions, the general frailty and impairments of the participant, and the level of carer support and involvement required for a successful programme completion. For example, a group participant whose carer attended most sessions also had considerable comorbidities. It is understandable that those participants with more comorbidities that are more limiting would require more care commitments and therefore the carer would have a greater role in facilitating the involvement in an intervention programme. The frequency of reporting of carer involvement in the field notes also reinforces the essential consideration of this supportive role within any intervention programme for this population.

Emotional influences on and within the sessions

The participant's emotions and the influences they had on and within the sessions was a recurrent but inconsistently reported theme. Some emotional influences were dementia-specific such as a recent diagnosis. Other emotional influences arose from other aspects of the participant's lives such as loss, loneliness, and mortality. Whilst not directly influencing the ability of the participants to complete the sessions, discussing these aspects did extend the session length. Additionally, these are issues that are to be expected for an older population living alone.

In the home setting, more emotional considerations were noted as the programme progressed and indicated increasing familiarity and rapport with the researcher. Only one researcher undertook the intervention visits towards the end of the study and the field notes reflected a stronger rapport at this time with more emotional influences recorded. As the relationship between researcher and participant developed the amount a participant might divulge increased. The actions of the research therapist in these situations included: a) providing a safe and supportive environment for the participant to divulge their emotional aspects, b) listening to the participant when they wanted to divulge information in a supportive and non-judgmental manner, and c) seeking advice from more senior staff or considered the involvement of outside agents (such as GP) if appropriate.

Whilst it was not the intention of this study to explore or seek a remedy for these issues, it was apparent with one participant in particular that the intervention visits improved their mood. Enjoyment and the psychological benefits of completing exercise will influence a participant's emotions. Awareness of the emotional component to a participant agreeing to take part in an intervention programme needs to be transparent.

> *"participant reported that she "felt better" after my visit, when asked if she thought this was from having a visit from someone or from doing the exercise, she thought it was "a bit of both"."*
>
> *(Home; VB)*

Anxiety also impacted on participant's physical ability, increasing breathlessness or presenting as an unwillingness to do the exercises. This might influence the number of sessions attended by the participant if the support staff member was inexperienced (link to the staff theme).

In the group setting there was the added component of how each participant was viewed by the others and their emotional reactions. The researcher had to consider emotional responses and appropriately manage them, often led by the participant's wishes. Highlighting impairments was an issue apparent during inadvertent comparisons within a group session. In some instances, the emotional influences may be used as a motivator, but needed tailoring to the individual. Therefore, this theme linked to the staff supporting the sessions and their training and ability to choose the correct motivating emotion to utilise, as well as their experience and knowledge of the participants, and their abilities and communication styles.

Staffing the sessions

The staff supervising and supporting the sessions was a consistent theme in the field notes. Issues and recommendations regarding staffing are intrinsically linked with many of the other themes within both Content and Practical Considerations. The registered therapists generally provided the most support required by the participants to complete the intervention sessions. This ensured that the exercises were completed accurately and at the correct level for the participant, tailoring when required and progressing the exercise when able. Providing the correct prompt or response to a situation or issue could influence the further involvement of that participant within the programme.

There were very few mentions of the actual staff member as a component of the intervention in the field notes and therefore inferences on their suitability need to be made from the participants' comments. Generally, there was affirmation that the participants enjoyed their sessions, either through reporting that they would "miss" the sessions following the programme completion, or through the consistent attendance and lack of attrition during the study.

The staff supporting the sessions were assisted by unregistered individuals, including student volunteers and carers. Whilst quality of the unqualified staff support was not discussed, it was clear that a consistent supervisor was preferred.

"16007 noted that it was not ideal having different people running the sessions and not having a consistent helper/physio student here." (Phase 1; Group; VB)

In general, the qualified researcher wrote more detailed notes than when the unregistered supervisors documented the sessions. The staff consistently completed the session documentation, supporting the participant to report their sessions rather than just doing it for them. Some participants required more assistance with documentation than others, and it was the supporting staff who would judge how much assistance to provide to ensure the smooth running of the session.

The experience and training of the supporting staff was an important consideration. Whilst this was not overtly described within the field notes, it was apparent through the interpretation of the other themes that this was an important component. Whilst the participant was being supported to complete an intervention by another person, qualified (such as a therapist) or unregistered (such as a carer), that "supporter" was influencing the intervention.

Considerations of transport

Transportation to the sessions was a theme relevant to both settings. Although pre-paid taxis were available, group setting participants travelled to the sessions using a variety of transportation methods, such as taxi, car, and bus. In the home setting, the supporting staff travelled. No transportation issues were reported in any of the home setting field notes.

Environment issues

Each participant's home accommodated the safe completion of the programme through adaptation and advice from the researcher. A variety of support surfaces were used, such as a table, a window ledge, a wall, and a chair back.

Influence of the weather

During the course of the study, the programme was completed in a variety of seasons. The weather was only mentioned within one entry for the group sessions. Whilst the weather did not limit the exercises completed or number of attendances, there was an element of tailoring required to accommodate seasonal influences, such as completing exercises inside or advising on appropriate clothing and safety advice.

Attendance

Attendance was an emergent theme that contributed qualitative data on retention rates of participants, overlapping with the quantitative attendance rates reported in the next section (Chapter 6.4.5). Attendance at the intervention sessions was variable. Many of the participants missed sessions due to pre-arranged engagements such as holidays and hospital visits, or related to hobbies and interests. These participants were engaged in leisure activities and often prioritised those over the intervention programme. One participant reported that their activity levels increased during their holiday, therefore, to prioritise the intervention over the leisure activities would be counterproductive to the underpinning philosophy of activity promotion in the programme.

Allowing the intervention sessions to be flexible (such as day or time) occasionally caused confusion for the participants. Various methods were used to prompt future session arrangements to reduce non-attendance from memory problems. Illness was another reason for missed sessions and communication with the researcher leading the session appeared important to ensure sessions were re-arranged and to reduce the amount of wasted time by the intervention staff. Carers and comorbidities themes had close links to attendance and the ability to retain participants in a study of this nature.

6.4.5. Adherence to the intervention and retention to the study

Participants received a mean number of 10 intervention sessions (of the potential 12 sessions). Three participants received fewer than the mean: 6, 7 and 9 intervention sessions. Only two participants completed the full 12 sessions over 6 weeks. A total of 101 (84%) sessions were attended with 19 non-attended sessions. The reasons for non-attendance were: participant pre-arranged engagement or appointment (n=13), researcher pre-arranged engagement or bank holiday (n=2), and participant illness (n=4).

Participants were prescribed between 9 and 21 exercises (mean 16; ±3.7) which were completed twice per week with supervision of the researcher. One participant fell frequently and, whilst consenting to participate in the intervention sessions, could only complete a reduced number of the prescribed exercises (n=9). The number of exercises prescribed increased to a mean of 18 (±3.5, range 10-21) by the twelfth session. The median number of exercises completed during each session increased as the programme progressed, with the range narrowing and becoming more consistent across the participants towards the end of the programme (Figure 6.4).

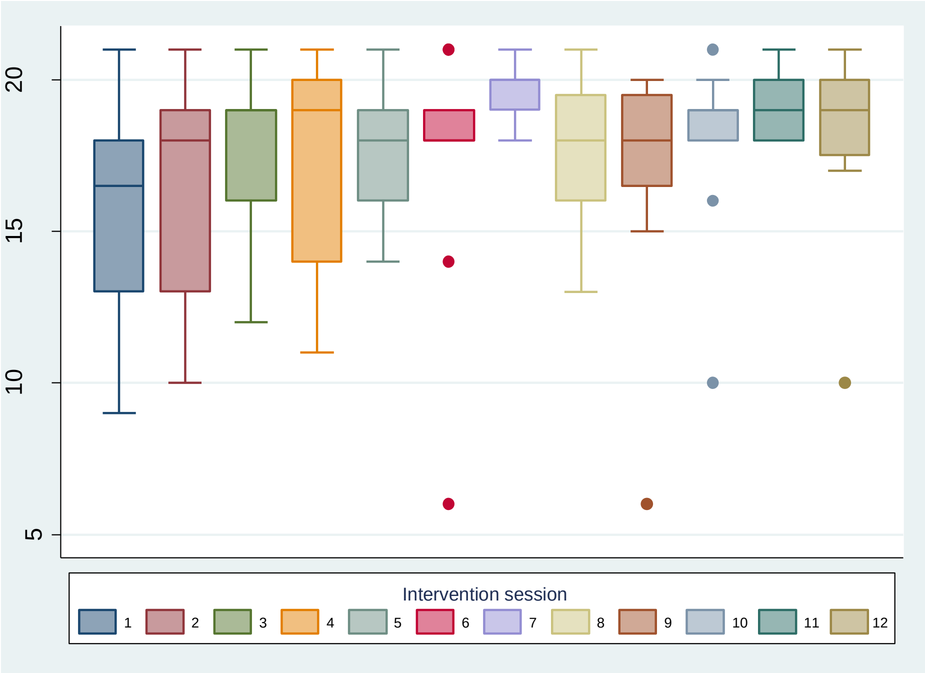


Figure 6.4: Boxplot of number of exercises per session

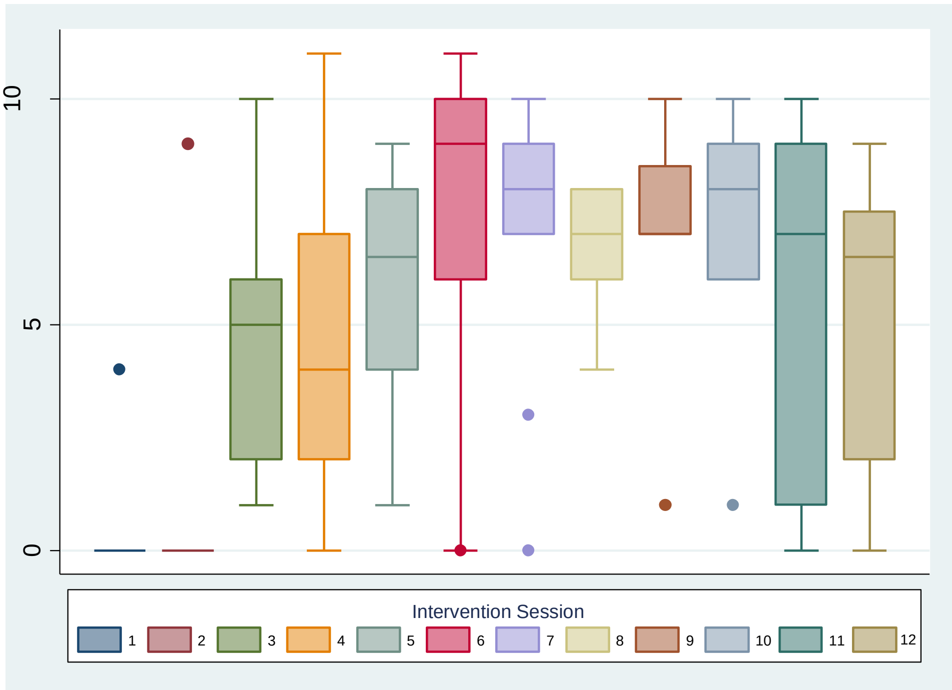


Figure 6.5: Boxplot of number of dual-task exercises per session

The number of dual-task exercises recorded varied during the course of the intervention programme. Dual-task exercises were not introduced into the intervention sessions until the participant was safe and confident with single component exercises. Most participants were introduced to dual-task training in the third session. One participant was able to safely start dual-task training in the first session. By the sixth session a mean of eight dual-task exercises (±3.5, range 0-11) were recorded, accounting for 45% of exercises completed in that session. The mean number of dual-task exercises recorded (5.1 ±3.4, range 0-9) had reduced by the end of the programme (12^{th} session), although still accounting for approximately one third (29%) of the exercises completed. A wide range of dual-task exercises were recorded across the intervention sessions, particularly between the third and the sixth, and the eleventh and the twelfth sessions (Figure 6.5).

6.4.6. Intervention effect

Outcome Measure	Pre-Intervention	Post-Intervention	Mean difference (CI)
Falls:			
Falls Risk (PPA)	2.03 (1.9)	1.5 (1.7)	-0.6 (-1.5,0.3)
Number of falls^ (6 week)	-	0 (0-6)	-
Falls Efficacy (FES-i)	27.7 (10.9)	25.8 (7.2)	-1.9 (-6.3,2.5)
Balance:			
Berg Balance Scale	44.3 (13.5)	47.1 (13.7)	2.8 (0.9,4.7)
Timed-Up and Go (secs)	16.6 (9.7)	15.7 (11.6)	-0.9 (-3.5,1.7)
Anxiety and Depression (HADS)	12 (8.4)	10 (6.1)	-2 (-5.7,1.7)
Global Cognition* (MoCA)	17.8 (1.5)	17.5 (3)	-0.3 (-2.9,2.5)
Gait:			
Velocity (m/s)	0.88 (0.33)	0.92 (0.37)	0.03 (-0.06,0.13)
Step-length (m)	0.51 (0.14)	0.50 (0.16)	-0.01 (-0.03,0.02)
Step-width (m)	0.10 (0.03)	0.11 (0.02)	0.01 (-0.00,0.01)
Double Support (%)	33.9 (9.41)	33.4 (9.71)	-0.5 (-1.7,0.7)
Step-length variability (%)	6.4 (2.9)	7.3 (4.2)	0.9 (-0.4,2.3)
Step-time variability (%)	16.5 (36.9)	11.8 (22.6)	-4.7 (-15.0,5.7)

Legend: Mean (standard deviation ±) for all except where stated, ^median and range, *from second phase data only (n=4), CI=confidence intervals, PPA=physiological profile assessment, FES-i=falls efficacy scale international, secs=seconds, HADS=hospital anxiety and depression score, MoCA=Montreal Cognitive Assessment, m/s=meters per second, m=meters, %=percentage

Table 6.4: Pre- and post-intervention outcome measures

All participants completed every outcome measurement in the pre- and post-assessments. The mean and standard deviation for outcome measures are presented following a visual examination of values (Table 6.4). Mean differences between pre- and post-intervention assessment demonstrated improvement following completion of the intervention in the PPA (MD=-0.6; CI -1.5,0.3), FES-i (MD=-1.9; CI -6.3,2.5), BBS (MD=2.8; CI 0.9,4.7), TUG (MD=-0.9; CI -3.5,1.7) and HADS (MD=-2; CI -5.7,1.7).

The mean MoCA scores for participants remained at 17 demonstrating that cognition did not change during the intervention period. Mean differences between pre- and post-intervention assessments for gait parameters produced mixed results. Some parameters indicated small improvements in gait pattern: gait speed increased (MD=0.03; CI -0.06,0.13), double support time reduced (MD=-0.52; CI -1.73,0.69), and step-time variability reduced (MD=-4.68; CI -15.03,5.67). However, some parameters indicated a small deterioration in gait pattern: step-length reduced (MD=-0.01; CI -0.03,0.02), step-width increased (MD=0.01; CI -0.00,0.01), and step-length variability increased (MD=0.92; CI -0.44,2.27).

DTC (%)		Pre	Post	MD (CI)
Gait speed	BC	13.9 (5.8)	20.1 (8.9)	6.3 (-1.7,14.2)
	VF	30.0 (11.5)	32.9 (15.1)	2.9 (-43.7,11.6)
Step-length	BC	6.3 (3.0)	6.9 (4.5)	0.6 (-2.6,3.7)
	VF	15.5 (6.5)	14.1 (7.3)	-1.4 (-4.9,1.9)
Step-width	BC	18.5 (17.2)	7.8 (5.6)	-10.63 (-24.4,3.1)
	VF	23.8 (18.5)	16.4 (13.5)	-7.35 (-16.1,1.4)
Double Support	BC	9.2 (5.8)	8.7 (5.2)	-0.6 (-5.1,3.9)
	VF	20.5 (12.9)	18.5 (12.3)	-2.0 (-7.5,3.5)
Step-length Variability	BC	28.5 (27.1)	15.5 (12.3)	-13.0 (-35.4,9.4)
	VF	33.3 (25.8)	44.9 (36.9)	11.7 (-15.5,38.8)
Step-time Variability	BC	76.3 (89.3)	36.0 (24.9)	-40.2 (-114.2,33.7)
	VF	78.1 (49.9)	66.5 (49.5)	-11.6 (-64.0,40.8)
Speed (total time to count)	BC	10.1 (4.4)	16.1 (18.1)	6 (-7.1,19.1)
Accuracy (number)	VF	23.9 (23.1)	36.3 (29.7)	12.4 (-10.1,34.8)
mDTC (gait speed/task speed)	BC	11.9 (3.2)	18.1 (11.1)	6.1 (-2.2, 14.5)
	VF	26.9 (13.9)	34.6 (16.7)	7.6 (-4.1, 19.3)

Legend: Mean (standard deviation) for all unless stated in table heading, DTC=dual-task cost, mDTC=mean dual-task cost, MD=mean difference, CI=confidence intervals, BC=backwards counting, VF=verbal fluency

Table 6.5: Pre- and post-intervention dual-task costs (DTCs)

The DTC results were also mixed (Table 6.5). An improvement in DTC was found in step-width (backwards counting MD=-10.6; CI -24.4, 3.1: verbal fluency MD=-7.4; CI -16.1, 1.4), double support (backwards counting MD=-0.6; CI -5.1, 3.9: verbal fluency MD=-2.0; CI -7.5, 3.5), and step-time variability (backwards counting MD=-40.2; CI -114.2, 33.7: verbal fluency MD=-11.6; CI -64.0, 40.8) in both dual-task walking conditions. However, gait velocity (backwards counting MD=6.3; CI -1.7, 14.2: verbal fluency MD=2.9; CI -43.7, 11.6), cognitive task speed (backwards counting MD=6; CI -7.1, 19.1), and cognitive task accuracy (verbal fluency MD=12.4; CI -10.1, 34.8) all increased in DTC following the intervention. Step-length and step-length variability DTCs were inconsistent in their changes between walking condition. The mDTC of both tasks increased following the intervention (backwards counting MD=6.1; CI -2.2, 14.5: verbal fluency MD=7.6; CI -4.1, 19.3).

6.5. Discussion

6.5.1. Summary of findings

A non-randomised feasibility study was successfully completed using a novel, dual-task based intervention comprising strength and balance exercises in persons with a mild dementia. Participants were successfully recruited from Memory Assessment Services and there were no issues in gaining consent. The intervention was delivered according to the protocol and participants tolerated the content and schedule well. Assessments completed were acceptable to the participants recruited in this study and all participants completed both pre- and post-intervention assessments in a timely manner. In summary, the intervention was acceptable to participants.

Measures of falls risk, balance, and mobility all improved following the 6-week intervention. The gait pattern of the participants showed both positive and negative changes. The participants walked faster, spent less time in double stance phase, and were less variable in their stepping time. However, they took shorter, wider, and more variable length steps.

The DTC was successfully measured in this patient population during walking with two separate concurrent cognitive tasks. All the participants recruited completed all the outcome measures. Overall, the DTC demonstrated mixed changes following the intervention period, with no consistent pattern of improvement or deterioration.

Sixteen themes were derived from analysis of researcher field notes related to Content and Practical Considerations of the intervention. There was considerable overlap between the themes indicating that both the content and how it is delivered are equally important in developing and implementing a successful intervention.

6.5.2. Strengths and limitations

The design of the study was suitable to the feasibility research questions and early stage of intervention development. However, results are restricted in generalisability because of this and the conclusions drawn are limited. The sample was representative of those attending memory clinics but was heterogeneous in physical ability, despite all having mild dementia and being recruited from the same memory assessment clinic. Physical ability may have influenced the measurements or the response to treatment, particularly considering the variability in the sample. The overall trend of improved physical function demonstrated that benefits could be found in older persons with mild dementia that have a range of physical ability.

The outcome measures were completed by the same researcher who completed the intervention, therefore an element of information bias may have been introduced. Whilst the gait measures were completed using an objective electronic gait mat, which provides some reassurance that these results are free from bias, there is an element of judgement in the other measures, such as the BBS and PPA (although these have good test-retest reliability).

The exercise sheets and study documentation could not be completed independently. The exercise documentation was heavily supported by the researcher and there were concerns that exercises were not documented or this was done inaccurately, resulting in miscounting. Therefore, the analysis of the number of standard and dual-task exercises completed is limited and potentially underestimated.

Documentation regarding the field note findings could be considered a limitation. The documentation of the sessions were clinical notes, not written for the purposes of future analysis. The content was not focused on documenting the acceptability and feasibility of the intervention, therefore, the notes were brief. However, they provided a valuable element of process evaluation into the feasibility study analysis, contributing to findings regarding process, methods of delivery, content, progression, and intervention provider.

The interpretation is from the perspective of the researcher who wrote the field notes. An unrelated researcher completing the analysis might interpret the content differently. The notes potentially elicited memories or meaning other than that documented and is a source of discrepancy, considering that not all the notes were written by the same researcher. Every effort was made by the researcher and study management group to ensure interpretation was only made from the information documented and that the evidence trail was transparent, however it is possible the results are biased. Other methods, such as interviews, would have been more specific, assessing intervention feasibility by questioning the researcher's opinion and the participant's perception of the acceptability of the programme.

Thematic analysis is valued for its flexibility and varied sources for analysis [300]. Despite a limited precedent of using clinical notes for this type of analysis, the notes were recorded in real-time, without influence of the future thematic analysis, and thus share similarities to traditional field-note documentation. The clinical and practical perspective is useful and provides an element of process evaluation to the study findings. However, it could be argued that the researcher who conducted the intervention had a greater insight into the practical components and content from completing it, and therefore provided a level of detail and understanding that might not be present from outside analysis. Elements of the field note analysis had strong parallels with the realist review, supporting some of the emergent response-mechanisms

(Chapter 5.3.5), such as tailoring, the influence and involvement of the carer as an intervention support, and the "professional" context features.

The study has strengths despite the limitations outlined above. There was no attrition during the course of the study: all the participants who consented continued and finished the programme. The same researcher recruited, consented, assessed, and completed the intervention visits for all the participants towards the end of the study period. A rapport was therefore built from the initial sessions and potentially this trust and relationship encouraged continuation in the study. The intervention was popular with participants, even at the recruitment stage. Many participants appeared to be motivated or pro-active about their memory problems and were keen to utilise any assistance to help them with their memory or physical limitations. Physiotherapy is not routinely offered for persons with mild dementia and therefore this intervention was additional to standard care, potentially enhancing compliance as the patients were keen to participate.

Research with persons with dementia and cognitive impairment is improving and increasing. The study results are promising and need further exploration in larger, randomised trials with comparison against standard care or placebos (such as social interventions) to determine effectiveness. The resultant recommendations from this study are a considerable asset. These practical considerations regarding the content are invaluable when attempting to design or implement a larger study.

6.5.3. Outcome measurements

The researcher was experienced with the outcome measures and the patient population, and was able to get all the assessments completed in the allocated period. Measurement of the cognitive task during dual-task tests was difficult to conceptualise, and in practice it was likely to be poorly valid. For example, the backwards-counting task was measured in seconds, as theoretically an improvement would be that an individual would get faster at counting backwards. However, an individual would get slower if they were being more accurate in this task: missing out 20 numbers would take less time than saying every single number. Inaccuracies in measurement of both cognitive tasks may have caused the inconsistent DTC results. Mean DTC is considered a more stable measure accounting for change in both physical and cognitive components [142] and could be used in future studies once the validity of the cognitive component is improved.

6.5.4. Context

The findings from this study are in keeping with other research trials in the field. The number of participants and low attrition rate is similar to another feasibility study in persons with mild dementia [99]. Wesson et al [99] also found high variability within their small sample (n=11 in their intervention group). Whilst the intervention in this study was only 6 weeks, a time-frame less than the Wesson feasibility trial, it was considerably less than the 12 months of exercise intervention in the first large-scale randomised trial in AD patients [103].

The FINALEX trial [103] primarily targeted function rather than balance or gait, but their 12 month intervention did halve the rate of falls and reduce the deterioration in function experienced in this patient population. Their results corroborate the field note findings from this study, which a home-based intervention provides consistent progression and tailoring to the individual, illustrated by their less effective group intervention compared with home intervention [103].

Vreugdenhil et al [292] also used a home exercise programme and found an improvement in the TUG. The improvement of 2.9 seconds was larger than that found in this study, but their participants were younger (mean age = 73.5 years) and were almost 7 seconds faster in their initial TUG.

Improvements in gait speed found in this study follow the findings from another dual-task based exercise intervention. Schwenk et al [101] found improvements in gait speed following dual-task training in older adults with dementia during a 12 week group intervention. Despite the population having both mild and moderate severity dementia, Schwenk et al [101] found both a faster mean walking speed and improvements in more of their gait parameters than this study. Themes identified echo results published from similar analysis of exercise-based independence promotion programmes [301, 302].

Although narratively described and grouped in a different way, Wu et al [301] also placed importance on progression during the course of the intervention, the consideration of emotion and its influence in completing an exercise programme, and the relationship between the participant and the supporting staff. All of these studies had relatively small samples but their results are promising, not just on reflection of their outcomes but also the attrition and completion of such interventions in older adults with cognitive impairment.

6.5.5. Interpretation

The usefulness and limitations of dual-task training as an intervention was an important research question and a lot of information was interpreted from the results of this study. Dual-task training could be completed in this patient population but there were no overall improvements in dual-task performance during the post-intervention assessment. The DTCs found in the gait parameters in this study were higher and more inconsistent than those recorded previously in a dementia population [141]. This could be due to issues with using DTC as an outcome rather than the intervention itself. Schwenk et al [141] used two dual-tasks and both produced similar inconsistencies. However, when a difficult dual-task (serial backwards 3) was used, the DTCs become more similar to those found in this study, both before and after the intervention [141].

The difficulty of the dual-task is important and needs to be tailored to the correct level of challenge for the participant (Chapter 2). This is relevant for implementation both as an intervention and as an outcome measure. In this study, the dual-task as an outcome was not matched to the individual as the intervention was. Level of education could have an impact on the individual's ability to dual-task and should be taken into consideration in future studies. Together with the difficulties found in recording the accuracy or speed of the dual-tasks used, this study concludes that a more suitable cognitive task should be used in this patient population.

The outcomes related to falls risk (PPA, BBS, TUG, and FESi) all demonstrated improvement following the intervention. The sample improved from a "marked" to a "moderate" risk of falls during the course of the intervention [40]. Whilst these markers are not significant or relatable to specific thresholds, they do describe the direction of improvement in the sample.

The initial score of 2.03 on the PPA scale was within the normal range expected for the age group, but this should not detract from the improvement and reduction in falls risk achieved. The PPA has been demonstrated to be reliable in

AD population and assists in the interpretation that the participants did improve, rather than just test-retest familiarity.

The sample improved in BBS, moving above the published cut-off (<45) indicating lesser risk of falls [303]. However, the change of 2.8 on the scale was just underneath the MCID of 3.3 [219]. The TUG for this sample was slower than the cut-off of 13.5 seconds for a community-dwelling older population [171], indicating that they were at risk of falls. The post-intervention TUG time followed that of the PPA falls risk demonstrating that the sample was still at risk of falls even after the intervention. Following the intervention, the sample did not achieve the 4.09 seconds MCID for older adults with AD [220].

There is no published MCID or minimal detectable change (MDC) for the HADS in either healthy older adults or persons with dementia. A study of coronary heart disease patients reported that a MDC of 5.68 in the total score [304], but to extrapolate these results to this study sample would be inappropriate.

All the gait parameters for this sample were outside the range for healthy-aged matched individuals [164] and older adults with MCI [106], indicating that even following the intervention their gait pattern was impaired. This may result from the variable physical abilities in the sample. All the pre-intervention gait parameters were comparable to the survey sample in Chapter 2 except gait variability which were higher (step-length variability: survey=5.2%, study=6.4%; step-time variability: survey=6.0%, study=16.5%). This is indicative that the study participants had greater variability to their gait pattern than others with mild dementia.

All the falls-related outcomes followed the same trend of improvement but there was some discrepancy with the gait parameters, with some improving and others deteriorating. One interpretation could be that all the stability-related gait measures showed deterioration. Theoretically, if an individual's balance improved then they should have better postural stability and take larger steps. However, in conjunction with the DTC information, an alternative interpretation is that the participants were taught during the intervention to compensate, taking shorter and wider steps to stay stable. Due to the inaccurate measurement of the cognitive task, it is difficult to determine which task was prioritised during dual-tasking. Potentially postural stability and the physical component may have compensated to improve ability in the cognitive task.

Another interpretation involves deterioration. Deterioration of ability is expected over time in older adults with dementia, as demonstrated by the FINALEX study [103]. Therefore, any reduction in that deterioration is a positive outcome for a trial. With no comparator control group, it cannot be assumed that there would be any significant deterioration expected in the 6-week study timeframe. However, this consideration is another potential explanation for outcomes following different trends. Not all the measures improved in the feasibility study by Wesson et al [99], with their PPA indicating a higher falls risk score post-intervention.

6.5.6. Implementation and recommendations

A list of recommendations has been summarised following the interpretation and synthesis of evidence from the different study findings. Table 6.6 informs the further refinement of the intervention and any further trials of the programme in this patient population.

Theme	Recommendation
Dual-Tasking Exercises	• The dual-task activity should be at the correct level of challenge, only commenced once one aspect of the dual-task is familiar (for example the physical component), and tailored to the interests or topics of familiarity for that individual. • Supervising staff should be aware of which dual-task component the individual is prioritising and consider how that may influence their ability within that exercise and overall aims.
Documentation	• Future studies should differentiate between what information is: i) required for an individual to complete the exercises, and ii) required by the researchers for the study evaluation. • Staff supervising the sessions need consider the impact of reminding the participant of their memory difficulties when supporting the documentation of the session. • The programme documents need to be in a format suitable and acceptable for the participant and their individual needs, potentially using clear pictorial, photographic or written instructions.
Design (of the sessions)	• The intervention should be set at home to ensure a consistent level of supervision, exercise tailoring and progression. • The order of the exercises should be considered, tailored to the individual and designed to optimise active time within the sessions.
Resistance (Methods of obtaining)	• Variable-weights should be used to provide progressive resistance.
Goal-Setting	• Goal setting should be used to direct and tailor the intervention to the individual, their everyday life and interests, and their carers wishes.
Progression (of the exercises)	• Progression is an important component of the exercise programme, can be utilised and demonstrated in a number of ways and ensures the correct level of challenge for the individual throughout the intervention programme. • Progress does not have to made within each session but the sessions should accommodate the individual’s other activities of daily living and the influence of their comorbidities.
Comorbidities	• Staff supervising the exercises should be aware of participants’ comorbidities, and what the normal, every-day symptoms they experience because of them are. • Adaptions or alternatives should be provided by the supervising staff before omission of an exercise, discussed and agreed with the participant, and tailored to the individual, their abilities, and presentation on a daily basis.

Tailoring (to the individual)	• The standard exercises need to be tailored to the individual, in a variety of ways, particularly considering their individual aims, comorbidities, daily life, environment, and carers involvement. • Staff supervising the sessions need to be trained in the different ways in which the exercises could be tailored or adapted.
Independent completion of exercise	• Participants and their carers (if involved) should be informed and encouraged to complete independent exercise outside of the intervention sessions from the beginning of the programme and time spent tailoring, demonstrating, and supporting the participant in the achievement of this. • Barriers to completing independent exercises needs to be further explored using an appropriate research design.
Carer (influence and involvement)	• Carer involvement might not be apparent within the intervention programme but any overt or "background" support needs to be considered by the supervising staff, particularly in relation to increase of burden.
Attendance	• Attendance at intervention sessions needs to be flexible around the individual's social and daily lives wherever possible. • Participants and their carers must have a reliable method to contact the staff supervising the sessions to limit non-attendance and improve flexibility around illness or other engagements.
Emotional influences	• Staff supporting the intervention sessions need to be aware of emotional influences in the participants. They should listen and reassure if issues arise, maintaining a professional relationship with the participant and their carer if involved, and liaise with the GP if required. • Emotional issues can influence physical ability and the delivery of the intervention, in which approaches need to be tailored to the individual (for example, increased time within a session, motivational approach).
Staffing	• The amount of support provided by the staff needs to be tailored to the individual, the stage of the programme, and the setting.
Transport and Access (to the sessions)	• Collaboration with the individual and their carer is needed to achieve successful access to the programme.
Environment issues	• Supporting staff need to risk assess the safety of completing the exercises within the individual's home environment and adapt the exercises or the environment where necessary.
Weather (influence of)	• Staff supporting the intervention need to provide advice and tailoring regarding participant safety in extremes of weather.

Table 6.6: Recommendations from the feasibility study

6.6. Conclusion

This study demonstrates that completing combined physical and cognitive rehabilitation is feasible and acceptable to older adults with mild dementia. Practical information on delivering a combined intervention including dual-task training has been summarised and indicates promise within a home setting, where individual tailoring and progression of resistance and dual-task exercises can be suitably achieved, irrespective of comorbidities. It is important for trained staff to consider emotional influences, the environment, and carer involvement in order to support delivery, documentation, access, and attendance. The study shows encouraging findings that a dual-task, exercise-based intervention can improve falls risk, balance, and gait, and suggests that this programme can be completed and may be useful for older adults with mild dementia.

Chapter 7. Discussion

Summary

This chapter will combine the results from all preceding sections. It will briefly summarise the results, evaluate the strengths and limitations of the project as a whole, and compare the findings to existing literature. The clinical implications are then outlined and future directions suggested.

7.1. Summary of results

7.1.1. Synthesis of findings

7.1.1.1. How does cognitive impairment affect gait parameters, including dual-task ability, balance measures and falls risk? Is there a relationship between these components?

Initially, the theoretically modifiable components were identified, described, and modelled (Chapter 1), focusing on physical measurements of gait, balance, and falls risk. The cross-sectional survey demonstrated that older adults with mild dementia experience falls (32% had fallen in previous 6 month). Having mild dementia had a detrimental effect on gait pattern, balance, and falls risk. The mean dual-task cost (mDTC) calculated exceeded previously reported levels for healthy older adults and were associated with reduced global cognition. Differences in gait, balance, and falls risk were noticeable between people who were falling compared with those who were not. The mDTC was not, however, different between *Fallers* and *Non-Fallers* in this sample. Gait speed and falls risk scores did indicate those individuals with a mild dementia who are more likely to fall. There was a clear relationship between the physical and cognitive components which contribute to a "model" of falls risk.

7.1.1.2. What interventions are used to reduce falls in older adults with cognitive impairment?

The second stage identified published interventions that had been used to reduce falls in older adults with dementia. The umbrella review (Chapter 3) identified seven reviews, one of which reported interventions specifically trialled in adults with cognitive impairment. Exercise and multifactorial interventions were most frequently reported in mixed population studies where adults with and without a cognitive impairment were included from community, residential care, and hospital settings.

None of the reported interventions demonstrated a consistent, significant reduction in falls across all included reviews. Results varied between reviews and between settings. Generally, exercise demonstrated a positive impact in community populations with less effect in a care home or institutional setting. Multifactorial interventions provided consistent positive results across all settings but were not statistically significantly effective on falls in populations with cognitive impairment. Whilst not providing conclusive evidence, further study regarding exercise and multicomponent interventions was indicated.

7.1.1.3. Has dual-task training been tested in older adults with cognitive impairment?

A focused meta-analysis (Chapter 4) to synthesise studies of multicomponent exercises incorporating both physical and cognitive components in older adults with cognitive impairment was completed. A small number of studies (n=8) were included, most of which were interventions incorporating physical and cognitive components as dual-task based exercises or training. Four studies reported number of falls, half of which had a significant difference between groups. However, due to differences in reporting, meta-analysis was not possible.

Meta-analysis was conducted with measures of balance and gait speed, which are intermediate outcomes, and demonstrated statistically significant improvements following the intervention when compared to controls. Dual-task training has been tested in older adults with cognitive impairment, and demonstrated promising results at improving the number of falls, gait speed, and balance. Further study of this intervention as a treatment component was indicated, particularly in relation to how dual-task training and exercise can influence falls outcomes.

7.1.1.4. How do exercise-based interventions reduce falls in older adults with cognitive impairment, in what circumstances and why?

Both preceding systematic reviews identified intervention components, but in doing so, they also raised questions on contextual factors and mechanisms of action required for further intervention development and implementation. A realist review refined the underpinning theoretical model, explored how exercise can reduce falls, and described circumstances required for successful intervention delivery. Data were extracted from a range of research material (n=35 documents).

An initial rough programme theory was developed into eleven middle-range theories, two of which were evidenced and refined from the literature: encouragement and physiological-responses. Evidence supported the initial rough programme theory definition of physiological-response mechanisms, illustrating that older persons with mild to moderate dementia can benefit from physiological-responses involving cognitive, gait, motor, and postural mechanisms through exercise. Contextual information on the type of exercise and its circumstances was collected and used to produce clinically-relevant recommendations. Data collected in the review also suggested that improvements in gait and postural ability can positively influence falls risk through mechanisms involving improved control. However, there was limited material linking cognitive and motor responses to falls outcomes. This finding mirrors the meta-analysis results (Chapter 4) where outcomes of gait and balance, rather than number of falls, demonstrated significant improvements in older adults with mild dementia.

Clear findings on encouragement emerged from the review. Perception of benefit is an initial mechanism-response which becomes a context for the secondary mechanism-response of support. When an older person with mild to moderate dementia has the perception that exercise will be beneficial, they can feel supported to complete an exercise programme.

Other contextual factors are required for the individual to feel support. For example, the presence of a "gate-keeper", such as a therapist or carer, who shares the person's perception of exercise as beneficial, can enable access to exercise programmes. Support and the perception of benefit were not strongly linked to falls outcomes but included benefits such as mood, behaviour, and enjoyment of everyday life. Various contextual circumstances were identified and were relevant for the design, delivery, and support of an exercise-based falls prevention intervention for older adults with mild dementia.

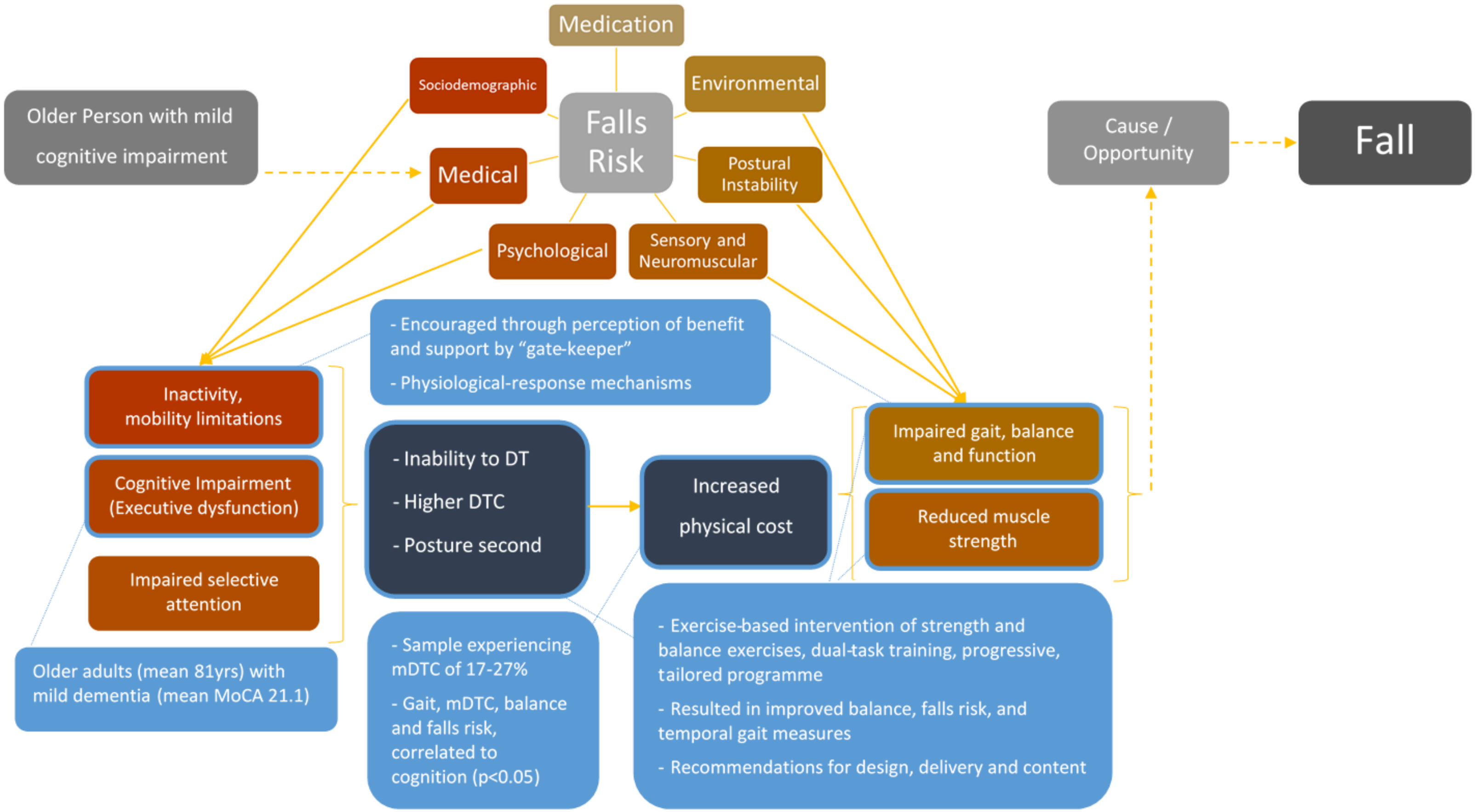
7.1.1.5. Does exercise-based dual-task intervention programme improve an individual's ability to dual-task and other falls risk factors?

The final stage explored the feasibility, acceptability, and delivery of a dual-task, multicomponent exercise-based intervention. Older adults with mild dementia were recruited into a small, non-randomised, pre-post feasibility study (Chapter 6). During the intervention programme adherence to the sessions was high, indirectly indicating acceptability. Mean differences demonstrated consistent improvement in falls risk, balance, and gait. Participants walked faster, spent less time in double stance phase, and were less variable in their stepping time, although they took shorter, wider, and more variable length steps. Dual-task cost was successfully measured but demonstrated mixed results, with no consistent pattern of improvement or deterioration. Themes derived from thematic analysis of researcher-clinical field notes had considerable overlap indicating that content and practical considerations were related when developing and implementing a successful intervention.

The intervention development process resulted in a testable training programme that refined content, methods of delivery, and procedures (Appendix 28). In conclusion, a combined physical and cognitive exercise-based intervention programme was deliverable, feasible, and acceptable to older adults with mild dementia, and shows promise at reducing falls risk.

7.1.2. Synthesis of findings on theoretical model

Synthesising findings requires summarising the components and combining them together into a coherent structure. The original theoretical model (Figure 1.3) was refined and illustrates where the evidence from the studies enhances the model (Figure 7.1).



Legend: DT=dual-task, DTC=dual-task cost, mDTC=mean dual-task cost, yrs=years, CI=cognitive impairment, MoCA=Montreal Cognitive Assessment

Figure 7.1: Diagram of refined theoretical model with research findings

7.2. Strengths and limitations

The strengths and limitations of each study have been discussed in the relevant chapters. The aim of this section is to critique and reflect on the strengths and limits of the research as a whole.

A mixed methods design was employed. The original research questions were complex and different methods were required to address each component. Quantitative and qualitative data were rigorously collected, analysed according to convention, and synthesised with equal value to produce clinically-relevant recommendations (Section 7.4). This is in accordance with the definition of mixed methods research, given by Tashakkori and Creswell [305] as "*research in which the investigator collects and analyzes data, integrates the findings, and draws inferences using both qualitative and quantitative approaches or methods in a single study or a program of inquiry*" ([305], p4).

Mixed method designs are well-established in health research [306] and the rationale for its use in this project was sound and a strength of the study. The approaches used were complementary to each other, providing incremental progression from one chapter and research question to another, and corroborating findings identified separately to enhance the overall validity of the study [306]. However, there is extensive literature that argues for the incompatibility of different methodologies due to differing epistemological paradigms [307], which could be considered a limitation. Teddlie and Tashakkori [308] situate mixed methods research within the Pragmatism paradigm. Realism [230] also employs and advocates mixed methods [114] thereby supporting this study design.

The cross-sectional survey was sufficiently powered to determine associations and contributing factors for falls in this population. However, to accurately test the dual-task paradigm, the measurements of DTC must also be accurate. The variability and inconsistencies found in the cross-sectional survey, dual-task meta-analysis, and feasibility study all highlighted the difficulty in measuring this outcome. The measurement and reporting of DTC as an outcome in this population was novel and a strength of the research. However, the variability and inconsistencies identified in the outcome is a limitation and highlights the need for further refinement.

The population of interest recruited for the cross-sectional survey and feasibility study was older adults with mild dementia. There was a lack of consistent diagnosis in the study samples. The participants were not diagnosed as having MCI or dementia, and by not accurately identifying subtype, the sample cannot be accurately described nor compared to other literature. However, both the survey and study provide a clinical perspective, describing the actual patient population being seen by community memory clinic services.

Three different literature reviews were included, each using a different method of synthesis and asking different research questions. Each review was completed in a rigorous, transparent, and reproducible manner. All have either had the protocol or full review published. However, it is always possible that literature was missed and considering the umbrella and dual-task review were published consecutively, there is potentially more literature available that has not been included.

The realist review was a novel and clinically-relevant method to explore and synthesise data from the literature. This is the first realist review in falls literature. Review findings were dependent upon the quality of the search strategy, the realist framework adopted (CMOcs), the included material, and the researcher completing the interpretation. Focus of the review was narrowed considerably from the initial rough programme theory. This ensured completion within set timeframes and enabled the review to influence the feasibility study. However, narrowing the focus also influenced breadth and reach of the review within the research and for publication.

Judgements on inclusion and interpretation were all made by the researcher with guidance from a second author or the stakeholder group. In a classic systematic review, this would cause considerable bias. Many realist projects have large teams upon which to progress concepts and formulate disputative discussions, refining the programme theory and improving rigour. Therefore, a single researcher with a small stakeholder group could be considered a limitation of this project.

Realist reviews are often a precursor to realist evaluations [309] and in this review the development of research questions to test was evident. Realist evaluation could have been used instead of the non-randomised feasibility study, providing continuity of research paradigm across the different studies. However, the ethical approval process had commenced prior to completion of the realist review, and analysing of the feasibility study results using only the two MRTs reported in Chapter 5 would have limited the analysis and conclusions.

Another potential limitation is the inability of the methods to produce definitive comment on effectiveness or implementation of the intervention. The feasibility study achieved its aims and was not designed to answer all potential feasibility questions. Small sample size and non-randomised or blinded design meant the study was achievable by the single researcher. However, the study design might limit inclusion in future meta-analysis on this intervention and would therefore not assist in developing the evidence-base.

Policy decisions and health service related changes are also not routinely based on such small-scale studies. The intervention needs to be rigorously tested.

Considering the stage of intervention development highlighted by the initial systematic reviews in Chapter 3 and 4, determining effectiveness was not the intent of the study. The quality of the intervention development is a considerable strength and lays the foundation for further empirical testing.

Considering the feasibility study had acceptability aims, the lack of qualitative evidence from the participants and their carers on their perspective of falls, falls interventions, and the dual-task training was a limitation. The mixed methods study design permitted questions regarding acceptability, and qualitative interviews of the participants would have complemented the field note thematic analysis. Omission of further qualitative work could be considered a silence in the intervention development but provides a natural progression for post-doctoral study.

Only one aspect of falls intervention was focused upon: exercise. This specificity is both a strength and a limitation. Falls, particularly in older adults with cognitive impairment, are multifactorial and there may be other, more influential factors in the theoretical model which exercise does not address. Only considering the influence of exercise-based interventions is simplistic. However, if all components of falls interventions were considered and tested together, it becomes difficult to isolate the "key ingredient" or modifiable component in the intervention model. The exercise component of a falls intervention programme is complex, as summarised by the umbrella review (Chapter 3). Focusing on only this component ensures it is well-developed from a theoretical and practical perspective.

Overall, the study has documented the development of a practical, clinically-considered, and relevant intervention with implementable recommendations (Section 7.4). The intent of this research is to improve patient care. Whilst directing the study components to practical recommendations is a strength, the influence of subjective knowledge and experience influencing interpretations is a contrary limitation. In both realist research and qualitative methods the "researcher in residence" model is well described [310, 311] and advocates transparency and acknowledgement of the researcher's background. The reader can then understand the research in light of the lens from which it is written.

7.3. Context and comparison to other literature

During the course of the study, similar material emerged. These will be considered according to the population, intervention, context, and outcomes.

7.3.1. Participants

Many comparable studies have also focused on mild to moderate severity cognitive impairment [99, 292, 312, 313]. The most recently published study by Taylor et al [312] had similar populations to both the cross-sectional survey (Chapter 2) and feasibility study (Chapter 6). Approximately half of the study population in Taylor et al [312] were female with mild dementia identified from MMSE (21.1 ±4.1), 50% of whom had experienced at least one fall preceding the commencement of the study. Whilst many similar intervention studies also recruited mild to moderate severity cognitive impairment, some have focused on institutionalised rather than community-dwelling populations.

In a similar intervention studying strength, balance, and gait retraining for 8 weeks, Perrochon et al [314] recruited institutionalised older adults with dementia. Despite the comparable intervention and focus on gait outcomes, the study had a fundamentally different participant population [314]. Older adults in an institutionalised setting are generally frailer [315] and less physically active [316] with lower functional fitness [317] and more severe disabilities [318]. Therefore, further comparisons need to be made with awareness of these differences.

7.3.2. Interventions

Many of the key characteristics of the study intervention were present in other published studies. Progressive, individually-tailored, balance and strengthening exercise programmes, delivered at home by qualified therapists have been completed in studies such as the Taylor et al [312] and the FINALEX study [103]. The most comparable intervention, in both content and delivery, was the FINALEX study [103] where a progressive balance and strengthening intervention with dual-task training was implemented in a group and home setting.

The interpretation from this research that a home programme would allow greater tailoring and progression of exercise was mirrored by Pitkala et al [103], who identified less deterioration in function within their home-based participants (compared with the group-based and control). Despite the similarity in content, the programme studied and reported by Pitkala et al [103] was a 12-month intervention and, as with Taylor et al [312], the primary outcomes were different. The intervention studied by Taylor et al [312] did not feature any dual-task training.

The combination of physical and cognitive exercises, or dual-task training, is less reported. However, as Chapter 4 concludes, there is potential to influence gait and balance, and there have been studies which tested this in older adults with cognitive impairment. Schwenk et al [101, 141] employed a dual-task intervention in institutionalised populations with cognitive impairment. Despite participant sample differences, the group intervention was comparable due to combining functional resistance and balance training with dual-task exercises. The intervention was also delivered using "*specific strategies to promote exercise in people with dementia*" ([101], p3) which compare to an experienced physiotherapist delivering the programme in the feasibility study.

The trial by Eggenberger et al [319] used video-games, verbal memory training, and treadmill combinations in their three-armed RCT. Video games and virtual reality share similar theoretical components with dual-task training such as dividing attention and allocation of resources. Therefore, whilst the intervention by Eggenberger et al [319] had similarities with the feasibility study, this highlights the variability associated with the term "dual-task training". At present, there is no consistent definition or use of terms for these types of interventions, and researchers and clinicians need to carefully consider the details of the intervention against results reported.

With regards to strength and balance exercises, these core components were consistently featured in other studies. An evidence summary for exercise (strength and balance) as a falls prevention intervention has recently been updated [320]. The meta-analysis by Sherrington et al [320] corresponds with the umbrella review (Chapter 3) regarding the limited amount of evidence reporting falls intervention in specific populations with cognitive impairment. Whilst the sub-group analysis by Sherrington et al [320] is comparable to this research material, this was not the main intent of the meta-analysis and therefore it is not as specific in search strategy as either review in Chapter 3, 4 or 5.

The most recent and comparable literature review was completed by Lach et al [321], which included 40 studies featuring only older adults with mild dementia [321]. Findings were consistent and corroborate that exercise and multifactorial interventions are the most prevalently tested and published interventions. Exercise, as a single intervention, has "potential" to reduce falls in this population [320, 321].

The study intervention has not been developed in isolation. The cross-sectional survey data were part of a data set from an NIHR Programme Development

Grant (Balance and The Mind - BATM). The researcher collected the data with the consideration for both the larger project and the study presented. The systematic reviews have informed further, successful, NIHR funding applications. Recently, Promoting Activity, Independence and Stability in Early Dementia (PrAISED) was awarded an NIHR Programme Grant and has started with randomised feasibility testing and intervention refinement prior to multicentre RCT [322]. PrAISED utilises many of the study's intervention components.

7.3.3. Context

Comparable studies are also completed in a home setting [292, 312, 313]. Many rely on carers supporting the intervention [243, 244, 313], with exceptions including the FINALEX study in which therapists delivered the programme [103]. Carer involvement was offered but not required in the feasibility study and was interpreted as fulfilling the role of "gate-keeper" through facilitation to access the intervention sessions. The realist review also recognised that having optional carer involvement would be the ideal solution, allowing for individual preferences and circumstances, which was offered during the feasibility study. However, carer well-being, burden, and opinion was not measured. Comparable studies have variable results in this outcome that range from less distress or burden [253, 292], to more burden [99, 313], as well as no change in well-being [312]. As the realist review suggests, these differences in carer burden could be due to contextual factors such as the carer's perception of benefit from completing the intervention programme.

Another contextual component worth considering is the number of contacts in the comparable studies. As with the feasibility study (Chapter 6), the intervention in Taylor et al [312] was delivered at home by qualified therapists.

However, there were only ten contacts with the physiotherapist in the six month intervention. This is similar to both the Suttanon et al [313] and Wesson et al [99] studies where a limited number of therapist contacts were implemented with the intent to support the carers who regularly supervised the intervention. Considering the importance of support and perceptions of the supporter identified in the realist review, the contextual factor of participants completing the exercise with a family member or carer versus a professional is a significant difference to the feasibility study.

Country of implementation and national health policy differences are also potentially influential contextual components. For example, the intervention within Taylor et al [312] and Wesson et al [99] was completed in Australia. The distances in rural Australia are considerably larger than in the UK, therefore time and money efficient interventions needed to be considered and may explain why there was such limited physiotherapist contact time.

7.3.4. Outcomes

Overall there are subtle differences in main outcomes of comparable studies. Balance and mood were identified as key modifiable outcomes from an earlier analysis by Taylor et al [41] and, whilst falls were recorded, there was no detailed gait assessment. Similar percentages of the Taylor sample [312] experienced falls to the current study participants (Taylor=34%; survey=32%; feasibility=50%). Changes to falls risk (PPA) are also comparable between studies (Taylor: pre=2.6, post=1.3; feasibility: pre=2.03, post=1.5).

Whilst there were considerable similarities, the differences were more substantial and led to the conclusion that different mechanisms of action were being employed [312]. Without detailed gait and mDTC reporting, results from

Taylor et al [312] cannot be compared to the current feasibility study to ascertain if dual-task training is an important component in these outcomes.

> *"these findings suggest that although cerebral processing is affected by the disease process of dementia, exercise interventions are able to yield positive changes in balance (a sensorimotor function relying on central information processing as well as sensorimotor input) in people with mild to moderate dementia." (p6, [312])*

Gait speed and other gait parameters were important outcomes reported in both the survey (Chapter 2) and feasibility study (Chapter 6). Unfortunately, the aforementioned comparable studies mainly focused on function [103], balance [312] or feasibility measures [99]. The study by Perrochon et al [314] did report detailed gait outcomes and found a greater increase in gait speed following their control and intervention period (Perrochon=0.12m/s; feasibility=0.03m/s). However, the initial and final speed were much slower (Perrochon: pre=0.18 m/s, post=0.28 m/s; feasibility study: pre=0.88 m/s, post=0.92 m/s). The difference in results between the current feasibility study and this comparator could be due to findings of the realist review: that individuals with a lower functional level may experience greater improvements. However, this was not sufficiently evidenced by the review papers and therefore definitive conclusions were not given.

Sub-group analysis of the large FINALEX study sample has recently been completed by Ohman et al [323] and found differences in outcomes between levels of cognitive impairment. The intervention reduced functional decline in those with mild cognitive impairment but did not reduce the number of falls experienced during the year-long programme. In comparison, the more severely impaired individuals did reduce their number of falls, but did not have any significant reduction in their functional decline [323]. This interesting comparison supports both the physiological-responses theory outlined in the realist review and quantitative data from the cross-sectional survey: whilst falls are experienced by persons with mild dementia populations, an exercise intervention influences physiological responses that underpin the "falls pathway" (Appendix 28). Most individuals with mild dementia are experiencing a low number of falls which could be from changes to their physical ability, which occur prior to a "fall". However, it is these components which are modifiable in this mild stage.

Schwenk et al [101, 141] report DTC and gait parameters respectively that are similar to the cross-sectional survey results (Chapter 2). However, the DTCs found in the gait parameters of the current feasibility study are all higher and more inconsistent than in the initial publication by Schwenk et al [141]. The influence of the actual dual-task used in the assessment has been discussed (Chapter 6). When a difficult dual-task (serial backwards 3) was used by Schwenk et al [141], the DTCs become more equal to that found in the current feasibility study both before and after the intervention. Neither of the Schwenk studies reported falls outcomes, nor progressed their theoretical assumptions and interpretations towards the effect of the intervention and their results on falls in this population.

Recently published studies have also considered the influence of dual-task training on other outcomes such as cognition rather than physical ability [319, 324]. It is clear from these comparisons that further work needs to be completed both on the methods and definitions of dual-task assessment, as well as dual-task training as an intervention component.

In general, the recent literature supports conclusions drawn from the current studies. Most of the studies were within the same sphere of evidence hierarchy:

non-randomised feasibility studies or small, single site randomised trials. The recently published literature reviews include the same studies as found for the syntheses in Chapters 3, 4 and 5. Following these reflections, it can be stated that this research is complementary to the literature in this field.

7.4. Interpretation and implications

7.4.1. Interpretation

The research questions originally proposed have been answered. Older adults experience falls through pathways involving cognitive impairment, deteriorations in walking pattern, reduced balance ability, and higher dual-task cost. Exercises involving physical and cognitive aspects are feasible to conduct and can modify gait and balance within mild levels of impairment, which are components of the falls pathway in these individuals. The content and the methods of delivery are important and have specific mechanisms (such as progression, tailoring, perceiving benefit and support) related to this population.

Has this research delivered an intervention that is ready for further testing? As demonstrated within Chapter 6, the MRC guidelines [294] have been used as a framework to describe the intervention development process within this project. The guidelines are broad, providing a general framework that covers all aspects of complex intervention development process from theory identification to full multi-centre RCT. However, there is sparse detail and depth, particularly in critical initial stages, and the guidelines signpost rather than inform.

One of the MRC suggested frameworks is RE-AIM by Glasgow et al [325]. The RE-AIM model suggests five factors for developing an intervention. Whilst highlighting the importance of implementation from the initial stages, particularly in regards to “reach” and “maintenance” of an intervention, Glasgow et al [325] do not provide details on what components a well-developed intervention should include. It is important to consider that each intervention will have unique aspects and a protocol for intervention development would not be feasible in accommodating all requirements. However, there is a dearth in the literature on this topic, specifically in regards to judging the quality of the development of innovative and novel interventions.

A more recent and relevant framework published by Wight et al [326] describes "six crucial steps" in a detailed model of "quality" intervention development. Despite being developed for public health interventions like the Glasgow RE-AIM framework, these stages are applicable to therapeutic interventions and have echoes of realist terminology. As such, this framework fits well alongside the development of this intervention and provides greater detail in how to develop the "theory" and "model" components of the MRC framework [123, 294].

Overall, none of the published frameworks provide the level of detail necessary on their own, but by combining them there is greater transparency and elements. Comparing the differences in frameworks and where the current studies are situated against them clearly identifies the need for further testing of the model (Table 7.1).

MRC Framework [123]	Wight et al [326]	Current Chapters/ Research Components
Evidence	Define the problem	Cross-sectional survey
		Umbrella review
Theory	Factors malleable to change	Meta-analysis on dual-task
	Identify change mechanism	Realist review
	Identify how to deliver change	
Model	Test and refine	Feasibility study
	Evidence effectiveness	-

Table 7.1: Comparison of intervention development frameworks

7.4.2. Implications

Implications of the thesis have been well described in each chapter. The findings and recommendations from each chapter have been combined (Table 7.2) and are intended for the further development, testing, and eventual implementation of a dual-task training, exercise-based intervention.

Topic	Recommendation
Participants	Older adults (>65 years) with mild to moderate cognitive impairment.
	If a person with dementia has the belief that exercise is advantageous, a positive attitude to exercise, the ability to understand the benefits of exercise or is able to identify the physical or functional changes from doing exercise, then they will perceive the benefit of doing exercise.
	If a person with dementia perceive the benefit, then they will participate in exercise-based intervention.
Intervention	Multicomponent exercise-based intervention that: • combines physical (including strength/resistance, balance, endurance/mobility, aerobic) and cognitive exercises (dual-tasking), • is correctly intensive and progressive, • is supported by suitable staff (who can interact, communicate and connect) and materials, • considers speed of initiation, longevity of intervention (including allowing time/resources from initial stages), encouragement of active lifestyle and enjoyment, • is delivered in a flexible manner for 15-20 minutes (or whatever can become or fit in with routine) 2-3 times a week for 6-12 months, • can be delivered at home (for those wanting or needing 1:1 support from the intervention staff) or in a group (for those wanting carer respite, increase in habitual physical activity or socialising aspects), • considers the order of the exercises, tailoring them to the individual and designing them to optimise active time in the sessions, • uses adjustable weights to provide progressive resistance, • can be tailored (according to intensity, progression, comorbidities, daily-life, goals, environment, carers, emotional influences).
	Dual-tasking exercises that: • are at the correct level of challenge, • only commenced once one aspect of the dual-task is familiar (for example the physical component), • are tailored to the interests or topics of familiarity for that individual.
Circumstances	Support can provide encouragement for completing an exercise-based intervention.
	Sources of support can include but are not exclusively supplied by trained intervention staff, carer, spouse, or a family member.
	Sources of support, such as carers or family members, may not be initially overt.
	If support is being provided by trained intervention staff, then they should have professional qualities including: • time-management, • knowledgeable, • firm but encouraging, • kind, friendly and supportive, • understanding of the issues experienced by persons with dementia, • rapport development, • reliable contact method.
	Trained intervention staff supporting an intervention should:

	• provide clear and repeated instructions in a format suitable and acceptable for the participant and their individual needs, potentially using clear pictorial, photographic or written instructions, • optimally progress the exercises, • tailor to provide the amount of supervision required by that individual and their needs, • understand the individuals other comorbidities, their everyday symptoms and be able to adapt an exercise programme accordingly, • understand the needs of persons with dementia, • be aware of which dual-task component the individual is prioritising and consider how that may influence their ability within that exercise and overall aims, • be considerate of the impact of reminding the participant of their memory difficulties when supporting the documentation of the session, • be aware of the safety of the environment completing the exercise within, including extremes of weather.
	If support is being provided by a carer, then the intervention should provide information and on-going support to enable that mechanism.
	Carers supporting an intervention should: • perceive and understand the benefit of the person with dementia doing exercise, • provide transport or consider practical arrangements for access to the intervention, • have a positive attitude, • implement supportive strategies and/or assistance in the manner required by the person with dementia, • collaborate or communicate with trained staff.
	If the carers' or supporters' perception of the benefits of doing exercise out-weighs the risk, concern, or burden of extra care duties, then the intervention will be encouraged.
	Benefits of exercise perceived by the carer or supporter for the person with dementia include: mood, behaviour, weight, flexibility, ageing, enjoyment of everyday life.
	Goal setting could be used to direct and tailor the intervention to the individual, their everyday life and interests, and their carers wishes.
Outcome	Measurements of a dual-tasking intervention in older adults with mild dementia should include: gait, balance or posture, muscle strength, executive functioning or cognition, DTC, and carer burden or health or well-being (if using carers as a contextual component).
	Measurements of DTC should be: • measured in both physical and cognitive components of the task, • calculated and published as mDTC, • at a level of difficulty suitable to the individual participant (using a task that can be individually titrated and comparable).

Legend: Recommendation source according to colour: more than one source, cross-sectional survey only, realist review only, feasibility study only.

Table 7.2: Overall research recommendations

7.5. Future research

Following the implications for future practice outlined in the previous section, a number of implications for future research will now be discussed.

In alignment with the MRC guidance for complex intervention development [123, 294], the progression of this research should be through a randomised feasibility study. The current non-randomised study tested the procedure of recruitment, intervention delivery, and novel intervention components in the intended population. Further work is now required to determine effectiveness and sample size. A randomised feasibility study would enable power calculations for an adequately powered effectiveness study.

Following the research findings, the main outcome of interest would need to be a physical outcome related to functional ability, such as gait speed and variability or a different measure of balance. It is apparent that not all older adults with mild dementia are falling, therefore a sufficiently powered study to determine change in number of falls would need a considerable sample. Activity based outcomes are being employed in PrAISED, although considering the modelling conducted in this research (Figure 7.1, p263), a physical measure identified in the causal pathway for falls in this population would be more advantageous.

Further work also needs to be completed on ascertaining and developing accurate and reliable dual-task based outcome measures. Future studies could ascertain the reliability of DTC as a research measure or explore its implementation as a screening measure for falls in a clinical environment. A consensus study on tasks, measurement techniques, repetitions, instructions and reporting could aid the reliability of DTC as an outcome.

Work currently conducted at Newcastle University is investigating a number of different dual-tasks using gait parameters [327], demonstrating that this is a swiftly moving field. The original concept of DTC in this population was identified from the clinical setting [68] and as such there is potential as an assessment component in both community and institutionalised populations. A future study could utilise an implementation design working with key stakeholders to promote, educate about, and implement DTC assessments in clinical settings.

Primary outcomes in future work should be related to the main modifiable component in the theoretical intervention model. Further work is required to refine the model according to the rest of the realist results and the full programme theory. Interpretation of all data extracted from the realist review would direct relevant areas for further enquiry. Qualitative interviews of participants, carers, therapists, and other stakeholders could then be completed to test the model and isolate key mechanisms for implementation or effectiveness testing. An example of this could be exploring what type of support mechanisms are best utilised in this population of mild dementia. Is there flexibility regarding the type of support provided? Does the support mechanism change according to the stage of an intervention programme in which the older adult with dementia is?

Further research could also be conducted regarding the modifiable physiological-responses identified in the realist review and theoretical model. The realist review developed mechanisms involving cognitive as well as physical (muscle, postural, cardiovascular) changes. Does this type of intervention influence the density or efficiency of brain matter? Could neuroimaging aid hypothesis development around more efficient synaptic pathways or improved blood flow? The University of Nottingham and Nottingham University Hospitals NHS Trust has recently received a large investment by the MRC for the Biomedical Research Centre, with core, world-leading expertise in magnetic resonance imaging (MRI) [328]. Therefore, capability and capacity in this field are optimally positioned to progress more biomedical focused studies in older adults with mild dementia.

Lastly, further intervention refinement such as duration, intensity, implementation, and adherence should be conducted and related to efficacy. The 6-week intervention was relatively short in duration and only the immediate effects of the dual-task training were considered. What are the long-term effects of completing such an intervention? Exercise programmes need to be sustained for continued effectiveness in healthy older adults [320]. How this transpires in mild dementia populations is unknown, particularly in consideration of the underlying progression of the condition. Is the aim for an exercise-based intervention to see improvements or to slow decline?

Considering the sustained adherence to such an intervention, other methods of delivery and completion need to be explored. How can older adults with mild dementia adhere to an exercise-based intervention in the long-term? Is a formal exercise programme with qualified therapist support more beneficial or acceptable than a routine programme where length of adherence is placed more highly than intensive and progressive exercise? Research into behaviour change and adherence has already started in healthy older adults, but further work needs completing in populations with cognitive impairment, at all levels of severity.

The influence of comorbidities, particularly in exercise motivation and adherence would also aid implementation of such interventions. The realist review and feasibility study thematic analysis suggested that comorbidities may have a role to play in support mechanisms of exercise. Are there some conditions which make exercise harder to engage with? Is there a relationship between the number of comorbidities and the motivation of an older adult with cognitive impairment to adhere or participate in an exercise intervention?

Overall there are a number of avenues into which further exploration is possible. Decisions upon future research will be guided by patient representatives, clinical need and the National Dementia Strategy [9].

7.6. Conclusion

Mild dementia negatively influences characteristics of gait, reduces efficiency and ability in completing dual-tasks, reduces balance, and increases the risk of falls. Gait speed and falls risk were influential in determining if older adults with mild dementia would fall and contributed to a model of falls in these participants. Interventions to reduce the risk of falls have not proven efficacy in this population. Exercise and multicomponent based programmes show potential, particularly at influencing gait speed and balance when dual-task training is a core component.

A model of dual-task, exercise-based intervention was proposed. Physiological-responses and encouragement were mechanisms engaged in a multicomponent, exercise-based intervention model. Such an intervention was feasible and acceptable to older adults with mild dementia, improving gait pattern, balance ability, and falls risk scores. Whilst the 6-week dual-task inclusive intervention was unable to influence dual-task cost, the intervention was a promising component to influence falls risk in older adults with cognitive impairment. Recommendations have been synthesised to guide future research and practice of dual-task exercise-based interventions.

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Chapter 9. Appendices

Appendix 1: Standardised protocol for data collection

Data collection standard operating procedure

Arranging:

- Contact log is checked daily to identify participants that have been recruited, consented, and completed Visit 1.
- Phone call to participant to arrange Visit 2 appointment.
- Letter is sent to participant to confirm Visit 2 appointment time and date (please include map and directions) if appointment is >4 working days away.
- If unable to send letter, participant will be phoned on day of appointment to confirm time and location of Visit 2.
- Complete contact log.

Pre-assessment:

- Equipment must be set-up at least 30 minutes prior to appointment time.
- Ensure have copy of Visit 2 data collection sheet.
- Inform NUHRU staff if will be seeing participants after 4pm.
- Check that both researchers are present for the length of assessment.
- Ensure the room is free from clutter and non-BATM study based equipment i.e. jigsaw table is removed and placed outside the room, that the bed is at correct height with clean cover, and that there are x2 chairs within the room – one placed at the foot of the plinth facing towards the door.

During assessment:

- Show participant and accompanying person into research room, welcome and offer a drink.
- Explain what will happen during the assessments; that they can stop or rest at any point, length of time expected to take, etc.
- Confirm consent.

- Complete **FESi.**
- Explain that the purpose of this questionnaire is to determine their feelings around falls.

- Complete **HADS** – participant needs to complete this independently if possible.
- Explain that this questionnaire looks at their feelings in general.

PPA Equipment:

- Contrast sensitivity chart
- Reaction-time recorder and mouse
- High chair
- Electronic weight scale
- Ankle straps and comfort pads
- Pen and stickers
- Clear plastic proprioception angleometer
- Adjustable table
- Foam pad with hygienic cover placed
- Graph paper, pen and ruler
- Waist belt
- Stop watch

- Complete **PPA** following instructions from PPA booklet.
- Explain that the following short tests look at different aspects of their balance, they may rest between each section, and they can stop at any point.

TUG Equipment:

- Chair with arms placed at foot of plinth facing door
- Stop watch

- Complete **TUG.**
- Explain that this is looking at the speed of their walking and turning.
- Instructions: *On the word GO you will stand up, walk to the line on the floor, turn around and walk back to the chair and sit down. Walk at your regular pace.*
- Start timing on the word GO and stop once the participant is seated again correctly in the chair. There is no time limit, the participant may stop and rest but not sit down.

BBS Equipment:

- Laminated instruction sheet
- Stop watch
- Functional reach laminated sheet
- (Use bottom rung of high chair as step)
- (Use whiteboard pen as object to pick up from ground)

- Complete **BBS** using instructions on laminated sheet.
- Explain that this test looks at aspects of their standing balance.

- In sitting.
- Explain that we are now going to look at their **cognitive speed** and **accuracy completing** 2 thinking tasks, and that we will use these same thinking tasks in a few minutes when looking at their walking.
- Instructions: *When I say GO, count backwards from 50 to 1. For example, 50, 49, 48, 47, and so on. We will time how long it takes for you to reach 1 and how many mistakes you make.*
- Start timing when you say GO and stop once they reach 1. Record time taken and number of inaccuracies.

- Instructions: *When I say GO, name as many words beginning with the letter …. . Try not to give the same word twice, and try to not say names or places. For example, if the letter was F, I could say FROG, FEELINGS, FIELDS, but not FREDDY or FRANCE. We will do this for 1 minute.*
- Repeat instructions if needed.
- Start timing when you say GO and record how many words are said and if any are repeated.

- Explain that when we look at their walking, we will do the same thinking tasks again.

Equipment in room:

- Plinth (bed)
- Pillow and hygienic cover
- Clinel wipes
- BP cuff

- Explain that we now need to measure their **blood pressure** as they change position, starting with lying down.
- Assist into lying if needed. If participant does not want to lie-down, ask them to sit quietly for same time period and mark BP in sitting instead.
- Participant lays still for 5 minutes without interruption.
- Measure BP in lying.
- Keeping BP cuff in place, ask client to stand up in as timely a manner as possible.
- Measure BP in standing straight away – ask participant how they feel.
- Ask participant to remain standing, inform them we will measure it again in 1 minute, keep stopwatch running.
- Measure BP in standing after 1 minute – ask participant how they feel.
- Ask participant to remain standing, inform them we will measure it again in another 2 minutes.
- Measure BP in standing after 3 minutes – ask participant how they feel.

GAITRite Equipment:

- Carpeted walkway with power-plug and transistor box
- Laptop
- Mat to cover wires
- Extension cord
- Chair at end of walk approx 3m away from end and to the side of the walkway
- Stopwatch

- Explain that we are now going to complete their **walking** assessment and walk with them to where the GAITRite is set-up, and sit them in the chair close to the equipment.
- Instructions: *In the next few minutes we will be asking you to walk along this carpet. The carpet has sensors in it which show us your foot prints as you are walking. We will ask you start walking a few paces away from the carpet, then walk onto it without slowing, walk along, then off the end a few paces, before stopping and turning around. We will ask you to do this a few times. You may stop in between each walk, but when on the carpet try to keep going until you reach the end. You can stop the test at any point. I will be walking next to you but I won't be talking to you so I don't distract you. Try to stay within the boundaries of the carpet as your walking.*
- Assistant sets up computer and stays at the screen whilst the other researcher remains with the participant. Once system reads BEGIN WALK researcher instructions client to start walking. Researcher walks along-side the participant, off the carpet and slightly behind.
- Participant completes 6 walks if able.
- Rest and drink offered once finished.

- Instructions: *We are going to do that walking again. But this time, as you are walking, I would like you to count backwards from 50 to 1. You may remember that we did this before. For example, 50, 49, 48, 47, and so on. Only count backwards whilst you are walking on the carpet, I will tell you to start and stop. I will walk next to you but I won't talk to you so I don't distract you. You may stop in between each walk, but when on the carpet try to keep going until you reach the end. You can stop the test at any point.*
- Assistant sets up computer and stays next to the screen whilst the other researcher remains with the participant – ensure MEMO for walk identifies which dual-task condition.
- Once system reads BEGIN WALK researcher instructions client to start walking. Researcher walks along-side the participant, off the carpet and slightly behind.
- Assistant times how long it takes for participant to count backwards to 1, and notes inaccuracies by the participant. If the participant reaches 1 before finishing the walks, the assistant stops timing but the participant starts again from 50.
- Participant completes 6 walks if able.
- Rest and drink offered once finished.

- Instructions: *We are going to do that walking again. But this time, as you are walking I would like you to name as many words beginning with the letter …. . Try not to same the same word twice, and try to not say names or places. For example, if the letter was F, I could say FROG, FEELINGS, FIELDS, but not FREDDY or FRANCE. You may remember that we did this before. I will walk next to you but I won't talk to you so I don't distract you. You may stop in between each walk, but when on the carpet try to keep going until you reach the end. You can stop the test at any point.*
- Assistant sets up computer and stays next to the screen whilst the other researcher remains with the participant – ensure MEMO for walk identifies which dual-task condition.
- Once system reads BEGIN WALK researcher instructions client to start walking. Researcher walks along-side the participant, off the carpet and slightly behind.
- Assistant records number of words and repetitions said by the participant.
- Participant completes 6 walks if able.
- Rest and drink offered once finished.

Post-assessment:

- Explain that all the assessments have now finished.
- Assist participant in travel arrangements home.
- Ensure all equipment is cleaned if needed and stored in correct area.
- Fill out contact log.

Appendix 2: Data collection form

Version 6 16/12/2013

Date:
Study number:

Verbal consent to assessment: ◻ Yes

DOB:

BALANCE AND THE MIND

Baseline data collection sheet: Visit 2

All questions contained in this data collection sheet are strictly confidential.

FALLS EFFICACY SCALE INTERNATIONAL

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.

		Not at all concerned 1	*Somewhat concerned 2*	*Fairly concerned 3*	*Very concerned 4*
1	Cleaning the house (e.g. sweep, vacuum or dust)	1 ☐	2 ☐	3 ☐	4 ☐
2	Getting dressed or undressed	1 ☐	2 ☐	3 ☐	4 ☐
3	Preparing simple meals	1 ☐	2 ☐	3 ☐	4 ☐
4	Taking a bath or shower	1 ☐	2 ☐	3 ☐	4 ☐
5	Going to the shop	1 ☐	2 ☐	3 ☐	4 ☐
6	Getting in or out of a chair	1 ☐	2 ☐	3 ☐	4 ☐
7	Going up or down stairs	1 ☐	2 ☐	3 ☐	4 ☐
8	Walking around in the neighbourhood	1 ☐	2 ☐	3 ☐	4 ☐
9	Reaching for something above your head or on the ground	1 ☐	2 ☐	3 ☐	4 ☐
10	Going to answer the telephone before it stops ringing	1 ☐	2 ☐	3 ☐	4 ☐
11	Walking on a slippery surface (e.g. wet or icy)	1 ☐	2 ☐	3 ☐	4 ☐
12	Visiting a friend or relative	1 ☐	2 ☐	3 ☐	4 ☐
13	Walking in a place with crowds	1 ☐	2 ☐	3 ☐	4 ☐
14	Walking on an uneven surface (e.g. rocky ground, poorly maintained pavement)	1 ☐	2 ☐	3 ☐	4 ☐
15	Walking up or down a slope	1 ☐	2 ☐	3 ☐	4 ☐
16	Going out to a social event (e.g. religious service, family gathering or club meeting)	1 ☐	2 ☐	3 ☐	4 ☐

Hospital Anxiety and Depression Scale

~ Scoring Sheet ~

	Yes definitely	Yes sometimes	No, not much	No, not at all
1. I wake early and then sleep badly for the rest of the night.	3	2	1	0
2. I get very frightened or have panic feelings for apparently no reason at all.	3	2	1	0
3. I feel miserable and sad.	3	2	1	0
4. I feel anxious when I go out of the house on my own.	3	2	1	0
5. I have lost interest in things.	3	2	1	0
6. I get palpitations, or sensations of 'butterflies' in my stomach or chest.	3	2	1	0
7. I have a good appetite.	0	1	2	3
8. I feel scared or frightened.	3	2	1	0
9. I feel life is not worth living.	3	2	1	0
10. I still enjoy the things I used to.	0	1	2	3
11. I am restless and can't keep still.	3	2	1	0
12. I am more irritable than usual.	3	2	1	0
13. I feel as if I have slowed down.	3	2	1	0
14. Worrying thoughts constantly go through my mind.	3	2	1	0

PHYSIOLOGICAL PROFILE ASSESSMENT

Number of falls in previous year	0 1 2 3 4+						
Edge contrast sensitivity (dB)							
Reaction time (ms)	Practice		Test				
	1		1				
	2		2				
	3		3				
	4		4				
	5		5		Average		
			6				
			7				
			8				
			9				
			10				
Knee extension strength (kg)							
Proprioception (degrees)	1						
	2						
	3		Average				
	4						
	5						
Postural sway on foam rubber mat (On foam eyes open) (mm)	Antero-posterior						
	Medio-lateral						

TIMED UP AND GO TEST

D Unaided		D With mobility aid (which aid)				D Unable	
Trial 1 (sec)		Trial 2 (sec)		Trial 3 (sec)		Average (sec)	

BERG BALANCE TEST

Test	1	2	3	4	5	6	7	8	9	10	11	12	13	14	Total/56
Score/4															

BATM visit 2 data collection sheet V5 16/12/2013

DUAL TASK ACCUARCY IN SITTING

	Time taken	Number of inaccuracies
Backward counting from 50 to 1		
	Total number in one minute	Number of inaccuracies
Words beginning with		

BLOOD PRESSURE

Time of day:		**Time of last food:**
Lying BP		
Standing BP 0min		Symptoms ▢ Yes ▢ No
Standing BP 1min		Symptoms ▢ Yes ▢ No
Standing BP 3min		Symptoms ▢ Yes ▢ No

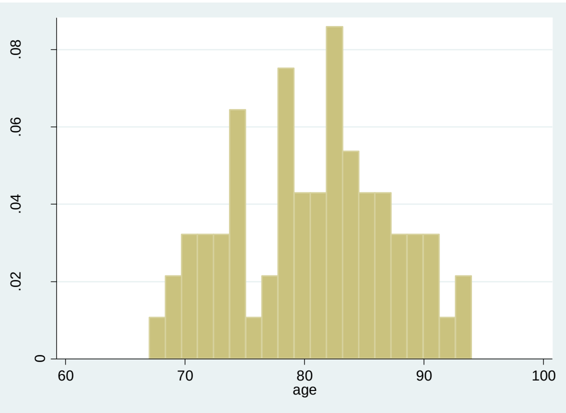
GAIT PARAMETERS

Single Task	
Gait speed (m/s)	
Step-length (m)	
Step-width (m)	
Double support (%)	
Coefficient of variation of step-time (%)	
Coefficient of variation of step-length (%)	
Dual Task (Backwards counting)	**Time taken 50 to 1:**
Gait speed (m/s)	
Step-length (m)	
Step-width (m)	
Double support (%)	
Coefficient of variation of step-time (%)	
Coefficient of variation of step-length (%)	
Dual Task (Verbal fluency)	**Number of words in 1 minute:** **Inaccuracies:**
Gait speed (m/s)	
Step-length (m)	
Step-width (m)	
Double support (%)	
Coefficient of variation of step-time (%)	
Coefficient of variation of step-length (%)	

BATM visit 2 data collection sheet V5 16/12/2013

Appendix 3: Histograms of sample characteristics

For: age (a), global cognition (MoCA score) (b), falls risk (PPA score) (c), number of falls reported in six months (d), anxiety and depression score (HADS) (e), fear of falling (FES-i) (f), balance score (BBS) (g) and functional mobility (TUG) (h).



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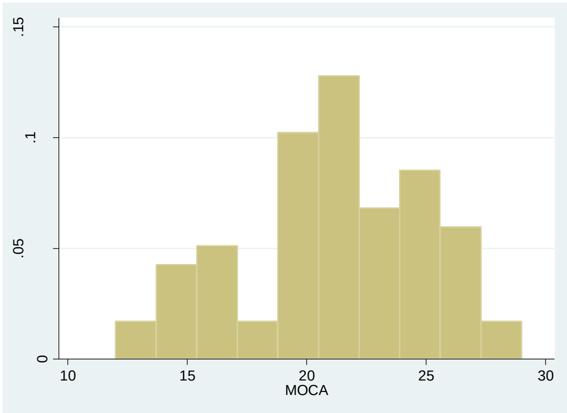

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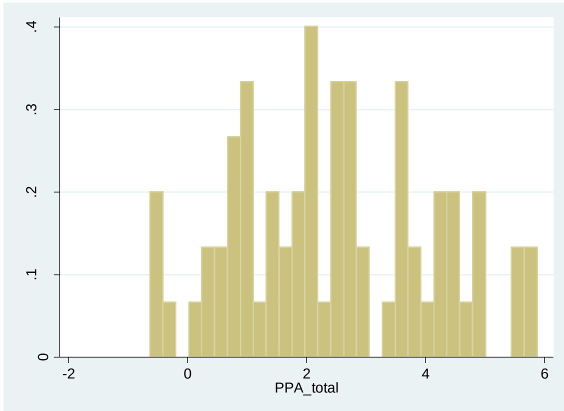

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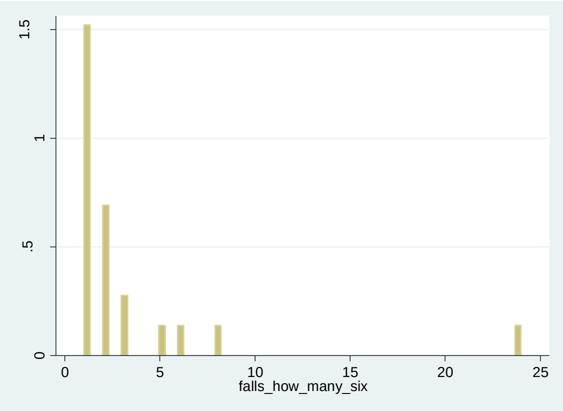

0
.5
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5
10
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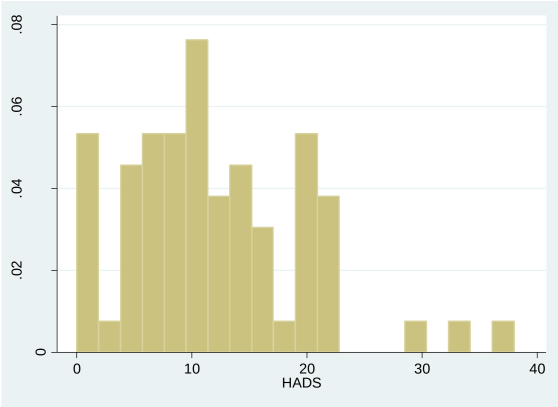
25
falls_how_many_six

d



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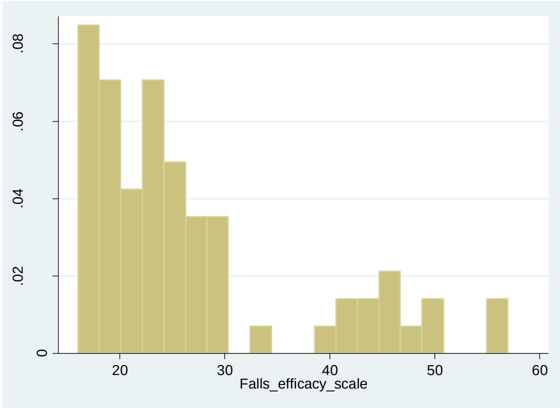
30
40
HADS

e



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50
60
Falls_efficacy_scale

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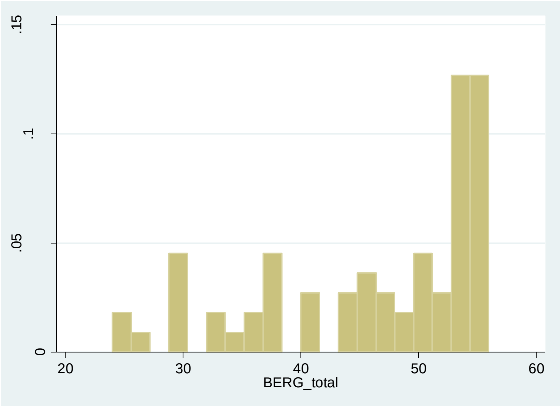

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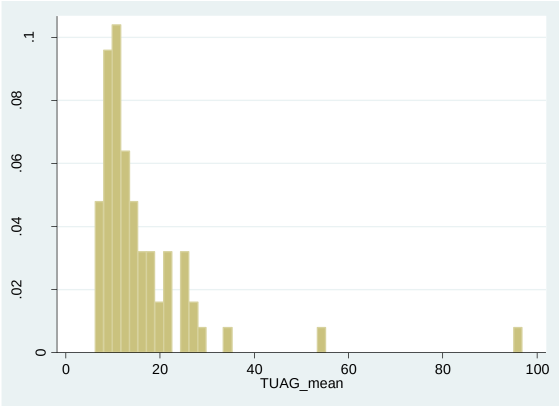
60
BERG_total

g



0
.02
.04
.06
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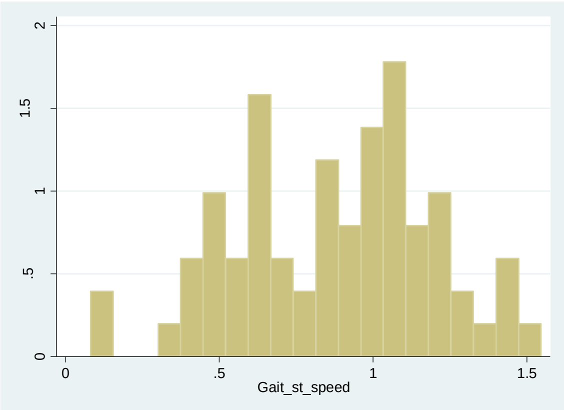
.1
0
20
40
60
80
100
TUAG_mean

h

Appendix 4: Histograms for gait measures

For: gait speed (a,b,c), step-length (d,e,f), step-width (g,h,i), double support (j,k,l), step-time variability (m,n,o), step-length variability (p,q,r), and mean dual-task cost (mDTC) (s,t).



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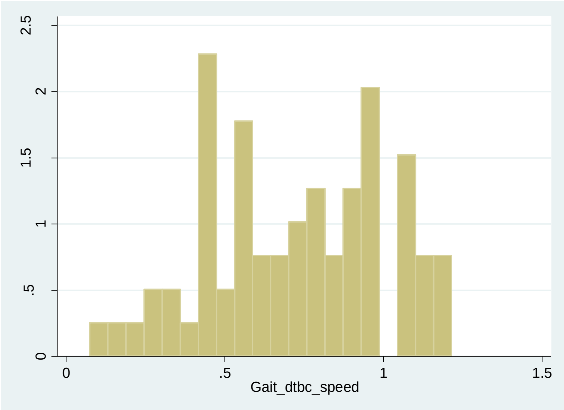

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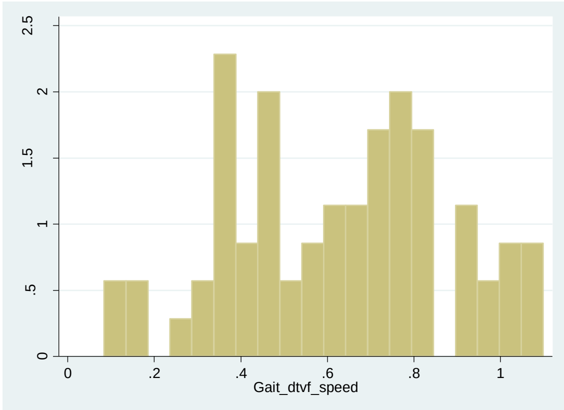

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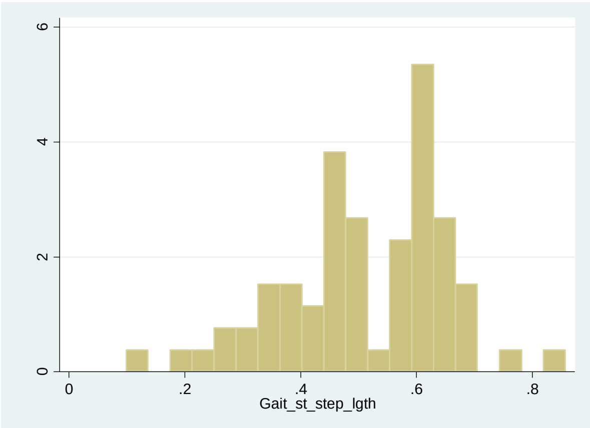

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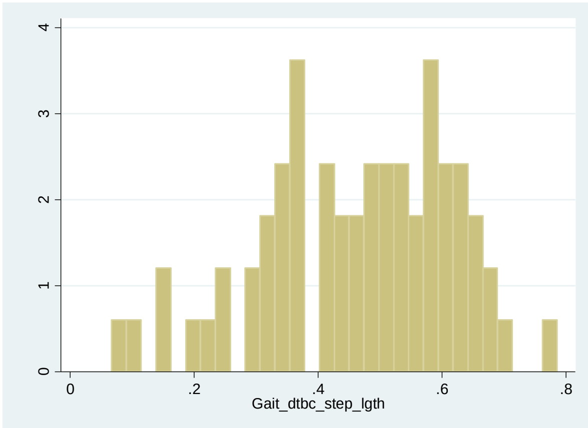

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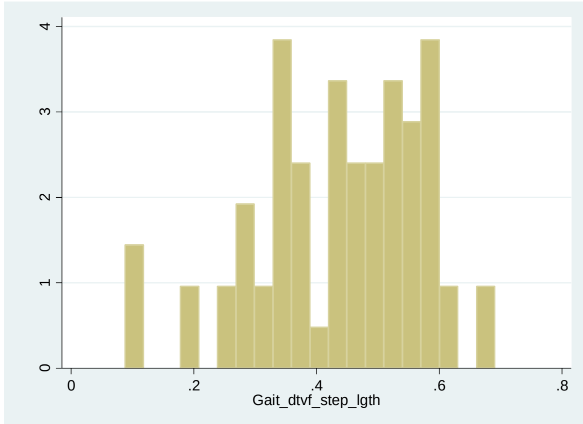

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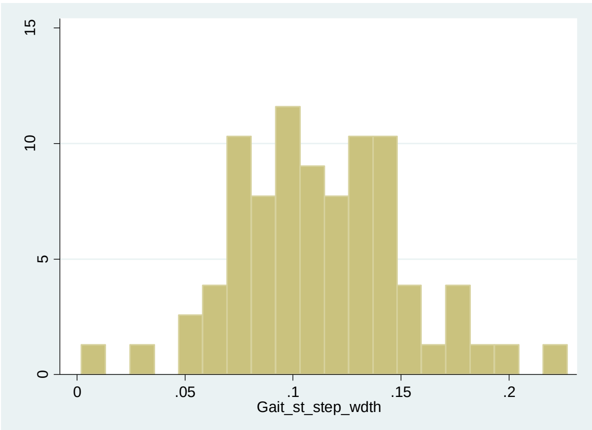

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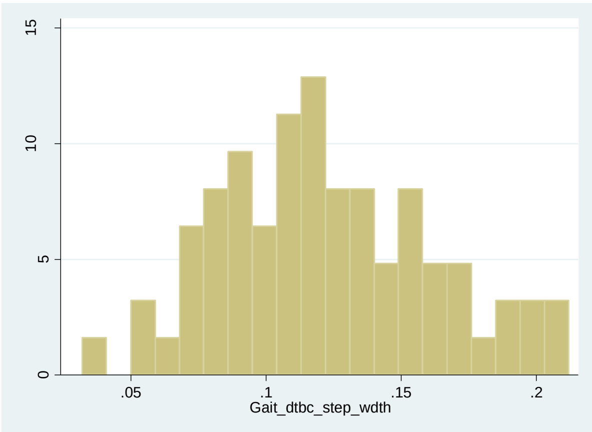

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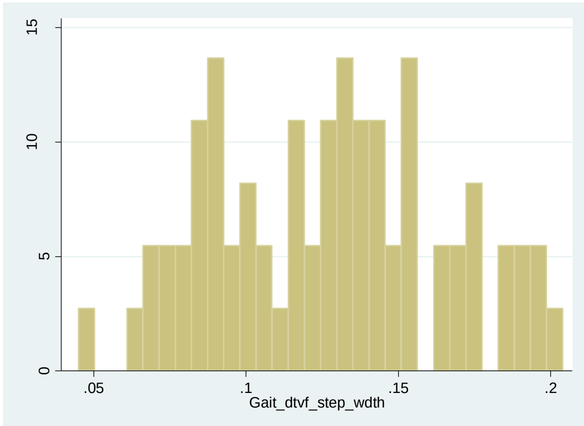

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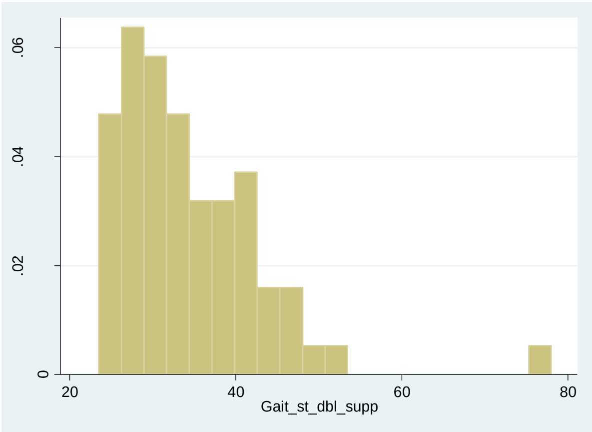
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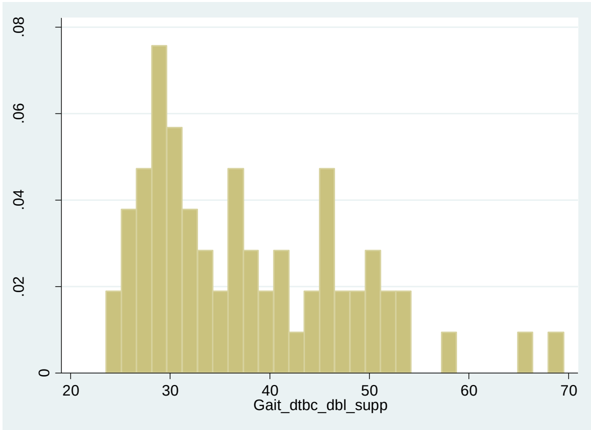
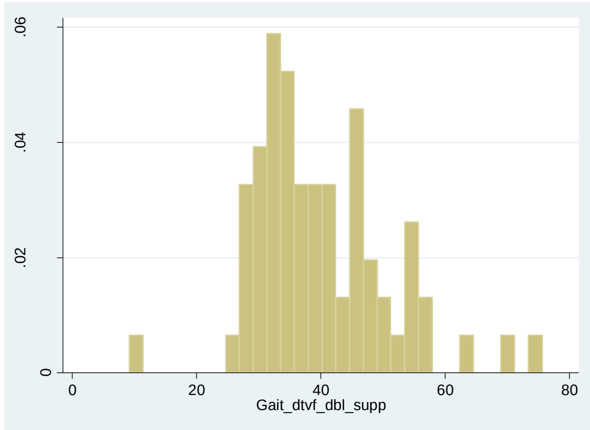
Gait_st_dbl_supp

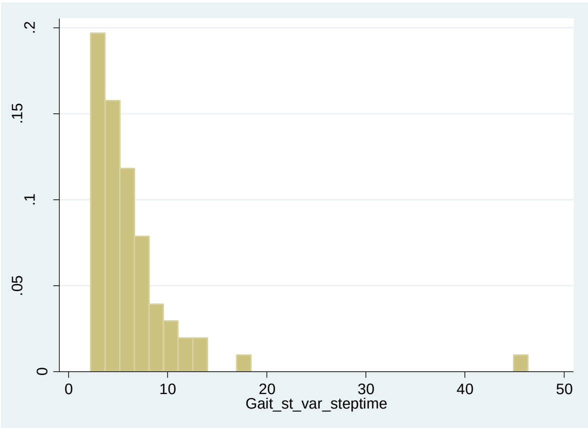
j


0
.02
.04
.06
.08
20
30
40
50
60
70
Gait_dtbc_dbl_supp

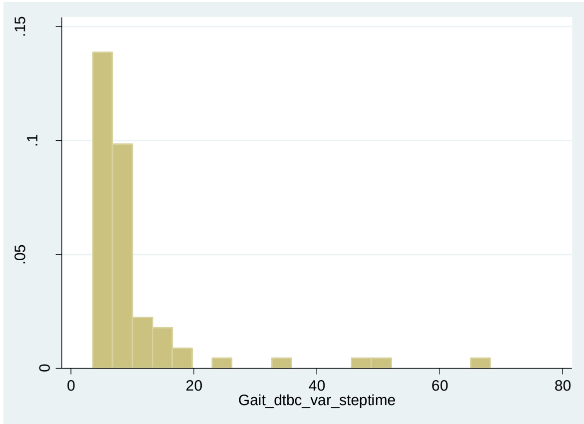
k


0
.02
.04
.06
0
20
40
60
80
Gait_dtvf_dbl_supp

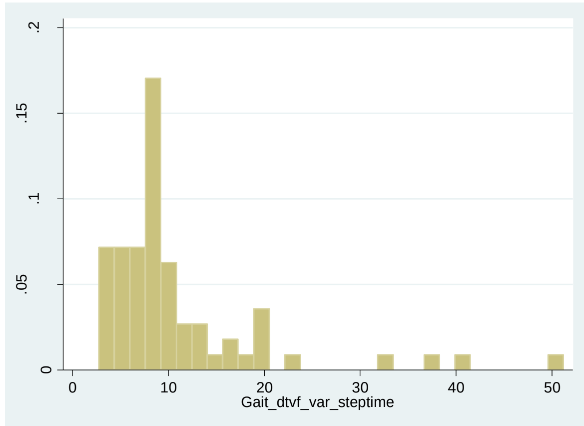
l


0
.05
.1
.15
.2
0
10
20
30
40
50
Gait_st_var_steptime

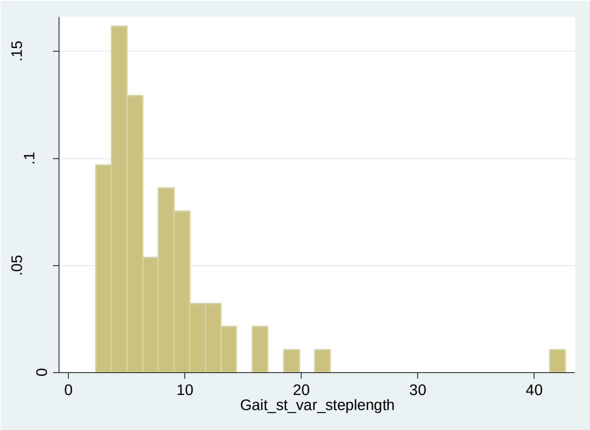
m


0
.05
.1
.15
0
20
40
60
80
Gait_dtbc_var_steptime

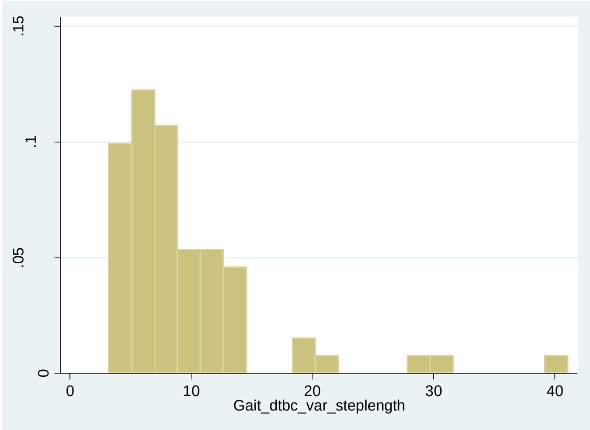
n


0
.05
.1
.15
.2
0
10
20
30
40
50
Gait_dtvf_var_steptime

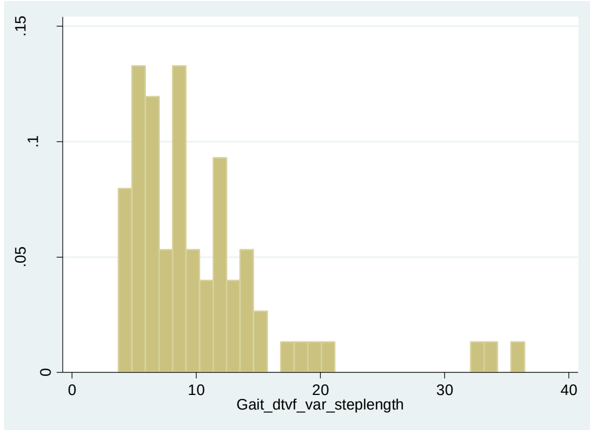
o


0
.05
.1
.15
0
10
20
30
40
Gait_st_var_steplength

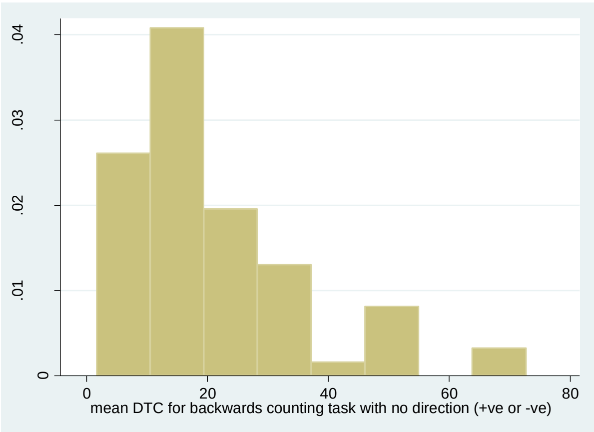
p


0
.05
.1
.15
0
10
20
30
40
Gait_dtbc_var_steplength

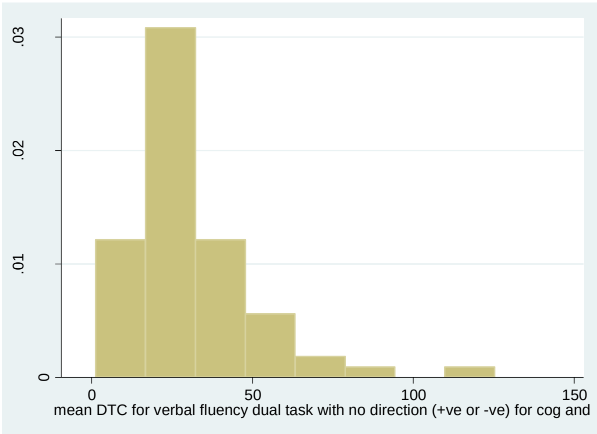
q


0
.05
.1
.15
0
10
20
30
40
Gait_dtvf_var_steplength

r


0
.01
.02
.03
.04
0
20
40
60
80
mean DTC for backwards counting task with no direction (+ve or -ve)

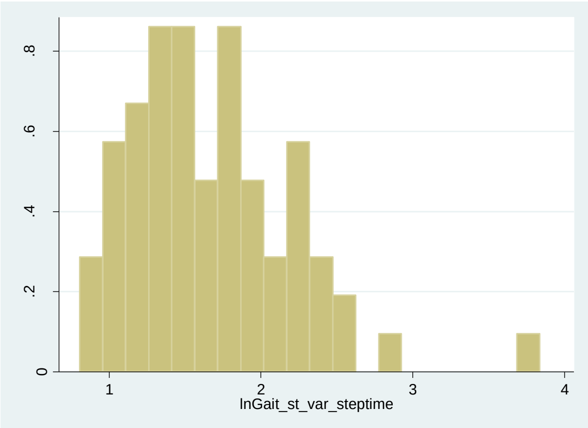
s

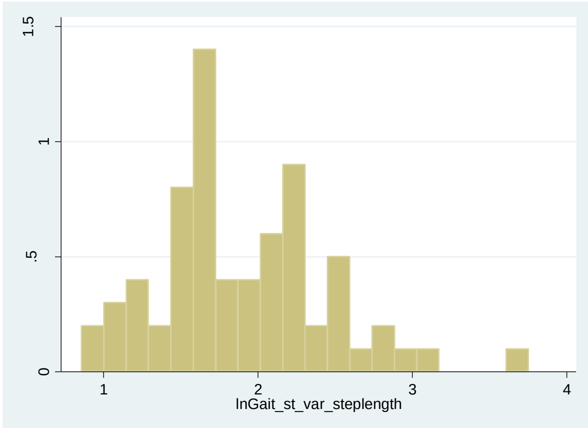

0
.01
.02
.03
0
50
100
150
mean DTC for verbal fluency dual task with no direction (+ve or -ve) for cog and

t

Appendix 5: Log transformed histograms

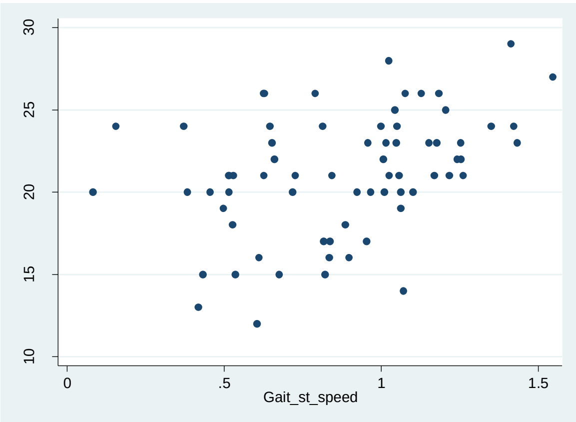
For: step-time (a) and step-length (b).

a 

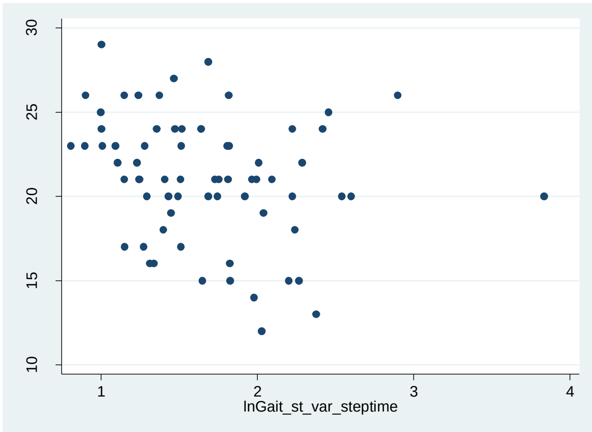
b 

Appendix 6: Scatter graphs for correlations

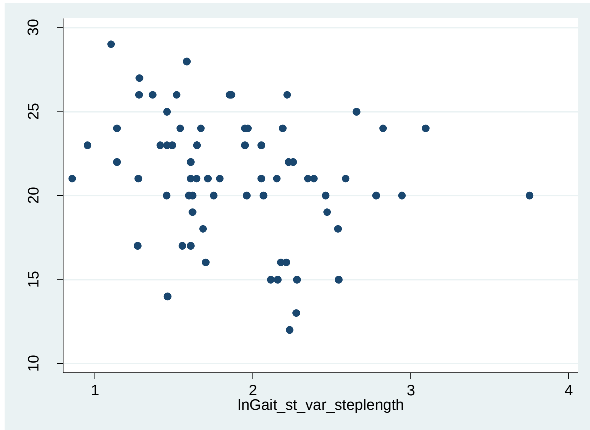
Between cognition and gait speed (a), step-time variability (b), step-length variability (c), mDTC backwards count (d), mDTC verbal fluency (e), falls risk (f), and balance (g)



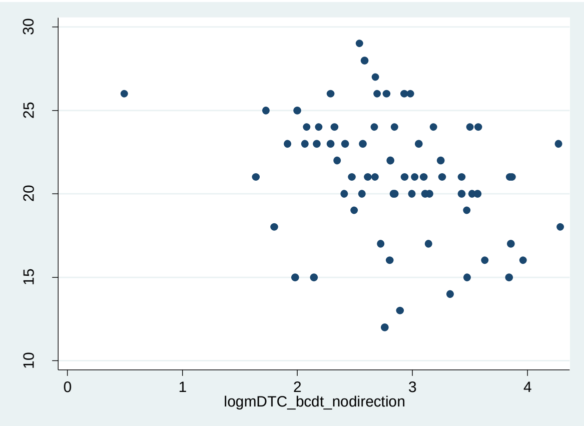
a



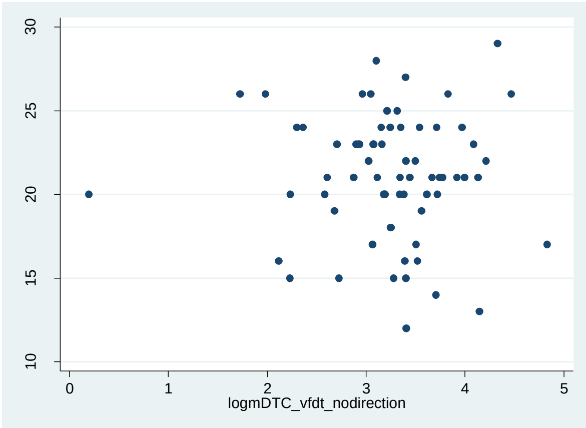
b



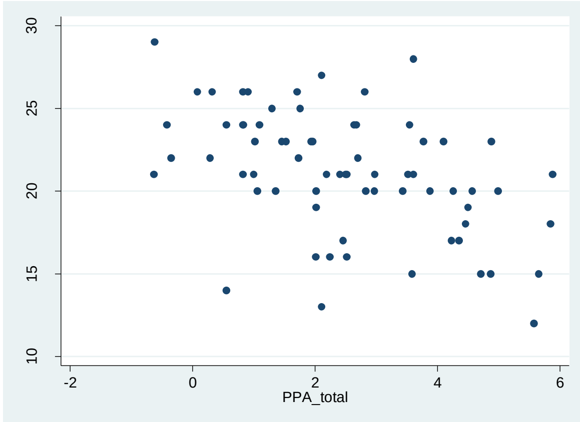
c


30
25
20
15
10
0
1
2
3
4
logmDTC_bcdt_nodirection

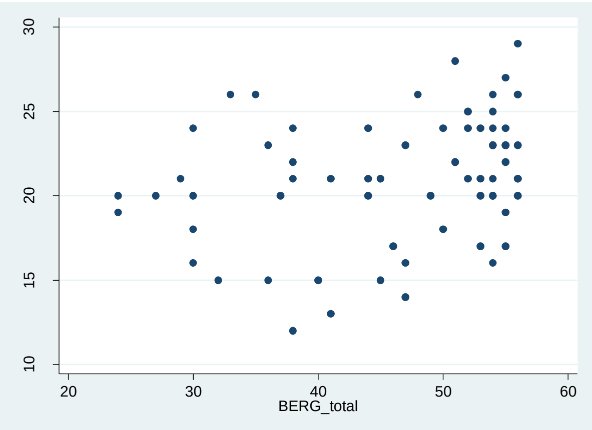
d


30
25
20
15
10
0
1
2
3
4
5
logmDTC_vfdt_nodirection

e


30
25
20
15
10
-2
0
2
4
6
PPA_total

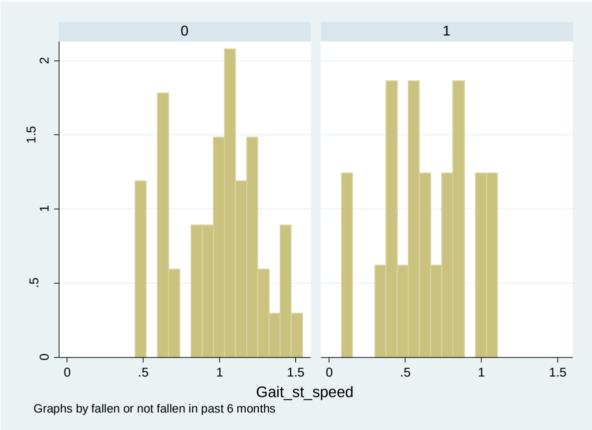
f


30
25
20
15
10
20
30
40
50
60
BERG_total

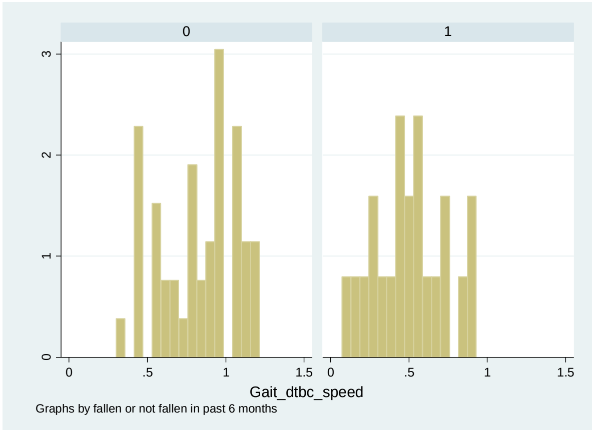
g

Appendix 7: Histograms comparing participants who did and did not fall

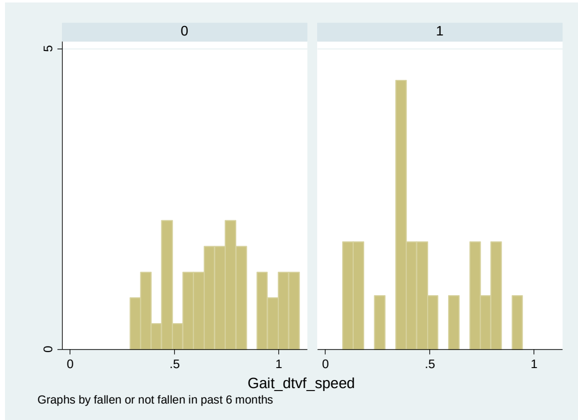
Comparing non-fallers (0) and fallers (1) in gait speed (a,b,c), step-length (d,e,f), step-width (g,h,i), double support time (j,k,l), step-time variability (m,n,o), step-length variability (p,q,r), mDTC (s,t), for each walking condition (single, backwards counting and verbal fluency).



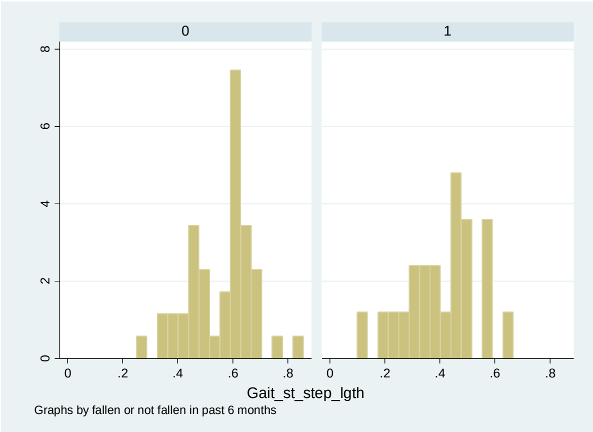
a

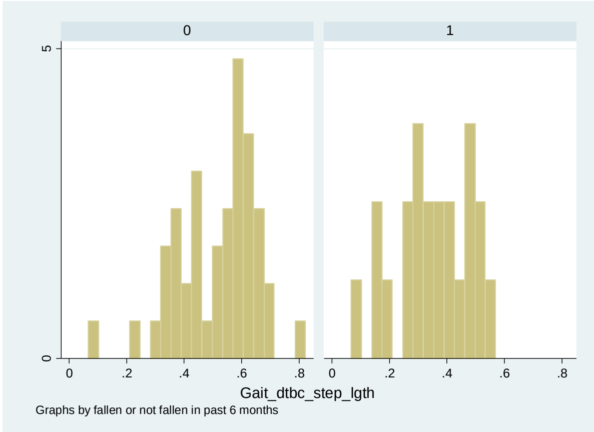


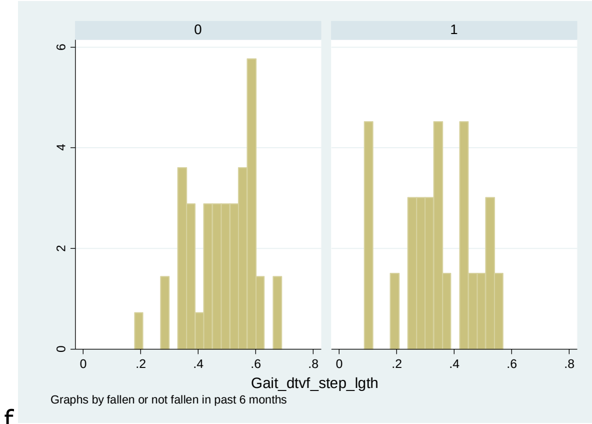
b

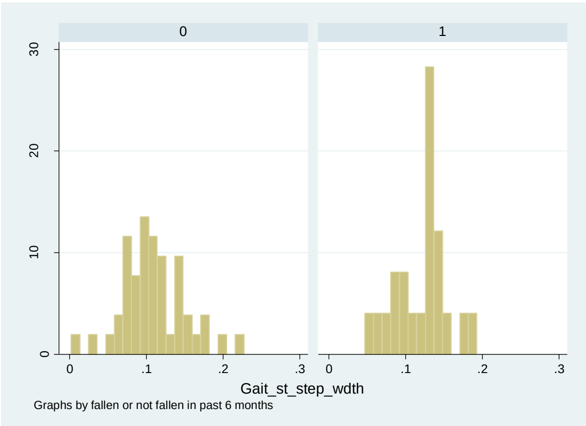


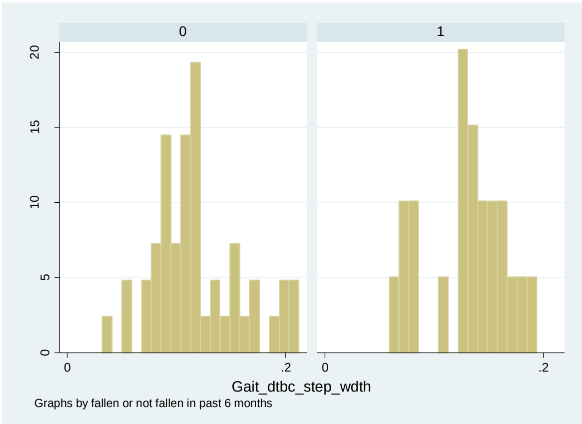
c

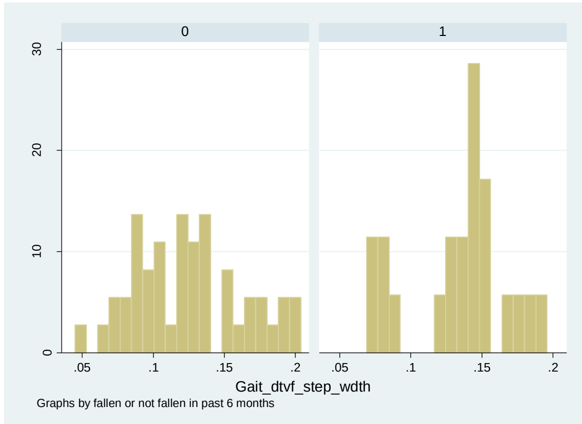

0
1
Gait_st_step_lgth
Graphs by fallen or not fallen in past 6 months
d

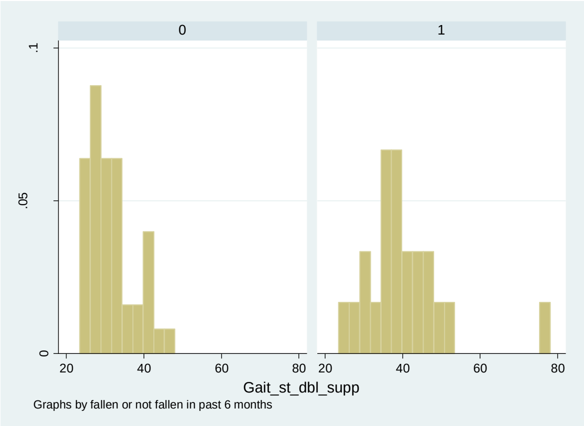

0
1
Gait_dtbc_step_lgth
Graphs by fallen or not fallen in past 6 months
e

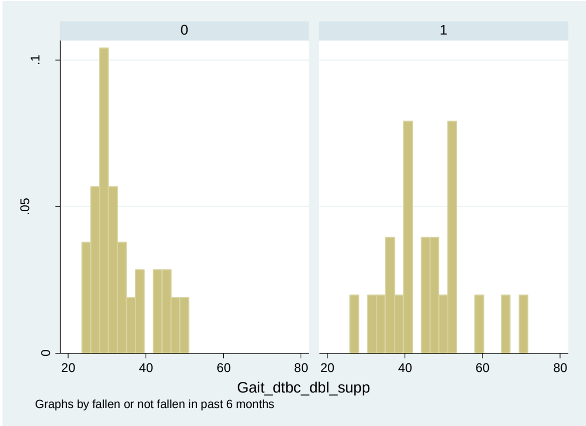

0
1
Gait_dtvf_step_lgth
Graphs by fallen or not fallen in past 6 months
f

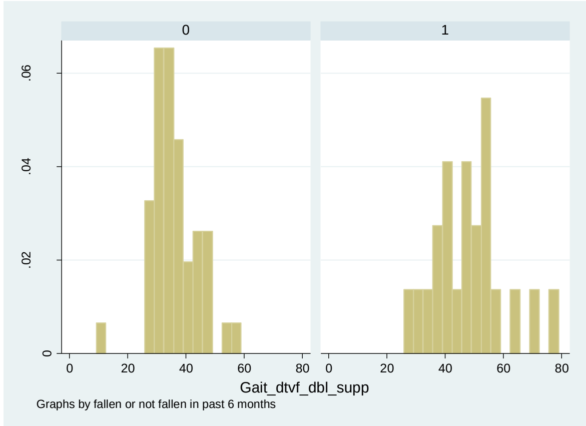

0
1
Gait_st_step_wdth
Graphs by fallen or not fallen in past 6 months
g

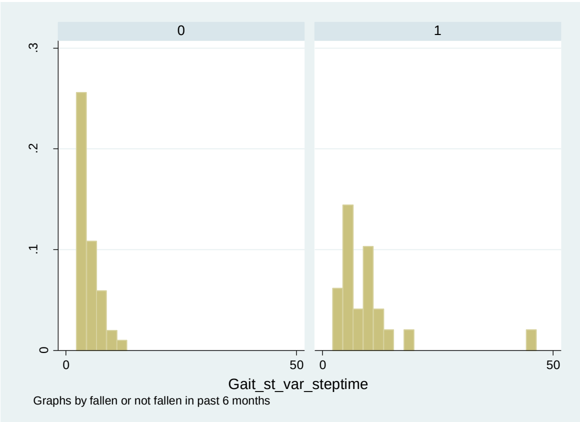

0
1
Gait_dtbc_step_wdth
Graphs by fallen or not fallen in past 6 months
h

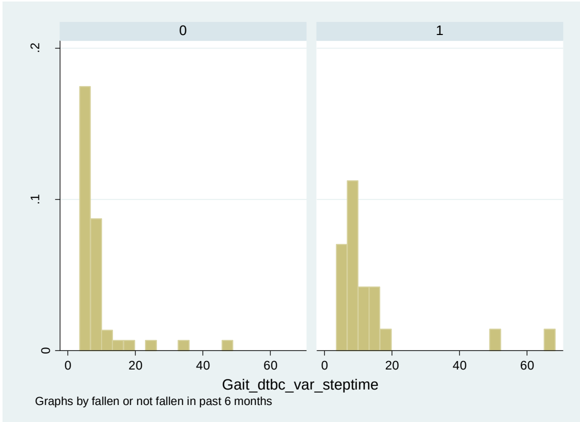

0
1
Gait_dtvf_step_wdth
Graphs by fallen or not fallen in past 6 months
i

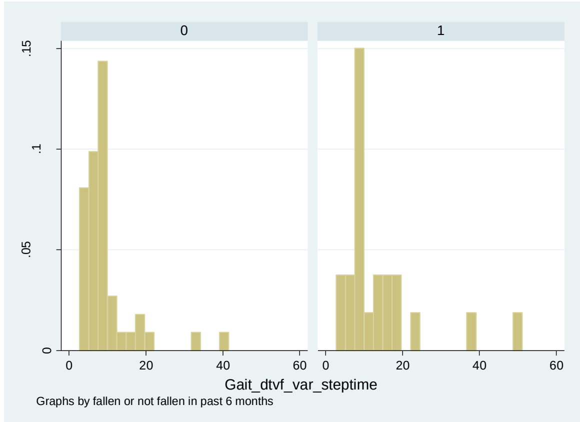

0
1
Gait_st_dbl_supp
Graphs by fallen or not fallen in past 6 months
j

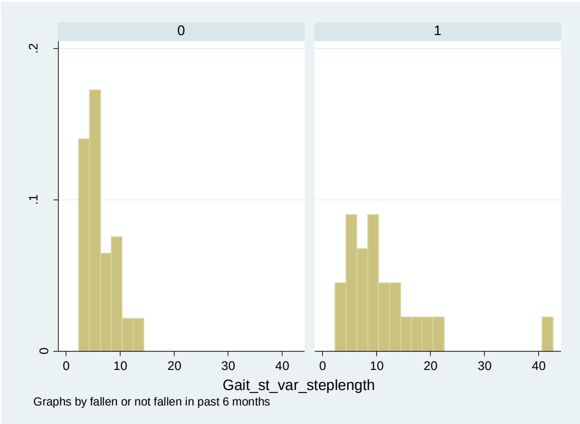

0
1
Gait_dtbc_dbl_supp
Graphs by fallen or not fallen in past 6 months
k


0
1
Gait_dtvf_dbl_supp
Graphs by fallen or not fallen in past 6 months
l


0
1
Gait_st_var_steptime
Graphs by fallen or not fallen in past 6 months
m

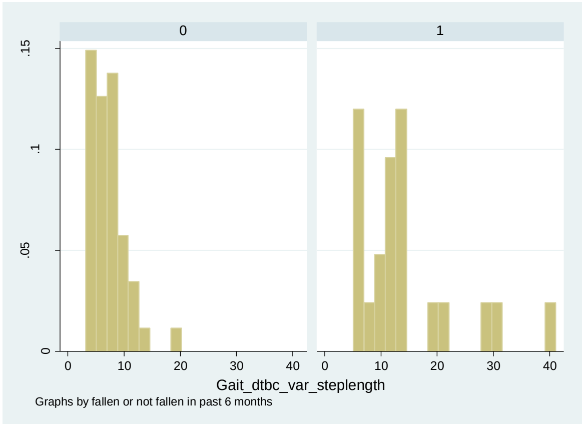

0
1
Gait_dtbc_var_steptime
Graphs by fallen or not fallen in past 6 months
n


0
1
Gait_dtvf_var_steptime
Graphs by fallen or not fallen in past 6 months
o



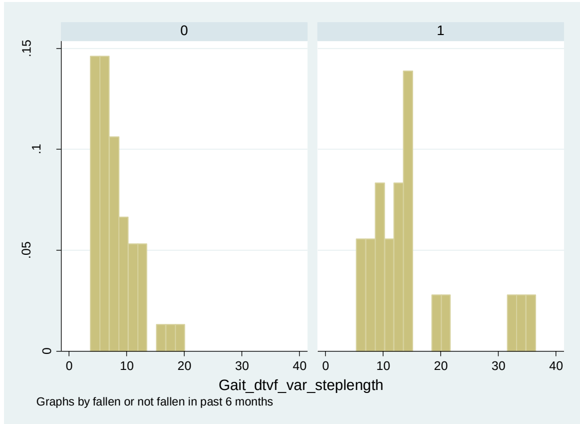
0
1
Gait_st_var_steplength
Graphs by fallen or not fallen in past 6 months

p



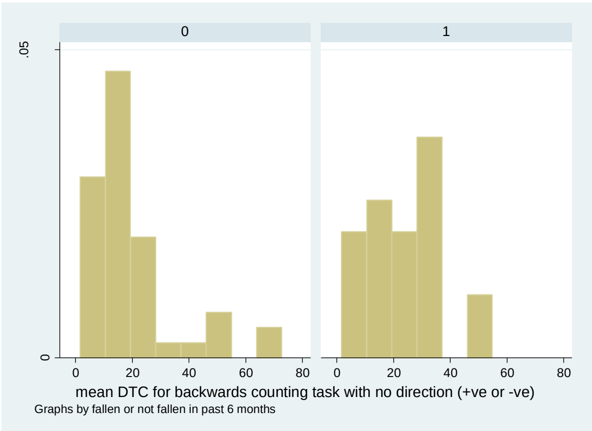
0
1
Gait_dtbc_var_steplength
Graphs by fallen or not fallen in past 6 months

q



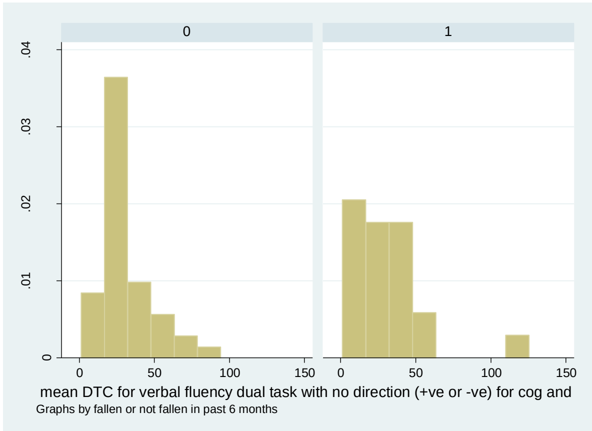
0
1
Gait_dtvf_var_steplength
Graphs by fallen or not fallen in past 6 months

r



0
1
mean DTC for backwards counting task with no direction (+ve or -ve)
Graphs by fallen or not fallen in past 6 months

s



0
1
mean DTC for verbal fluency dual task with no direction (+ve or -ve) for cog and
Graphs by fallen or not fallen in past 6 months

t

Appendix 8: Stata output

For binominal logistic regression (a), estimated odds ratios (b), predicted probabilities (c, d, e), likelihood ratio (f, g), and overall model fit (h, i).

a.

```
. logit hist_falls_6_mnths age sex MOCA Gait_st_speed mDTC_bcdt_nodirection BERG_total PPA_total

Iteration 0:   log likelihood = -42.806086
Iteration 1:   log likelihood = -31.110428
Iteration 2:   log likelihood = -30.379355
Iteration 3:   log likelihood = -30.372496
Iteration 4:   log likelihood = -30.372492
Iteration 5:   log likelihood = -30.372492

Logistic regression                             Number of obs   =         68
                                                LR chi2(7)      =      24.87
                                                Prob > chi2     =     0.0008
Log likelihood = -30.372492                     Pseudo R2       =     0.2905

---------------------------------------------------------------------------------------
     hist_falls_6_mnths |      Coef.   Std. Err.      z    P>|z|     [95% Conf. Interval]
------------------------+--------------------------------------------------------------
                    age |  -.0741231    .056499    -1.31   0.190    -.1848592    .0366129
                    sex |  -.5343974    .710627    -0.75   0.452    -1.927201    .8584059
                   MOCA |   .0734707    .099973     0.73   0.462    -.1224728    .2694142
          Gait_st_speed |   -5.54771   2.290698    -2.42   0.015     -10.0374   -1.058023
  mDTC_bcdt_nodirection |     -.0097   .0239094    -0.41   0.685    -.0565615    .0371615
             BERG_total |   .0297108   .0611274     0.49   0.627    -.0900968    .1495183
              PPA_total |   .4891375    .252336     1.94   0.053     -.005432    .9837071
                  _cons |   6.124039   5.695516     1.08   0.282    -5.038969    17.28705
---------------------------------------------------------------------------------------
```

b.

```
. logit hist_falls_6_mnths age sex MOCA Gait_st_speed mDTC_bcdt_nodirection BERG_total PPA_total, or

Iteration 0:   log likelihood = -42.806086
Iteration 1:   log likelihood = -31.110428
Iteration 2:   log likelihood = -30.379355
Iteration 3:   log likelihood = -30.372496
Iteration 4:   log likelihood = -30.372492
Iteration 5:   log likelihood = -30.372492

Logistic regression                             Number of obs   =         68
                                                LR chi2(7)      =      24.87
                                                Prob > chi2     =     0.0008
Log likelihood = -30.372492                     Pseudo R2       =     0.2905

---------------------------------------------------------------------------------------
     hist_falls_6_mnths | Odds Ratio   Std. Err.      z    P>|z|     [95% Conf. Interval]
------------------------+--------------------------------------------------------------
                    age |   .9285573   .0524626    -1.31   0.190     .8312213    1.037291
                    sex |   .5860223   .4164433    -0.75   0.452     .1455551    2.359397
                   MOCA |   1.076237   .1075946     0.73   0.462       .88473    1.309197
          Gait_st_speed |   .0038964   .0089254    -2.42   0.015     .0000437    .3471413
  mDTC_bcdt_nodirection |   .9903469   .0236786    -0.41   0.685     .9450084    1.037861
             BERG_total |   1.030157   .0629708     0.49   0.627     .9138427    1.161275
              PPA_total |   1.630909   .4115371     1.94   0.053     .9945827    2.674352
                  _cons |   456.7054   2601.173     1.08   0.282     .0064804    3.22e+07
---------------------------------------------------------------------------------------
```

c.

```
. sum prlogit

    Variable |        Obs        Mean    Std. Dev.       Min        Max
-------------+---------------------------------------------------------
     prlogit |         69     .328821    .2747259   .0080314   .9631177
```

d.

```
. quietly logit hist_falls_6_mnths age sex MOCA Gait_st_speed mDTC_bcdt_nodirection BERG_total PPA_total

. prvalue, x(Gait_st_speed=.88) rest(mean) delta lev(95)

logit: Predictions for hist_falls_6_mnths

Confidence intervals by delta method

                                95% Conf. Interval
  Pr(y=1|x):          0.2433   [ 0.1137,    0.3730]
  Pr(y=0|x):          0.7567   [ 0.6270,    0.8863]

             age          sex         MOCA  Gait_st_sp~d  mDTC_bcdt_~n    BERG_total     PPA_total
x=     80.911765    .55882353    21.088235           .88     21.281429     46.205882     2.4611765

. prchange

logit: Changes in Probabilities for hist_falls_6_mnths

              min->max      0->1     -+1/2    -+sd/2  MargEfct
         age   -0.3693   -0.0006   -0.0138   -0.0888   -0.0138
         sex   -0.1011   -0.1011   -0.0995   -0.0498   -0.0997
        MOCA    0.2263    0.0046    0.0137    0.0511    0.0137
Gait_st_sp~d   -0.9562   -0.8351   -0.8207   -0.3269   -1.0345
mDTC_bcdt_~n   -0.1183   -0.0020   -0.0018   -0.0265   -0.0018
  BERG_total    0.1604    0.0021    0.0055    0.0526    0.0055
   PPA_total    0.5693    0.0489    0.0911    0.1518    0.0912

              0       1
Pr(y|x)  0.7520  0.2480

                 age          sex         MOCA  Gait_st_sp~d  mDTC_bcdt_~n    BERG_total     PPA_total
   x=        80.9118      .558824      21.0882       .875515       21.2814       46.2059       2.46118
sd_x=        6.42926      .500219      3.72861       .321737       14.6774       9.48929       1.66985

. margeff8

Average marginal effects on Prob(hist_falls_6_mnths==1) after logit

------------------------------------------------------------------------------------
   hist_falls_6_mnths |      Coef.   Std. Err.       z    P>|z|     [95% Conf. Interval]
----------------------+-------------------------------------------------------------
                  age |  -.0107713   .0078591    -1.37   0.171    -.0261748    .0046323
                  sex |   -.076418   .0988612    -0.77   0.440    -.2701824    .1173465
                 MOCA |   .0106765   .0143488     0.74   0.457    -.0174466    .0387995
        Gait_st_speed |    -.80617   .2839609    -2.84   0.005    -1.362723   -.2496169
mDTC_bcdt_nodirection |  -.0014096   .0034546    -0.41   0.683    -.0081804    .0053612
           BERG_total |   .0043174   .0088414     0.49   0.625    -.0130113    .0216462
            PPA_total |   .0710794   .0329277     2.16   0.031     .0065423    .1356165
------------------------------------------------------------------------------------
```

e.

```
. quietly logit hist_falls_6_mnths age sex MOCA Gait_st_speed mDTC_bcdt_nodirection BERG_total PPA_total

. prvalue, x(PPA_total=2.5) rest(mean) delta lev(95)

logit: Predictions for hist_falls_6_mnths

Confidence intervals by delta method

                                95% Conf. Interval
  Pr(y=1|x):          0.2515   [ 0.1210,    0.3820]
  Pr(y=0|x):          0.7485   [ 0.6180,    0.8790]

           age          sex         MOCA  Gait_st_sp~d  mDTC_bcdt_~n    BERG_total     PPA_total
x=   80.911765    .55882353    21.088235     .87551471     21.281429     46.205882           2.5

. prchange

logit: Changes in Probabilities for hist_falls_6_mnths

              min->max      0->1     -+1/2    -+sd/2  MargEfct
         age   -0.3693   -0.0006   -0.0138   -0.0888   -0.0138
         sex   -0.1011   -0.1011   -0.0995   -0.0498   -0.0997
        MOCA    0.2263    0.0046    0.0137    0.0511    0.0137
Gait_st_sp~d   -0.9562   -0.8351   -0.8207   -0.3269   -1.0345
mDTC_bcdt_~n   -0.1183   -0.0020   -0.0018   -0.0265   -0.0018
  BERG_total    0.1604    0.0021    0.0055    0.0526    0.0055
   PPA_total    0.5693    0.0489    0.0911    0.1518    0.0912

              0       1
Pr(y|x)  0.7520  0.2480

              age          sex         MOCA  Gait_st_sp~d  mDTC_bcdt_~n    BERG_total     PPA_total
   x=     80.9118      .558824      21.0882       .875515       21.2814       46.2059       2.46118
sd_x=     6.42926      .500219      3.72861       .321737       14.6774       9.48929       1.66985

. margeff8

Average marginal effects on Prob(hist_falls_6_mnths==1) after logit
```

hist_falls_6_mnths	Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
age	-.0107713	.0078591	-1.37	0.171	-.0261748	.0046323
sex	-.076418	.0988612	-0.77	0.440	-.2701824	.1173465
MOCA	.0106765	.0143488	0.74	0.457	-.0174466	.0387995
Gait_st_speed	-.80617	.2839609	-2.84	0.005	-1.362723	-.2496169
mDTC_bcdt_nodirection	-.0014096	.0034546	-0.41	0.683	-.0081804	.0053612
BERG_total	.0043174	.0088414	0.49	0.625	-.0130113	.0216462
PPA_total	.0710794	.0329277	2.16	0.031	.0065423	.1356165

f.

```
. logit hist_falls_6_mnths, nologge

Logistic regression                                 Number of obs    =         68
                                                    LR chi2(0)       =       0.00
                                                    Prob > chi2      =          .
Log likelihood = -42.806086                         Pseudo R2        =     0.0000
```

hist_falls_6_mnths	Coef.	Std. Err.	z	P>|z|	[95% Conf.	Interval]
_cons	-.7375989	.2592174	-2.85	0.004	-1.245656	-.2295421

```
. est store intercept_only
```

g.

```
. lrtest fmodel intercept_only

Likelihood-ratio test                                 LR chi2(7)  =     24.87
(Assumption: intercept_only nested in fmodel)         Prob > chi2 =    0.0008

. lrtest fmodel n1model

Likelihood-ratio test                                 LR chi2(1)  =      0.17
(Assumption: n1model nested in fmodel)                Prob > chi2 =    0.6801

. lrtest fmodel n2model

Likelihood-ratio test                                 LR chi2(2)  =      0.81
(Assumption: n2model nested in fmodel)                Prob > chi2 =    0.6672

. lrtest fmodel n3model

Likelihood-ratio test                                 LR chi2(3)  =     22.39
(Assumption: n3model nested in fmodel)                Prob > chi2 =    0.0001
```

h.

```
. quietly logit hist_falls_6_mnths age sex MOCA Gait_st_speed mDTC_bcdt_nodirection PPA_total BERG_total

. estat class

Logistic model for hist_falls_6_mnths

              -------- True --------
Classified |         D            ~D  |      Total
-----------+--------------------------+-----------
     +     |        10             5  |         15
     -     |        12            41  |         53
-----------+--------------------------+-----------
   Total   |        22            46  |         68

Classified + if predicted Pr(D) >= .5
True D defined as hist_falls_6_mnths != 0
--------------------------------------------------
Sensitivity                     Pr( +| D)   45.45%
Specificity                     Pr( -|~D)   89.13%
Positive predictive value       Pr( D| +)   66.67%
Negative predictive value       Pr(~D| -)   77.36%
--------------------------------------------------
False + rate for true ~D        Pr( +|~D)   10.87%
False - rate for true D         Pr( -| D)   54.55%
False + rate for classified +   Pr(~D| +)   33.33%
False - rate for classified -   Pr( D| -)   22.64%
--------------------------------------------------
Correctly classified                        75.00%
--------------------------------------------------
```

i.

```
. quietly logit hist_falls_6_mnths age sex MOCA Gait_st_speed mDTC_bcdt_nodirection PPA_total BERG_total

. fitstat

Measures of Fit for logit of hist_falls_6_mnths

Log-Lik Intercept Only:        -42.806   Log-Lik Full Model:            -30.372
D(60):                          60.745   LR(7):                          24.867
                                         Prob > LR:                       0.001
McFadden's R2:                   0.290   McFadden's Adj R2:               0.104
ML (Cox-Snell) R2:               0.306   Cragg-Uhler(Nagelkerke) R2:      0.428
McKelvey & Zavoina's R2:         0.480   Efron's R2:                      0.311
Variance of y*:                  6.322   Variance of error:               3.290
Count R2:                        0.750   Adj Count R2:                    0.227
AIC:                             1.129   AIC*n:                          76.745
BIC:                          -192.425   BIC':                            4.669
BIC used by Stata:              94.501   AIC used by Stata:              76.745

.
end of do-file
```

Appendix 9: Critical appraisal checklist for umbrella review

JBI Critical Appraisal Checklist for Systematic Reviews and Research Syntheses

Reviewer _________________________ Date ________________
Author __________________________ Year ______ Record Number

		Yes	No	Unclear	Not applicable
1.	Is the review question clearly and explicitly stated?	☐	☐	☐	☐
2.	Were the inclusion criteria appropriate for the review question?	☐	☐	☐	☐
3.	Was the search strategy appropriate?	☐	☐	☐	☐
4.	Were the sources and resources used to search for studies adequate?	☐	☐	☐	☐
5.	Were the criteria for appraising studies appropriate?	☐	☐	☐	☐
6.	Was critical appraisal conducted by two or more reviewers independently?	☐	☐	☐	☐
7.	Were there methods to minimize errors in data extraction?	☐	☐	☐	☐
8.	Were the methods used to combine studies appropriate?	☐	☐	☐	☐
9.	Was the likelihood of publication bias assessed?	☐	☐	☐	☐
10.	Were recommendations for policy and/or practice supported by the reported data?	☐	☐	☐	☐
11.	Were the specific directives for new research appropriate?	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info ☐

____

____

____

Appendix 10: Data extraction instrument for umbrella review

JBI Data Extraction Form for Review for Systematic Reviews and Research Syntheses

Study Details	
Author/year	
objectives	
Participants (characteristics/ total number)	
Setting/context	
Description of Interventions/ phenomena of interest	
Search Details	
Sources searched	
Range (years) of included studies	
Number of studies included /	
Types of studies included	
Country of origin of included studies	
Appraisal	
Appraisal instruments used	
Appraisal rating	
Analysis	
Method of analysis	
Outcome assessed	
Results/Findings	
Significance/direction	
Heterogeneity	
Comments	

Appendix 11: Excluded studies from umbrella review

Excluded Studies at full-text stage			
Repeats	**Method**	**Focus**	**Unable to obtain**
Amboni (2013) (x2)	Amboni (2013)	Axer (2010)	Cumming (2002)
Axer (2010)	Shaw (2007)	Campbell (2006)	Shaw (2002)
Gillespie (2012)	Soriano (2007)	Chaabane (2007)	Shaw (2003)
Jensen (2011) (x2)	Staples (2006)	Crownover (2012)	
Shaw (2002)	Taylor (2012)	Gard (2000)	
Shaw (2003)	Walker (2004)	Gordon (2008)	
Staples (2006) (x2)		Segev-Jacubovski (2011)	
		Verheyden (2013)	
		Weerdesteyn (2008)	
		Willgoss (2010)	

Appendix 12: Example Search strategy for meta-analysis

Database: Ovid MEDLINE(R) <1946 to June week 25 2015> Search Strategy:

----

1 exp Accidental Falls/ (16517)

2 fall*.mp. (178538)

3 exp Postural Balance/ (15634)

4 postural balance.mp. (15738)

5 1 or 2 or 3 or 4 (191261)

6 exp Mild Cognitive Impairment/ (3030)

7 cognit* impair*.mp. (33828)

8 exp Dementia/ (126460)

9 exp Alzheimer Disease/ (71422)

10 (dementia or alzheimer*).mp. (159252)

11 6 or 7 or 8 or 9 or 10 (191911)

12 aged/ or "aged, 80 and over"/ or frail elderly/ (4196772)

13 (older adult* or elderly or frail or aged or old* person or "65 years").mp. (4222125)

14 12 or 13 (4222125)

15 exp Exercise/ (127011)

16 exp motor activity/ (207600)

17 exp Walking/ (21627)

18 (exercise* or physical activit* or walk* or physical function* or daily activit* or activit* daily).mp. (358461)

19 15 or 16 or 17 or 18 (445224)

20 exp Cognitive Therapy/ (17676)

21 exp Cognition/ (115994)

22 exp Executive Function/ (6409)

23 exp Attention/ (61713)

24 (cognit* therap* or cognit* psychotherap* or cognit* behav* therap* or cognit* or cognit* activit* or metacognit*

or executive function* or attention).mp. (509724)

25 exp Rehabilitation/ (156195)

26 exp Intervention Studies/ (7796)

27 (dual* rehabilitat* or training* or intervention*).mp. (808432)

28 25 or 26 or 27 (926495)

29 20 or 21 or 22 or 23 or 24 (548010)

30 19 and 29 (25502)

31 exp Gait/ (19146)

32 28 or 30 (943427)

33 5 or 31 (207565)

34 11 and 33 (2948)

35 14 and 34 (2288)

36 32 and 35 (844)

Appendix 13: MAStARI appraisal instrument for meta-analysis

JBI Critical Appraisal Checklist for Randomised Control / Pseudo-randomised Trial

Reviewer _ Date _

Author _ Year _ _ _ _ _ _ _ Record Number _ _ _ _ _ _ _

	Yes	No	Unclear	Not Applicable
1. Was the assignment to treatment groups truly random?	☐	☐	☐	☐
2. Were participants blinded to treatment allocation?	☐	☐	☐	☐
3. Was allocation to treatment groups concealed from the allocator?	☐	☐	☐	☐
4. Were the outcomes of people who withdrew described and included in the analysis?	☐	☐	☐	☐
5. Were those assessing outcomes blind to the treatment allocation?	☐	☐	☐	☐
6. Were the control and treatment groups comparable at entry?	☐	☐	☐	☐
7. Were groups treated identically other than for the named interventions	☐	☐	☐	☐
8. Were outcomes measured in the same way for all groups?	☐	☐	☐	☐
9. Were outcomes measured in a reliable way?	☐	☐	☐	☐
10. Was appropriate statistical analysis used?	☐	☐	☐	☐
	☐	☐	☐	☐

Overall appraisal: Include ☐ Exclude ☐ Seek further info. ☐

Comments (Including reason for exclusion)

Appendix 14: MAStARI data extraction instrument for meta-analysis

JBI Data Extraction Form for Experimental / Observational Studies

Reviewer _______________ Date _______________

Author _______________ Year _______________

Journal _______________ Record Number _______________

Study Method

RCT	☐	Quasi-RCT	☐	Longitudinal	☐
Retrospective	☐	Observational	☐	Other	☐

Participants

Setting _______________

Population _______________

Sample size

Group A _______________ Group B _______________

Interventions

Intervention A _______________

Intervention B _______________

Authors Conclusions:

Reviewers Conclusions:

Appendix 15: Excluded studies from meta-analysis

Population (n=29)	Intervention (n=38)	Outcome (n=13)	Method (n=30)	Unable to Obtain (n=4)
Day (2015)	Bharwani (2012)	Davis (2013)	Abreu (2013)	Christofoletti (2008a)
Dorfman (2014)	Bosner (2012)	Feng (2014)	Bharti (2014)	Glaesmer (2003)
Farag (2015)	de Carvalho (2004)	Gill (2013)	Cadore (2014)	Kubicki (2014)
Granacher (2010)	Dorner (2007)	Hars (2014)	Chao (2014)	Whitney 2011
Hall (2009)	Faes (2011)	Hauer (2012)*	Clair (2006)	
Jeon (2014)	Fairhall (2014)	Hopman-Rock (1999)	Coelho (2013)	
Krotish (2008)	Ferrer (2014)	Maki (2012)	Dal Bello-Haas (2012)	
Li (2010)	Francese (1997)	Park (2012)	de Andrade (2013)	
Maclean (2014)	Garuffi (2013)	Schwenk (2010)*	de Oliveira (2014)	
Nadkarni (2013)	Hageman (2002)	Schwenk (2014)*	Dorresteijn (2011)	
Pichierri (2012)	Hatch (2010)	Shimada (2012)	Dorresteijn (2013)	
Rogers (2010)	Hughes (2014)	Suzuki (2012)	Fan (2011)	
Roth-Shema (2014)	Jensen (2004)	Suzuki (2013)	Gregory (2014)	
Silsupadol (2008)	Jirovec (1991)		Hakim (2003)	
Silsupadol (2009)	Kamegaya (2014)		Halvarsson (2013)	
Silsupadol (2009)	Kemoun (2010)		Halvarsson (2014)	
Silsupadol (2006)	Kerse (2008)		Hernandez (2010)	
Szturm (2011)	Klages (2011)		Lo (2014)	
Ullmann (2008)	Kovacs (2013)		Litchke (2012)	
Ullmann (2010)	Lawowski (1999)		Makizako (2012)	
Van Swearingen (2011)	Littbrand (2011)		McCaffrey (2014)	
Westlake (2007)	Littbrand (2006)		McEwen (2014)	
Yamada (2011)	Manckoundia (2014)		Mirolsky-Scala (2009)	
Yamada (2010)	Mansdorf (2009)		Nitz (2011)	
Yamada (2011)	Nakamura (2012)		Reelick (2010)	
You (2009)	Pomeroy (1999)		Ries (2010)	
Zamfirescu (2012)	Rapp (2008)		Shimada (2014)	
Zijlstra (2009)	Resnick (2009)		Shubert (2010)	
Zijlstra (2011)	Rolland (2000)		White (2014)	

	Rosendahl (2006)	Yao (2013)
	Santana-Sosa (2008) Shaw (2003) Steinmetz (2014) Suttanon (2013) Teri (1998)	
	Toulotte (2003) Wenger (2009) Wesson (2013)	

Key: *=study presenting results from already included study (Zieschang 2013)

Appendix 16: Combined physical and cognitive exercises from meta-analysis

Study	Intervention Description	Combined Physical and Cognitive Exercise Descriptions
Christofoletti et al [210]	Interdisciplinary programme with multicomponent exercise	• Kinesiotherapeutic exercises that stimulated strength, balance, and cognition such as concentrated attention, recognition, immediate memory, working memory, and praxis. • In-group activities of arts and crafts that associated motor coordination exercises with cognition such as pictures, paintings, drawings, and embroidering.
D'Souza [211]	Postural control training in dual-task condition with manual-cognitive tasks in graded sensory	• Manual tasks graded dual to multiple, unilateral to bilateral, bilateral symmetrical to bilateral asymmetrical and gross-fine. • Cognitive tasks gradually increasing in complexity like more number of items to remember, more information processing to finally tasks requiring problem solving. • Sensory challenges by manipulating sensory inputs (vision, somatosensory, & vestibular).
Doi et al [212]	Multicomponent exercise programme	• Gait training at intensity and included dual-task walking, such as; walking whilst conducting a conversation or creating a poem. • Ladder training exercise (learning pattern of stepping into consecutive square segments, with speed and accuracy). • Combined exercises, such as; circuit training including stair stepping, ladder training and endurance walking.
Lam et al [213]	Tai Chi	• Coordinated bodily movements, balance training, and continuous attention to visual imagery and verbal memory.
Pitkala et al [103]	Multicomponent exercise programme	• Exercise including climbing stairs, balance training, transfer training, walking, dual tasking, and outdoor activities. • Balance training included walking on a line, training with a bouncing ball, climbing a ladder, and practicing getting up from the floor. • Executive functioning training included throwing a ball as accurately as possible, or doing 2 different functions with the left and right hands while counting numbers forward or backward at the same time. • Music and sing-alongs.
Trombetti et al [106]	Music-based multitask exercise programme	• Multitask exercises involving the handling of objects which became gradually more difficult, such as; percussion instruments or balls. • Basic exercises of walking in time to the music and responding to changes in the music's rhythmic patterns.

		• Exercises involved a wide range of movements and challenged the balance control system mainly by requiring multidirectional weight shifting, walk-and-turn sequences, and exaggerated upper body movements when walking and standing.
Yoon et al **[214]**	Cognitive activity with multicomponent exercise	• Cognitive training and exercise at the same time included rhythmically repeated simple actions to build up reactionary movement. • Cognitive training included sequential memory recall tasks, such as the “three-back verbal working memory”.
Zieschang et al **[215]**	Multicomponent exercise programme	• Adaptations for cognitively impaired patients, including simple instructions, haptic support, and use of mirror techniques instead of complex verbal instructions supported the training process and created a familiar, empathetic training atmosphere. • Functional training focused on basic ADL related motor functions such as: keeping balance while standing, walking, stepping, sitting down, and standing up, progressing to advanced levels such as climbing stairs, crossing obstacles on the floor, walking over foam surfaces to challenge the participants' balance system, and walking with additional cognitive or motor tasks. • Simple games.

Appendix 17: Glossary of terms for realist review

This glossary of terms is provided to assist the reader in understanding the terms associated with realist reviews. The definitions are sourced from the RAMESES realist review training materials document [237] unless otherwise stated. It is well recognised that even within the field of Realist Enquiry that there are multiple definitions of the same term. This glossary is provided so the reader may understand the researcher's acceptance and knowledge of these terms and how they have been used within the previous review protocol.

Context

The context describes anything in the social or physical world, such as the environment, the history of the programme or individual, cultural norms and values, beliefs or attitudes. The context is related to the mechanism, in that only those components which influences, triggers or modifies the behaviour of a mechanism are relevant.

Context-Mechanism-Outcome configuration (CMOc)

A CMO configuration is a relationship between particular contexts, mechanisms and outcomes. It can be reported as a statement, diagram or drawing. A sentence would be structured as so: "*In 'X' context, 'Y' mechanism generates 'Z' outcome*."

Mechanism

It is widely acknowledged that mechanisms are difficult to define, have many definitions, and are the most debated aspect within the field of realist enquiry. In this review, mechanisms generate outcomes, they are context specific and sensitive, and they are often hidden or not observable [329]. Mechanisms can be divided into Resources and Responses.

Outcome

The outcome is the effect from the mechanism, in the particular contextual situation. It can be intended or unintended, positive or negative.

Programme theory

"*A programme theory is an explicit theory or model of how an intervention, such as a project, a program, a strategy, an initiative, or a policy, contributes to a chain of intermediate results and finally to the intended or observed outcomes*." ([236], pxix).

Rough programme theory

The rough programme theory is the starting theory to be tested against the literature during the review process. It is generated from the CMOcs and is therefore related to specific context characteristics, but can also be generalisable across subject fields or domains. It is expected that the rough programme theory will develop and change as the review progresses. Rough programme theories are similar to candidate programme theories, a term used in other realist enquiry methods.

Middle Range Theory

"*A theory that is specific enough to generate hypotheses (for example in the form of propositions) to be tested in a particular case, or to help explain findings in a particular case, but general enough to apply across a number of cases or a number of domains*." ([237], p15)

Appendix 18: Initial rough programme theory

A. Physiological changes

An older adult with dementia (C) completing a strength and balance exercise programme ($M^{resource}$) will experience a physiological response ($M^{response}$) which improves their physical ability (O^1) and reduces their risk of falls (O^2).

The hypothesised physiological responses are:

- Motor system: stronger muscles, quicker motor response, longer endurance, less fatigue, better control, and coordination of muscle synergy.
- Sensory system: improved proprioception.
- Postural control: improved postural muscle activation and maintenance, quicker and more appropriate balance strategies (ankle, hip or stepping strategy) and response to perturbation.
- Cognition: increased capacity to divide and maintain attention, improved visuospatial awareness, neuroplastic adaptations, and changes.

B. Enjoyment

An older adult with dementia who has had a previously positive experience of falls or community services or exercise, who has a positive belief in exercise, and who has the physical capability to do the exercises either independently or with support (C), will feel enjoyment ($M^{response}$) from doing (O^1) a strength and balance exercise programme ($M^{resource}$) and this will reduce their risk of falls (O^2).

C. Encouraged (positive reinforcement)

An older adult with dementia who may not identify themselves as at risk of falling or remember any previous falls, who has poor or limited physical functioning, who is not used to doing exercise but is being appropriately supported (physically or emotionally) by a therapist ($M^{resource2}$) or network ($M^{resource3}$) and is well briefed or educated by that therapist or network (C) will feel encouraged ($M^{response1}$) to do (O^1) the strength and balance exercise programme ($M^{resource1}$) and will recognise the positive benefits from participating in the programme (O^2)

Once an older adult with dementia recognises the positive benefits from participating in a strength and balance exercise programme (C^2) they will feel motivated ($M^{response2}$) to continue with the programme (O^3) and will reduce their risk of falls (O^4).

D. Fearful of Negative Consequences

An older adult with dementia who identifies themselves as at risk of falls, who remembers that they have previously fallen or had a "near miss", who has limited physical activity or function or ability and who believes that they may deteriorate either physically or cognitively (C) or who listens to the education or warnings of the therapist ($M^{resource2}$), will feel fearful ($M^{response1}$) or concerned ($M^{response2}$) and will do (O) the strength and balance exercise programme ($M^{resource1}$).

E. Empowered to Achieve Goal

An older adult who has something they want to achieve, whose goals align with that of the therapist ($M^{resource2}$) and who believes that their goals can be achieved with the strength and balance exercise ($M^{resource1}$) programme (C), will feel empowered ($M^{response}$) to do (O^1) the strength and balance exercise and achieve their goal (O^2).

F. Influenced by Social and Cultural Expectations or Beliefs

An older adult with dementia who believes that exercise is good, who associates exercise with youth or vigour or health and well-being, who believes that the therapists or doctors "know what is best for them" ($M^{resource2}$) and who has a network that reinforces or imposes these beliefs (C) will feel influenced ($M^{response}$) to do (O) the strength and balance exercise programme ($M^{resource1}$).

Appendix 19: Data extraction sheet for realist review

Reference:

1. Relevance: *Are the contents of a section of text within an included document referring to data that might be relevant to our programme theories? Which ones?*
A. Physiological changes: B. Enjoyment: C. Encouraged (positive reinforcement): D. Fearful of negative consequences: E. Empowered to achieve goal: F. Influenced by social and cultural beliefs:

2. Interpretation of meaning: *If it is relevant, do the contents of a section of text provide data that may be interpreted as being context, mechanism (resource/response) or outcome?*

3. Judgements about Context-Mechanism-Outcome-Configurations: *What is the Context-Mechanism (resource)-Mechanism (response)-Outcome Configuration (CMOC) (partial or complete) for the **data**?*			
Context	**Resource/Intervention**	**Response/Mechanism**	**Outcome**

4. Judgements about programme theory:
• *How does this (full or partial) CMOC relate to the programme theory?* • *Within this same document are there data which informs how the CMOC relates to the programme theory?* • *If not, are these data in other documents? Which ones?* • *In light of this CMOC and any supporting data, does the programme theory need to be changed? How?*

5. Rigour:
• *Are the data sufficiently trustworthy and rigorous to warrant making changes to the CMOC?* • *Are the data sufficiently trustworthy and rigorous to warrant making changes to the programme theory?*

6. Contextual Information:
• Age: • Cognitive status/level: • Intervention setting: • Intervention details:

Notes:

Appendix 20: Excluded studies from realist review

Reason for Exclusion	
Study Population	**Publication Language**
Bolandzadeh (2014)	Gogulla (2012)
Cadore (2014)	Steinert (2009)
Christofoletti (2008)	
Dorner (2007)	
Jirovec (1991)	
Kovacs (2013)	
Kumar (2011)	
Rolland (2000)	
Santana-Sosa (2008)	
Schwenk (2010)	
Schwenk (2014a)	
Schwenk (2014b)	

Appendix 21: Characteristics of included studies in realist review

Reference	Context - Cognitive level	Context - Type of intervention	Context - Dose (*total hours*)	Context - Setting
Pitkala (2013)	Alzheimer's disease (67.1% with moderate or severe).	Intense, long-lasting physical exercise in either home (HE) or group (GE). HE=Dementia-specialist physiotherapists administered goal-oriented, individually tailored training, addressing the patient's individual needs and problems in daily functioning or mobility. GE=10 participants supervised by 2 dementia-specialist physiotherapists administered predetermined exercise programme consisted of endurance, balance, and strength training, as well as exercises for improving executive functioning.	HE = 1 hour, 2 a week, for 12 months (*104*) or GE = 4 hours, 2 a week, for 12 months (*416*).	Community (home or day centre), Finland.
Jeon (2014)	Mild dementia.	Exercises focusing on stretching, balance, strengthening, and endurance.	40 minutes, 1-2 times per day, 3 times per week, for 12 months (*156*).	Community, South Korea.
Shimada (2012)	Diagnosis of MCI and amnesic MCI.	Multi-component exercise (including aerobic exercises, strength training, postural balance retraining using multiple conditions to stimulate executive functions), supervised by physiotherapists.	90 minutes per day, 2 days a week, for (a total of 80 times over) 12 months (*156*).	Community (group), Japan.
Shimada (2014)	Amnesic MCI.	Multi-component exercise (including aerobic exercises, strength training, postural balance retraining using multiple conditions to stimulate executive functions), supervised by physiotherapists.	90 minutes per day, 2 days a week, for (a total of 40 times over) 10 months (*130*).	Community (group), Japan.
Park (2012)	Amnesic MCI.	Multi-component exercise (including aerobic exercises, strength training, postural balance retraining using multiple	90 minutes per day, 2 days a week, for (a total of 80 times over) 6 months (*78*).	Community (group), Japan.

		conditions to stimulate executive functions), supervised by physiotherapists.		
Makizako (2012)	Amnesic MCI.	Multi-component exercise (including aerobic exercises, strength training, postural balance retraining using multiple conditions to stimulate executive functions), supervised by physiotherapists.	90 minutes per day, 2 days a week, for (a total of 40 times over) 6 months (*78*).	Community (group), Japan.
Hernandez (2010)	Mild to moderate AD.	Systematic and supervised programme of regular physical activity with the aim of promoting the motor and cognitive stimulation.	60 minute session, 3 times a week (on non-consecutive days), for 6 months (*78*).	Community (group), Brazil.
Davis (2013)	Older adults with subjective memory complaints (MoCA 22).	RT=Progressive, high intensity resistance training. AT=Aerobic training using outdoor walking. BAT=Balance and tone training involving exercises for stretching, range of motion, basic core-strength, balance, and relaxation techniques.	60 minutes, twice a week, for 6 months (*52*).	Community (group), Canada.
Hauer (2012)	Mild to moderate diagnosed dementia (MMSE 21.7).	Progressive resistance and functional training programme.	2 hours, twice a week, for 3 months, supervised by a qualified instructor (*52*).	Community (out-patient groups), Germany.
Pedroso (2012)	AD (mean MMSE 20.1±4.6).	Programme of physical activity with cognitive task (coordination, aerobic resistance, flexibility, balance and agility and, at the same time, the performance of a cognitive task).	60 minute sessions, 3 three times a week on non-consecutive days, for 4 months (*51*).	Community (group), Brazil.
de Andrade (2013)	Seniors with AD (mild to moderate dementia).	Protocol of aerobic exercises, muscle strengthening, flexibility and balance exercises, and cognitive components.	60 minute session, 3 times a week (on non-consecutive days), for 16 weeks (*48*).	Community, Brazil.
Garuffi (2013)	Clinically diagnosed AD.	Resistance training.	60 minute session, 3 times a week (on non-consecutive days), for 16 weeks (*48*).	Community (weights room in university), Brazil.

Huger (2009)	Mild to moderate dementia (MMSE 17–26).	Regimen of progressive resistance and functional training (such as, standing - static and dynamic postural control - walking, sitting down and standing up from a chair, or climbing a stair, and including attention-depending motor-cognitive demands) in small groups (4-6 participants).	2 hour session, 2 times per week, for 12 weeks (*48*).	Community (groups), Germany
Frederiksen (2012)	Mild to moderate AD.	Aerobic exercise programme (different exercise machines), supervised by physiotherapist.	3 times a week for 1 hour over 14 weeks (*42*).	Community, Denmark.
de Oliveira (2014)	Mild to moderate AD.	Physical therapy following a distinct exercise protocol.	Once a week, for 6 months (*26*).	Residential (group), Brazil.
Hageman (2002)	Dementia of any aetiology (MMSE 18.03±6.2).	Resistance training using exercise-band, with 1:1 supervision.	2-3 sessions per week, for 6 weeks (*18*).	Community (day centre), USA.
Ries (2010)	AD (mean MMSE 23.2).	Balance exercise group intervention, with 2:1 participant to instructor (consistent physiotherapist) ratio.	45 minutes each session, 2 sessions per week, for 8 weeks (*12*).	Community (day centre), USA.
Suttanon (2012)	Mild to moderate dementia, diagnosis of AD.	Tailored (individualised) home-based balance exercise programme, provided by a physiotherapist.	6 home visits over 6 months (2 visits in the first month after the baseline assessment, 2 further visits in the second month, then 2 more home visits 4-6 weeks apart for the remaining times). Participants asked to do 5 exercise sessions and 5 walking sessions per week (*6*).	Community (home), Australia.
Cedervall (2015)	Mild AD.	Physical activity (i.e. regular outdoor walks, cycling, mowing the lawn, raking leaves, shovelling snow. Group exercises were rare).	Range of physical activity – almost never going outdoors to performing health-promoting PA for more than one hour a day.	Community, Sweden.
Cedervall (2010)	Mild AD.	Outdoor walking.	"Routine" of every day.	Community (home), Sweden.

Malthouse (2014)	Alzheimer's disease (AD) (MMSE 18 to 21).	Physical activity.	"Routine".	Community, UK.
Hauer (2006)	Moderate to severe dementia.	Physical training.	Various. 30–150 minutes, 2–7 days a week, for 2–30 weeks (*2-525*).	Mixed settings, mixed countries.
Burton (2015)	Dementia of any aetiology (MMSE 18.9±5.5).	Exercise or physical activity programme.	Various. 1-5 times a week, for 3-12 months (*13-260*).	Mixed settings, mixed countries.
Blankevoort (2010)	Dementia of any aetiology.	Physical activity.	Various.	Mixed settings, mixed countries.
Chan (2015)	Cognitive impairment (by cognitive assessment or dementia diagnosis).	Physical exercise (such as, balancing and strength training, flexibility, walking, coordination training, and exercises for executive function).	Various.	Mixed settings, mixed countries.
Stubbs (2014)	Dementia, confirmed diagnosis.	Physical activity.	Various.	Community, mixed countries.
Liu-Ambrose (2009)	n/a	Aerobic and resistance training.	Twice weekly.	n/a
van Alphen (2016)	Alzheimer's disease (AD).	Physical activity (aerobic exercise consisting of cycling or walking, work-related activity, active recreation, dancing, gardening, playing active games, organised and competitive sport, household activities, telehealth-delivered exercise, upper extremity cycle ergometer, home-based balance exercise).	n/a	Community, mixed countries.

Studies not included: Protocol of study included in review - Pitkala (2010), Hill (2009); No intervention or dose recorded or summarised – Boyle (2007), Christofoletti (2007), Erickson (2013), Leandri (2009), Sageat (2014).

Appendix 22: Quality appraisal of included material in realist review

Reference	Is the material cohesive?	What is the value?	What is the position in relation to the programme theories?	Broad/ Narrow	Thick/ Thin
31. Suttanon (2012)	Yes - clear questions, responses and conclusions made. Summarises the main points nicely and brings clinical relevance and future research into the paper. Series with Hill (2009).	Considerable. Considerable detail. Adds significantly to the review and the field. Slight methodological issue - only asking people engaged in physical activity to comment, therefore restricted inferences.	Adds and supports many of the MRTs.	Broad	Thick
34. Cedervall (2015)	Yes - clear story followed throughout paper. Initial theories outlined are explored and summarised. Series with Cedervall (2010).	Considerable. Adds significantly to the review and the field. Similar methodological issue to Suttanon (2012) - only asking people engaged in physical activity to comment, therefore restricted inferences.	Aligned with other material within the field. Noticeably positive outlook. Adds information to a variety of different MRT.	Broad	Thick
32. van Alphen (2016)	Yes - clear story regarding reasoning, data collected and summaries made.	Valuable. Adds value as a summary document to the field. Well conducted systematic review.	Aligned with other papers in the field. Some discrepancy in the interpretation – supports and refutes the same MRT.	Broad	Thick
33. Cedervall (2010)	Yes - concepts brought into the introduction were followed into the results/conclusions. Conclusions are a little vague. Series with Cedervall (2015).	Valuable. Adds value to the field, providing patient and carer perspectives. Small but detailed qualitative study.	Aligned with other material in the field. In agreement with "Enjoyment" and some aspects of "Encourage" but against "Fearful".	Broad	Thick
35. Malthouse (2014)	Yes – clear story with repetition within the discussion of results.	Valuable. Adds value to the field. Awareness from authors that asking participants about activity might change their activity levels or perception regarding if they should be exercising or not.	Aligned with the field but there are some contradictory statements - i.e. carers facilitate and limit activity without too greater depth of interpretation on this.	Broad	Thick
7. de Andrade (2013)	Yes - follows the aim of verifying the effects of a multimodal intervention. Reasonably well evidenced conclusions with some anecdotal and opinion information.	Valuable. However, some components of method are not clear i.e. how falls were measured.	Aligned with other material published in field.	Narrow	Thick

15. Hernandez (2010)	Yes – consistent story told throughout paper. However, very little results on falls (i.e. no falls risk outcome measures) considering the title.	Valuable. Adds to the field. Demonstrates that the physical activity programme held benefit over just a social group but no detail on social/control group.	Strong discussion on "Physiological" responses with some touches on other aspects.	Narrow	Thick
14. Hauer (2012)	Yes - cohesive story throughout paper. Holistic approach is considered regarding the training programme with introduction of other theories but does not fully explore.	Valuable. Adds to the field. Appears to clearly show that training can improve outcomes in dementia.	Adds to the "Physiological" theory in detail and some contribution to other MRTs.	Narrow	Thick
25. Pitkala (2013)	Yes – consistent theme throughout the paper. Main outcome measure is related to function.	Valuable. This is the first very positive results for this sort of study. Does have some shortfalls - low numbers of participants and no blinding of assessors, but is cohesive and aligned.	Aligned with other studies in that there are positive and not-so-positive outcomes. Considerably adds to "Function" with some "QoL" components. Strongly favourable to home interventions.	Narrow	Thick
12. Hageman (2002)	Yes - clearly focused on gait, and does not focus on anything else. Some limitations in design but cohesive.	Limited value. Adds to the "Physiological Gait" MRT only. Does not make distinct conclusions.	Aligned with other studies in the field and supports the "Physiological Gait" theory with links into "Functional".	Narrow	Thick
11. Garuffi (2013)	Yes - demonstrates that resistance training has an effect compared to social gathering, but not an "outright" or overall improvement	Valuable. Adds to the literature regarding resistance training in dementia. However components of the socialization/control group are not explored.	Aligned with other studies. Focus on "Function" and "Physiological". Indicates at social aspects of an intervention without any exploration.	Broad	Thin
1. Blankevoort (2010)	Yes - aimed to identify the effects of physical activity on many different outcomes but did not do a meta-analysis and unclear if this was intended or planned. Appears trustworthy despite having no clear method of synthesis and only narrative opinions.	Valuable. Repetition that there is not enough evidence to make recommendations. Some evidence that higher training creates better outcomes. Potentially too many outcomes therefore had too broad a focus.	Neither adds nor detracts from the theoretical development and MRTs.	Broad	Thin
3. Burton (2015)	Yes - clear outline and parameters for the meta-analysis, results follow aims and clear conclusion. Appears trustworthy in conclusions drawn.	Valuable. Well conducted meta-analysis on a specific population. Adds to the field a great deal but limited in regards to development of MRT's.	Positioned well within the falls literature as follows the findings from healthy older persons in falls exercise studies.	Broad	Thin

26. Ries (2010)	Yes – story follows throughout the paper. Nice justification for tailoring an intervention. Has some limited discussion and consideration of a theoretical underpinning.	Valuable. Builds on the potential of mixed MRT's where they all interlink.	Aligned with the rest of the studies in this review. Adds mainly to "Tailoring" MRT but some "Encouraged" and "Enjoyment". Nicely links a few of the MRTs together.	Broad	Thin
30. Stubbs (2014)	Yes - cohesive and interesting story. Brings new information about socio-ecological theories and covers a wide range of MRTs whilst maintaining focus.	Valuable. Article is a literature review and is in alignment with other research in the field but synthesises the information in a different way.	Adds information to a few different MRTs.	Broad	Thin
17. Huger (2009)	No – clear outline proposed but there is no ending as only a protocol.	Limited value as only a protocol.	Aligned with "Physiological" but introduces a more holistic approach - considering the emotional aspects as much as the physical and that relate to "QoL".	Broad	Thin
10. Frederiksen (2012)	Yes – but limited. Feasibility focus with some conclusions drawn which go beyond the scope of the study design.	Very limited value due to small sample size (n=8 participants) and length of paper. Theory suggestions rather than evidence.	Adds to the "Depression" and "QoL" but not enough evidence to fully support or refute.	Broad	Thin
13. Hauer (2006)	Yes - clear aims, method and discussion. Conclusions drawn are appropriate for the evidence provided.	Valuable. Adds to "picture" of physical training research, however since 2006 more studies have been produced so an old review of the evidence.	Aligned with various MRTs but very poor detail (typical pattern with a review).	Narrow	Thin
6. Davis (2013)	Yes - cohesive economic evaluation therefore different story than intervention study.	Limited value. Corroborates the findings from other studies (would have greater value from the original paper rather than this economic evaluation).	Aligned with the various MRT however only provides limited data to feed into them.	Narrow	Thin
4. Chan (2015)	Yes - clearly outlined and followed story. Small discrepancy in that similar review of same year included different studies (Burton 2015).	Valuable. Important addition to the evidence base as clear meta-analysis on single exercise as an intervention to reduce risk of falls. However, not very valuable at developing theory.	Aligned. Small addition to "Tailoring" and MRT involving participation.	Narrow	Thin
5. Christofoletti (2007)	Yes - very limited in detail in all sections. Systematic review with poorly graded papers included. Narrative reporting of results.	Limited value - only addition to MRT development is from secondary sources. Conclusions are vague.	Aligned with other reviews and material in this field.	Narrow	Thin

9. Erickson (2013)	Yes - material is evidence summary and opinion piece. Summarises that more research is needed. Some cross-over of included studies from this review.	Valuable. Starts to question the medical model of only medicines/drugs are effective at improving cognition. Editorial in nature therefore secondary information but reported in a rigorous manner (strengths and limitations of studies included).	Aligned with other published material as summarises their findings and reaches similar conclusions.	Narrow	Thin
23. Pedroso (2012)	Yes - story is well outlined regarding the problem, intervention and results.	Valuable. Adds to field as a longitudinal study of dual-tasking type interventions conducted in population of interest.	Aligned with "Physiological" theories and some exploration into "Function" with an interesting perspective on where the "Functional" mechanism might sit (before or after reduced fall risk).	Narrow	Thin
20. Liu-Ambrose (2009)	Yes - brief story described but overall the material is not very cohesive.	Valuable as summary piece that starts to think about how clinicians need to propose exercise to older generation. Is more focused on older adults rather than those with dementia.	Aligned with "Physiological" MRT and starts to consider the influence of the therapist or trained staff.	Narrow	Thin
2. Boyle (2007)	Yes - article follows the title, aims and results. Tells a story and summarises nicely.	Limited value. Confirms there is motor dysfunction within a mild population but does not make this link to anything clinical (has a more vascular focus).	Aligned well with "Physiological" MRT.	Narrow	Thin
18. Jeon (2014)	Yes - story focuses on balance and postural sway, but does not put it into the context of falls or why poor balance would be an issue/problem. Blinding is unclear. Authors make appropriate claims considering their limitations.	Limited value. Addition to "Physiological" theory and does take a small step into "how" improved balance might be beneficial but does not make step to "falls".	Data only related to "Physiological".	Narrow	Thin
16. Hill (2009)	Yes – clear story but limited as no conclusions due to only being a protocol. Paper linked with Suttanon (2012).	Limited value.	Aligned with "Physiological" and some new information on "Tailoring" for safety and increased support.	Narrow	Thin
24. Pitkala (2010)	No – protocol only with little detail, limited discussion on theory underpinning the intervention and no conclusions. Paper linked with Pitkala (2013).	Limited value but meets inclusion criteria and adds contextual details.	Aligned with MRTs and adds specifically to "Physiological" with some extract for "How" and another for "Depression".	Narrow	Thin

29. Shimada (2012)	Yes - extremely brief. Difficult to determine as only a conference abstract.	Limited value. Adds very little value to review and only provides little value to field.	Aligned with "Cognitive" and "Gait" performance improvement following exercise but no theoretical discussion at all.	Narrow	Thin
19. Leandri (2009)	Yes. Not an intervention study but paper does tell a "story" about postural readings and relates to clinical problems/context.	Limited value. Starts exploring how the components are linked and might result in falls. Draws from other research to aid explanations.	Aligned to "Physiological" MRT but does not include any others or any theoretically useful discussion.	Narrow	Thin
22. Park (2012)	Yes - extremely limited in detail as only an abstract with no depth of thought. Difficult to determine as only a conference abstract. Linked to Makizako (2012).	Limited value. Does not add any MRT other than "Cognitive" and contextual detail.	Aligned with "Cognitive" MRT only.	Narrow	Thin
28. Shimada (2014)	Yes - extremely brief. Difficult to determine as only a conference abstract.	Limited value. Adds very little value to the review and only provides little value to the field.	Aligned with "Cognitive" in that there is performance improvement following exercise but only within memory not verbal fluency.	Narrow	Thin
21. Makizako (2012)	Yes - extremely brief. Difficult to determine as only a conference abstract. Linked to Park (2012).	Limited value. Adds very little other than to "Gait" aspect of the MRT for "Physiology".	Aligned with "Gait" component "Physiological" MRT.	Narrow	Thin
27. Sageat (2014)	Yes - extremely brief. Difficult to determine as only a conference abstract.	Minimal value. It is in alignment with other studies regarding different dual-task studies.	Aligned with the "Physiological" MRT only.	Narrow	Thin
8. deOliveira (2014)	No – only useful information is from the picture with no textual descriptions or interpretations.	Limited value. Adds intervention context information - all the inferences about the programme theories are made from the perspective of the researcher.	Difficult to ascertain. Follows the programme theories it's related to but only through interpretation.	Narrow	Thin

Legend: Dark blue shading = initial search first wave; light blue shading = initial search second wave; green shading = second iterative search materials

Appendix 23: Intervention programme

Training Programme

A study of falls prevention in people with memory problems

02/11/2014 A study of falls prevention in people with memory problems Version 1 1

Training Programme

Description of the Intervention

- The intervention is a 6-week individually-tailored strength, balance, and dual-tasking training programme. The strength and balance exercises are used clinically and have been adapted from the well-evidenced Otago exercise programme. The dual-tasking exercises aim to challenge the participants cognitive flexibility and attention, by completing a cognitive task at the same time as doing a balance task/exercise.

- The exercises will be chosen according to the individual participants ability, identified at the pre-intervention assessment.

- The sessions will be approximately 90 minutes, twice a week, in the participant's home. The sessions will be 1:1 with the participant and the investigator/student.

Balance Exercise / Level:	Knee Bends	Back-wards walking	Walking and turning	Side-ways walking	Tandem stance	Tandem walking	One-leg stance	Heel walking	Toe walking	Tandem back-wards walking	Sit to stand	Stair walking
Level A	X10 reps holding support				10 sec's holding support						X5 stands 2 hands support	as instructed
Level B	X10 reps repeat holding support X10 reps no support	X10 steps x4 holding support	Walk and turn around (figure 8) x2 walking aid	X10 steps x4 walking aid	10 sec's no support		10 sec's holding support				X5 stands one hand X10 stands 2 hands	as instructed
Level C	X10 reps repeat no support		Walk and turn around (figure 8) x2 no support	X10 steps x4 no support		X10 steps repeat holding support	10 sec's no support	X10 steps x4 holding support	X10 steps x4 holding support		X10 stands no support X10 stands one hand repeat	as instructed
Level D	X10 x3 no support	X10 steps x4 no support				X10 steps repeat no support	30 sec's no support	X10 steps x4 no support	X10 steps x4 no support	X10 steps repeat no support	X10 stands no support repeat	as instructed repeat

<table>
<tr><th>Strength Exercise
Level:</th><th>Knee ext
(sitting)</th><th>Knee flex
(Stand)</th><th>Hip abd
(Stand)</th><th>Ankle PF / calf-raises
(Stand)</th><th>Ankle DF / toe-raises
(Stand)</th></tr>
<tr><td>Level A</td><td rowspan="4">X10 reps with ankle weight</td><td rowspan="4">X10 reps with ankle weight</td><td rowspan="4">X10 reps with ankle weight</td><td>X10 reps sitting</td><td>X10 reps sitting</td></tr>
<tr><td>Level B</td><td></td><td></td></tr>
<tr><td>Level C</td><td>X10 reps holding support</td><td>X10 reps holding support</td></tr>
<tr><td>Level D</td><td>X10 reps no support</td><td>X10 reps no support</td></tr>
</table>

Executive function:	Working Memory	Working Memory	Verbal Fluency	Attention	Attention/ Memory	Motor Task
Dual-Task / Level:	Counting backwards	Digit-span recall	Say as many words in a topic i.e. Animals, Tree's	Listening to music	Talking	Walking whist carrying
Level A	10, 20, 30 in 1's	3 to 5 digit recall				One glass (little liquid)
Level B	30, 50, 100 in 2's or 5's	5 to 7 digit recall		Focus/whistle along to the music	Discuss different topics of conversation	Full glass Tray with a glass
Level C	37, 53, 204 in 3's, 7's, 9's	7 to 9 digit recall, or 9+, or backwards	Saying topic word for each letter of alphabet			Tray with multiple
Other option			Spell word backwards – 5 letter word only			Transferring/throwing object from one to the other.

Dual-task schedule

• Week 1:	Sessions 1-2	No dual-task (allow familiarisation with physical exercises)
• Week 2:	Sessions 3-4	Numbers focus
• Week 3:	Sessions 5-6	Words focus
• Week 4:	Sessions 7-8	Motor focus
• Week 5:	Sessions 9-10	Mixture
• Week 6:	Sessions 11-12	Mixture

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Example training session

This is an example of a typical training session:

- Introduction, check participant able to do training session, any issues from previous session identified, find training programme folder and open to exercise sheets
- Complete the exercises using the sheets in the folder (see slide 10-11)
  - Exercises completed from those selected at the pre-assessment data collection session from the full list of potential exercises (see slides 5-7)
  - Support/prompts are given from the research physiotherapist
  - Progression of exercises instructed by the research physiotherapist, if possible (see levels A-D on slides 5-7)
  - Dual-tasking is included in up to 50% of the total number of exercises, if possible (see slide 7)
  - The type of dual-tasking completed is dependent upon the week within the intervention schedule (see slide 8)
- Complete participant reported effort rating from session (see slide 12), check all exercise sheets have been completed/ticked
- Encourage completion of weekly activity diary, and confirm next session date/time and ensure written on weekly activity diary (see slide 13)

Sideways walking

Exercise Intensity Level	Date	Date	Date	Date	Date	Date	Date	Date	Date	Date	Date	Date
X10 steps x4 walking support												
X10 steps x4 no support												

Heel-toe standing still	Exercise Intensity Level	Date	Date	Date	Date	Date	Date	Date	Date	Date	Date	Date	Date
	10 sec's holding support												
	10 sec's no support												

<u>Effort Scale</u>

How much effort was the exercise you have just done?

1 2 3 4 5 6 7 8 9 10

NO EFFORT AT ALL
(i.e. breathing normally)

MAXIMAL EFFORT
(i.e. completely out of breath)

Weekly Activity Diary

What physical activity did you do this week?

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday ....

<u>Example of Progression</u>

Walking and turning	Exercise Intensity Level	Date 1st Feb 2016	Date 4th Feb 2016	Date 8th Feb 2016	Date 11th Feb 2016	Date 15th Feb 2016	Date 18th Feb 2016	Date 22nd Feb 2016	Date 25th Feb 2016	Date 29th Feb 2016	Date 3rd Mar 2016	Date 7th Mar 2016	Date 10th Mar 2016
													
	Walk and turn around (figure 8) x2 Support (sups)	X2 laps x2 sups	X2 laps x1 sups	X4 laps x1 sups	X4 laps x1 sups +DT	X4 laps x1 sups +DT					X2 laps x1 sups +DT		
	Walk and turn around (figure 8) x2 no support						X2 laps no sups	X4 laps no sups	X2 laps no sups +DT	X2 laps no sups +DT		X2 laps no sups +DT	X4 laps no sups +DT

Appendix 24: Ethical approval letter for feasibility study

West Midlands - South Birmingham Research Ethics Committee

Royal Standard Place
Nottingham
NG1 6FS
Telephone: 0115 8839428

25 November 2015

Professor Pip Logan

B108a, School of Medicine, Queens Medical Centre,
University of Nottingham

Nottingham
NG7 2UH

Dear Professor Logan

Study title:	**A proof-of-concept study of an exercise and dual-task based fall prevention intervention in community dwelling older adults with mild dementia.**
REC reference:	**15/WM/0412**
Protocol number:	**15094**
IRAS project ID:	**187303**

The Research Ethics Committee reviewed the above application at the meeting held on 17 November 2015. Thank you for attending with Victoria Booth and Maureen Godfrey to discuss the application.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Ms Penelope Gregory, nrescommittee.westmidlandssouthbirmingham@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below. .

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

1. Make the following changes to the participant information sheet:

a) Include details at the end of the participant information sheet of an independent source of advice should the participant wish to discuss the research with someone unconnected to the study.

b) Include information that participants will have at least 24 hours to decide whether or not they wish to take part in the study.

c) Include information in the participant information sheet to correspond with point 5 of the consent form.

d) Insert the name of the REC (South Birmingham Research Ethics Committee)

2. Make the following changes to the consent from:

a) Transpose points 7 and 8 of the consent form

b) At point 6, insert the words ' and anything untoward identified during the course of the study' after the word 'study'.

3. Make the following changes to the GP letter: **a)** Delete the word 'automatically'.

You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which can be made available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations. Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non NHS sites

The Committee has not yet completed any site-specific assessment(s) (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. I will write to you again as soon as an SSA application(s) has been reviewed. In the meantime no study procedures should be initiated at non-NHS sites.

Summary of discussion at the meeting

The Committee welcomed Professor Logan, Victoria Booth and Maureen Godfrey to the meeting and thanked them for attending.

- **Social or scientific value; scientific design and conduct of the study** The

Committee considered the application to be well thought out.

The Committee noted the application indicates participants may keep the research materials but also states that the materials will be collected in at the end of the study. Members asked the applicant to clarify this aspect.

The applicant responded that the participants may keep the exercises sheets after the study has ended if they wish to but the diaries would be handed in.

The Committee noted A35 of the IRAS form states that should a participant indicate they wish to withdraw during the intervention period, they will be contacted four times by telephone. The Committee was mindful that participants do not have to state why they wish to withdraw from a study and although the researchers may ask why; the participant is under no obligation to say. Members were unclear whether contacting the participant four times meant speaking to the participant on four separate occasions or trying to contact them by telephone four times.

The applicant advised that this meant it was the set number of calls which will be made to participants if there is no answer.

The Committee asked the applicants whether the exercises in the research were used as standard care.

The applicants confirmed that the strength and balance exercises are used as part of standard care.

- **Care and protection of research participants; respect for potential and enrolled participants' welfare and dignity**

The Committee expressed some concern that there may be potential for participants to 'overdo it' however members noted that the protocol does state that participants will not be asked to undertake or do anything which is outside of their capability.

The Committee asked the applicants whether they had any concerns regarding the safety of participants undertaking the exercises when unsupervised.

The applicants responded that participants will only undertake exercises that they have already done, adding that participants will not be asked to do anything else beyond this.

- **Informed consent process and the adequacy and completeness of participant information**

The Committee advised the applicant that changes will be required to the participant information sheet, consent form and GP letter but these will be detailed in the letter.

The Committee advised the applicants that the participant information sheet should include details of an independent source of advice should the participant wish to discuss the research with someone unconnected to the study.

The Committee advised the applicants that the participant information sheet should state that potential participants will have at least 24 hours to decide whether or not they wish to take part in the study.

In private discussion the Committee agreed that points 7 and 8 on the consent form should be transposed. Members agreed that the point 5 of the consent form requires corresponding information to be included within the participant information sheet. The Committee agreed that some additional words regarding consent to inform the participants GP should be added to point 6 of the consent form.

- **Suitability of supporting information**

The Committee advised the applicant that the word 'automatically' should be removed from the GP letter.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Covering letter on headed paper [Covering Letter]		20 October 2015
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [2015 University of Nottingham Clinical Trials Insurance]		27 October 2015
GP/consultant information sheets or letters [GP LETTER Fall prevention in people with memory problems]	Final version 1.0	20 October 2015
IRAS Checklist XML [Checklist_02112015]		02 November 2015
Letter from sponsor [15094 Signed Sponsor Letter]		27 October 2015
Other [TRAINING PROGRAM Falls prevention in people with memory problems Version 1 02.11.2015]	v1.0	02 November 2015
Participant consent form [CONSENT Fall prevention in people with memory problems]	Final version 1.0	20 October 2015
Participant information sheet (PIS) [SHORT INFO SHEET Fall prevention in people with memory problems]	Final version 1.0	20 October 2015
Participant information sheet (PIS) [INFO SHEET Fall prevention in people with memory problems]	Final version 1.0	20 October 2015
REC Application Form [REC_Form_27102015]		27 October 2015
Research protocol or project proposal [PROTOCOL Fall prevention in people with memory problems]	Final version 1.0	20 October 2015
Summary CV for Chief Investigator (CI) [Pip Logan CV]		20 October 2015
Summary CV for student [Vicky Booth CV]		20 October 2015
Validated questionnaire [PARTICIPANT QUESTIONNAIRES Falls prevention in people with memory problems. Final Version 1. 02.11.2015]	v1.0	

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports

- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-thehra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

15/WM/0412	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

Professor Simon Bowman Chair

E-mail: nrescommittee.westmidlands-southbirmingham@nhs.net

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

"After ethical review – guidance for researchers" [SL-AR2 for other studies]

Copy to: *Miss Angela Shone*

Shirley Mitchell, Nottinghamshire Healthcare NHS Foundation Trust

West Midlands - South Birmingham Research Ethics Committee

Attendance at Committee meeting on 17 November 2015

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mr Michael Andrews	Retired Company Secretary	Yes	
Professor Simon Bowman	Consultant Rheumatologist	Yes	
Ms Philippa Burgon	Lay Member	Yes	

Rev'd Dr Barry Clark	Retired Hospital Chaplain	Yes	
Dr John David Cochrane	Retired GP	No	
Dr Mary Glover	University Lecturer and Psychotherapist	No	
Mrs Lynne Gray	Senior Biomedical Scientist	Yes	
Dr Peter Guest	Consultant Radiologist	Yes	
Mr Liviu Marius Hanu-Cernat	Consultant Maxillofacial Surgeon	Yes	
Dr Dalvina Hanu-Cernat	Consultant in Anaesthesia and Pain Medicine	Yes	
Dr Elizabeth Hensel	Honorary Research Fellow/Clinical Lecturer	No	
Dr Kathryn Kinmond	Psychologist and University Lecturer	No	
Professor Paula McGee	Professor of Nursing	Yes	
Mrs Andal Thirumalai	Plastic Surgeon	No	
Mr Sunil Solomon Thomas	Consultant Plastic Surgeon	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Victoria Booth	15/WM/0412
Mrs Maureen Godfrey	15/WM/0412
Miss Andrea Graham	Deputy Regional Manager
Ms Penelope Gregory	REC Manager
Professor Pip Logan	15/WM/0412

Appendix 25: Supporting evidence from field notes for each theme

Theme	Evidence Statements	Reference Example
Dual-Tasking Exercises	1. There are a range of dual-tasking exercises which can be completed in either a home or group setting. 2. The dual-task completed can focus on the overall cognitive process rather than the specific activity. 3. Dual-tasking can be introduced once the individual is familiar with one aspect of the dual-task. 4. Participants can prioritise either aspect of the dual-task. 5. Dual-tasking can be implemented into whichever exercises are suitable for that individual and their abilities. 6. Dual-tasking can be tailored to the topics/interests of the individual to promote enjoyment.	1. Table 7.3 summary from all field notes. 2. "*DT exercises focusing on words were completed (word association, items in rooms of house, types of dogs/football teams…"* (P1;G;VB) 3. "*During balance all were started at simple backwards counting with progression to larger numbers or 2-3s once accurate and balance maintained*." (P1;G;VB) 4. "*Noted that during figure 8 walking around slippers participant prioritised physical ability*." (P2;VB) 5. "*Walked outside for 10 mins with dual-task conversation – aimed to do spelling but ended up talking only*." (P1;H;VB) 6. "*After the session attempted to get recall of telephone number from 14026 – he verbally reported old telephone number. Note that this is a goal for participant and wife and to work on this over the weeks by breaking the task down with repeated recall during session (i.e. first x4 numbers only). Carer for 14026 was very keen to do this with participant*." (P1;G;VB)
Documentation	1. Participants required prompts from the supervising staff to document the exercise programme. 2. Participants that were more engaged with the documentation process during the initial stages of the study programme were more familiar with it and able to complete it with less support from the supervising staff. 3. Staff supervising the sessions had to be considerate of the impact of reminding the participants of their memory difficulties when supporting documentation of the session.	1. "*All exercise sheets were updated as the participants did the circuit and were filled in with assistance of VH, LH and BH*." (P1;G;VH) 2. "*I informed them that we'd eventually be asking them to do this each session and they can either fill in as they go or at the end* (P1;G;VB). "*Diary completed independently by the participant*" (P2;VB) 3. "*16007 forgot to bring blue folder with him – during completing the exercise sheets for today's session he requested that I not draw attention to the fact he had forgotten it*" (P1;G;VB)
Design (of the sessions)	1. A home setting enabled a consistent level of supervision and exercise tailoring. 2. A group setting required a consistent staff-participant ratio with increased awareness by the staff to ensure exercises were at the appropriate level. 3. The initial sessions of a group needed 1:1 staff-participant supervision, considering the exercises were unfamiliar.	1. All home entries 1:1 researcher: participant. 2. "*4 participants:1 physio for today's session therefore followed Monday's session plan and completed each station as a group..16007 finished exercises quicker than the others and had tendency to drift away from the group, kicking a football or paying attention to another aspect of the room*." (P1;G;VB)

	4. The order of the exercises could be tailored to the individual and designed to maintain active time within the sessions.	3. "*Each participant needed 1:1 to understand the exercises and it seemed like they were quite "new" to this form of exercise*." (P1;G;VB) 4. "*…all repetitions completed on x1 leg working well and no muscle symptoms following change*." (P2;VB)
Resistance (Methods of obtaining)	1. Variable-weights were a more consistent and effective method at providing resistance than exercise-band. 2. The order of the exercises could be tailored to increase or decrease the resistance.	1. "*Strength exercises were performed using exercise-band for each participant. Knee extension in sitting, hip abd and hip ext worked well using exercise-band. However knee flexion in standing was performed with weight as difficult to find a good place to secure exercise-band*." (P1;G;VH) 2. "*…all repetitions completed on x1 leg working well…"* (P2;VB)
Goal-Setting	1. Goal setting was used in this patient population, with and without the involvement of carers. 2. Goal setting was used as a measure of outcome, informed the research staff of the participants wishes and aims, and allowed some tailoring of the intervention to the individual participant and their everyday life and interests.	1. "*All were able to identify goals for attending the session*." (P1;G;VB) 2. *"…this is a goal for participant and wife and to work on this over the weeks by breaking the task down with repeated recall during session (i.e. first x4 numbers only). Carer for 14026 was very keen to do this with participant*." (P1;G;VB)
Progression (of the exercises)	1. The programme was started at a manageable level for the abilities of the participant with limited or no dual-tasking. 2. There were many ways in which the exercises and overall programme was progressed, including dual-tasking. 3. Only one aspect of a dual-task exercise was progressed at a time, and only when completed without errors. 4. Supervising staff acknowledged the progression of exercises as an improvement to the participant and their carers/family, when appropriate to do so. 5. A home setting allowed more accurate tailoring, progression and monitoring of dual-tasking within this patient population, compared with a group setting. 6. Effort scales were used to determine the participants' opinion of their effort, provide education regarding appropriate exercise levels, and indicate timing of progression. 7. Carers/family members were involved within the sessions and assisted in demonstrating progress to the participants. 8. Progress was not made in every session but accommodated other activities of daily living and individuals comorbidities.	1. "*No dual task added today but will be good to commence at next visit*." (P1;H;VH) 2. Table 7.4 summarises all from field notes. 3. "*All participants were encouraged to be accurate in their numeracy tasks and were not progressed unless able to complete in an errorless manner*." (P1;G;VB) 4. "*Participant's daughter reported impressed with how much progression 16078 has achieved*" (P2;VB) 5. "*Both participants worked with own instructor for this due to different walking pace. 16007 found this very difficult and could manage 2 stage tasks, and needed reminding for 3 stages. 14026 was pleased to manage 4 stage tasks and walked well during this activity*." (P1;G;VH) 6. "*Participant became breathless during stepping exercise – but reported an effort level of 1…Will need to add weight and increase repetitions next session*." (P2;VB) 7. (See reference example 4). 8. "*Had just walked to shop so no CV done today, but will next time commence 10-15 minute brisk walk*." (P1;H;VH)

Comorbidities	1. The presence of comorbidities did not stop the participation of this patient population in an exercise programme. 2. The participant and supervising staff decided together on the continuation, adaptation or omission of exercises. 3. Participants may have a unique way of managing their comorbidities which supervising staff need to know and utilise. 4. Comorbidities may limit some sessions or exercises but did not stop progress in other exercises or programme components.	1. "*Reported some back pain during the exercise session – normal for him when doing activities and happy to continue."* (P2;VB) 2. *"Some modification of exercises completed due to shoulder OA and long standing back pain."* (P2;VB) 3. "*Completed all exercises well – needed a sit down after CV exercises and had a sweet as felt short of breath*." (P1;H;VB) 4. "*Participant reported feeling a little breathless today…Added final stepping exercise into programme as participant did not appear fatigued during the session*." (P2;VB)
Tailoring (to the individual)	1. A standard set of exercises can be tailored to a variety of individuals with mild cognitive impairment. 2. Exercises were adapted, re-ordered or alternatives provided before they were omitted from the session, where possible. 3. The rest of the participants' day and daily life was considered when completing the exercise sessions. 4. The home setting allowed for greater flexibility to tailor standardised exercises to an individual.	1. "*Completed all exercises*" (P1;H;RT) 2. *"Some modification of exercises completed due to shoulder OA and long standing back pain."* (P2;VB) 3. "*Had a good holiday. Had to climb 37 stairs each day. Feels a bit tired but happy to exercise*." (P1;H;VH) 4. "*Used frame for support rather than windowsill for ergonomics of hand hold*." (P2;VB)
Independent completion of exercise	1. Participants required time, repeated demonstrations and support to complete exercise outside of the intervention sessions. 2. Participants that were informed of this requirement earlier in the programme were more likely to implement. 3. Participants required appropriate, tailored documentation of how to do the exercises outside of the intervention sessions. 4. Carers can be involved in supporting completion of exercises outside of the intervention sessions.	1. "*Discussed with all participants to complete the strength exercises at home x1 over the weekend. Demonstrated how to do each exercise with the exercise-band…"* (P1;G;VB) 2. "*16007 requested "something" he could do at home. Started discussion on what will be expected of them once the group stops*," (P1;G;VB) 3. "*Each participant took their blue folder home with the exercise-band and asked to bring the folder back in next session*." (P1;G;VB) 4. "*Participant reported that she has not done any of the exercises independently – discussed that I could show a member of her family how to do the exercises with her for once the study has finished*." (P2;VB)
Carer (influence and involvement)	1. The involvement of the carer can be varied, tailored to the individual and their circumstances, and whilst not essential for participation with all individuals, may provide support to the participant. 2. Carer involvement can be overt or in the "background". 3. Participation in an intervention programme of regular sessions might increase the burden on carers.	• "*Carer for 14026 had cataract surgery at the weekend so wished to observe only and not participate today*." (P1;G;VH) • "*call from participants daughter asking if therapist had visited on 02/03/2016 – this was confirmed and daughter asked if she could be informed of any changes to the timetable in the future as she thought her mother's dementia has deteriorated*." (P2;VB)

	4. The more comorbidities a participant experienced, the more involvement there appeared to be from carers.	• "*Initially asleep on arrival – participant's son-in-law opened door and daughter reported "forgetting about today"*"(P2;VB) • "*Participants daughter was under the impression the leg pain had greatly reduced otherwise she would have cancelled today's session – agreed time/date for next session*." (P2;VB)
Attendance	1. Individuals may not be able to attend every session in an intervention programme, due to illness, social engagements, other commitments, or holidays.	1. "*15034 did not attend as pre-arranged engagement – already known to the research team*." (P1;G;VB)
Emotional influences	1. Emotional issues can arise from dementia specific or general concerns during the course of the programme. 2. Individuals can experience emotional or psychological aspects of participating in a regular, long-term programme. 3. Emotional issues can influence physical ability and the delivery of the intervention, in which approaches need to be tailored to the individual (for example, increased time within a session, motivational approach).	• "*Initially 15034 was tearful – stepped outside and reported that she is still struggling to accept her diagnosis, is "ashamed" to tell people she has dementia and is very tearful. Consented to do the class*." (P1;G;VB) • "*participant reported that she "felt better" after my visit, when asked if she thought this was from having a visit from someone or from doing the exercise, she thought it was "a bit of both*"." (P2;VB) • "*Participant became tearful during the initial introductions…some time was spent discussing how he has been feeling (acknowledging sadness and bringing conversation around to his family members that he sees regularly)."* (P2;VB)
Staffing	1. A 1:1 supervisor-participant ratio consistently progressed the intervention appropriately. 2. Supervising staff required experience and training to be able to prescribe and progress the programme appropriately. 3. Once the exercises were established, supervising staff provided less experienced support and could be qualified or unqualified, although consistency in staff member was preferred. 4. Detailed field notes provided useful information.	1. "*In the group format it was much harder to target DT and approx. 50% of the time was done with a DT*." (P1;G;VH) 2. "*Completed all exercises with supervision and support from the therapist*." (P2;VB) 3. "*16007 noted that it was not ideal having different people running the sessions and not having a consistent helper/physio student here*." (P1;G;VB) 4. All entries. (P1;H)
Transport and Access (to the sessions)	1. Individuals with mild cognitive impairment use a variety of transportation methods and many are still driving. 2. Intervention sessions within a home environment reduced the impact of transportation issues on the participants.	1. "*16007 had driven to the appointment himself as he had an appointment at 12:00pm*." (P1;G;VH) 2. "*Taxi picked participants up early and were at HPL at 2pm*" (P1;G;VB) and all entries. (P2;VB)
Environment issues	1. An exercise programme can be completed within a home environment, using a variety of support surfaces.	1. "*Poor space to complete exercises – needed to use the back of a chair as support and hall for balance exercises*." (P2;VB)

Appendix 26: Dual-task exercises used in feasibility study

Setting	Dual-Tasking Activities
Group only	• Throwing the ball, saying your name, then the person throwing to, then x2 balls • Marching in a circle with choice of 2, 3 commands (1 to turn or 2 to march on spot) • Beanbag throws in a circle with 0, 1, 2 or 3 commands (1 to switch direction or 2 to target the centre of the star on the floor) • Opposite of command • Accuracy throwing • Remembering shopping list • Balancing bean-bag, ball, on a tennis racket, weaving in and out of cones • Football game played - pass the ball a certain number of times before shooting towards goal
Home/group	• Conversation – topic of interest, current events, previous jobs, • Verbal fluency tasks – such as naming trees, countries, girls' names, words beginning with certain letter, fruits, vegetables, capital cities, types of dog, word association, items in room of house, spelling words forwards/backwards, list of words recall, alphabet categories names/places/animals • Walking with glass • Passing from hand to hand whilst walking • Throwing and catching – standing normally or on wobble cushion • Backward counting in ones, twos or threes • Number recall forwards and backwards (digit span) in twos, threes, fours or fives

Appendix 27: Methods of progressing exercise used in feasibility study

Method of Progression	Example
Weight	• Resistance of exercise-band, KG weight, etc.
Repetition	• Number of times complete exercise.
Number of exercises	• Total number of exercises completed within the session.
Support used	• Two handed support, one handed support, stick, frame, table, etc.
Setting	• Inside, outside, etc.
Accuracy of task	• Spelling word correctly, giving the correct number recall, etc.
Speed of task	• Counting forwards quickly, counting backwards slowly, etc.
Prompts provided by staff/supervisor	• Written, photograph, few verbal prompts, etc.
Impact/influence of comorbidities	• Number of rests, number of toilet visits, etc.
Incline	• Steps, treadmill incline, outside gradient, etc.
Time spent on task	• Time spent continuously walking or stepping, etc.
Variety/specificity of task	• Narrow or specific topic of conversation, broad or general topics for verbal fluency task, etc.
Participation	• Documenting, recalling which exercise to complete next, preparing for the session, etc.
Order of exercises	• Reduced number of active rests, all weighted exercises on one leg at a time, etc.
Dual-tasking	• Addition of a secondary cognitive or physical task.

Appendix 28: Final intervention development table

MRC Development Component	Research Component	Summary of Findings (in relation to TIDieR components)
Evidence / Modelling	Cross-sectional survey (Chapter 2)	• Participants (older adults with mild CI) • Outcome measurements (falls risk, gait parameters including DTC, balance) • Recruitment – strategy (memory clinics)
Evidence / Theory	Falls interventions umbrella review (Chapter 3)	• Rationale – Research in field • Standard physical components (strength and balance/OTAGO exercises)
Evidence / Theory	Dual-task interventions meta-analysis (Chapter 4)	• Participants (older adults with mild CI) • Rationale – combined physical and cognitive exercise • Content (dual-task exercises) • Outcome measurements (number of falls, gait speed, balance)
Theory / Modelling	Realist review (Chapter 5)	• Rationale – exercise in mild dementia • Methods of delivery (support mechanisms, setting: home or group) • Requirements for intervention provider (registered, knowledgeable, supportive)
Theory / Modelling	Expert opinion	• Rationale – combined physical and cognitive exercise • Tailoring and modifications (implementation of components)
Theory / Evidence	Patient-carer interview study [295]	• Rationale – exercise in mild dementia • Tailoring and modifications • Content (goal-orientated)
Modelling / Theory	Clinician-expert workshops	• Rationale – combined physical and cognitive exercise • Methods of delivery (home and group) • Content (dual-task exercises) • Materials (use of individual folders, wording on participant material, use of pictures)
Modelling / Theory	PPI meetings	• Rationale – research in field, exercise in mild dementia, combined physical and cognitive exercise • Materials (wording on participant material, use of pictures) • Procedures (flexibility)
Modelling / Theory	Core knowledge and clinical experience	• Rationale (all) • Standard physical components (strength and balance/OTAGO exercises) • Requirements for intervention provider
Modelling / Evidence	Feasibility study (Chapter 6)	• Intervention deliverable, feasible and acceptable in population • Delivery and content refined • Dual-tasking concept proven can be practically implemented in population