Developing and evaluating a fall prevention exercise programme for older adults living in Aged Residential Care

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Abstract

Introduction

Falls in aged residential care (ARC) pose a major health problem with up to 70% of residents falling each year. Whilst there is strong evidence for effective falls prevention exercise programmes for community dwelling older adults the same cannot be said for older adults living in ARC. The populations are dissimilar and the different fall risk factors for older adults living in ARC are important to consider when designing fall prevention interventions for older adults living in ARC. High proportions of ARC residents have cognitive dysfunction and physical impairments, resulting in a population at high risk of falls. Despite the high incidence of falls in this population, fall prevention exercise programmes have not included components that target cognition. This thesis addresses both fall prevention exercise programmes and the potential for such programmes to be delivered in the context of ARC.

A programme of cognitive exercise (Cognitive Stimulation Therapy) has been found to improve cognition in older adults and is delivered to ARC residents in New Zealand (NZ). This programme is manualised and structured by activities such as discussions around news topics, singing and word games. As this was an established programme in ARC it had the potential to be explored as a possible vehicle to deliver physical fall prevention exercises *in addition* to its focus on cognitive exercise. On this basis, the first objective of this thesis was to develop and evaluate a fall prevention exercise programme that could be combined with Cognitive Stimulation Therapy that addressed the fall risk factors of cognitive dysfunction and decreased balance and lower limb weakness for older adults living in ARC.

The ARC environment can be viewed as a complex adaptive system. Characterised by uncertainty, emergence and unpredictability, the system responds to anything new by flexing, adjusting and adapting to a new way of working. When viewed this way, a fall prevention intervention programme is an event in the system and impacts on the interactions of the person-place-time network which changes relationships, displaces current activities and redistributes resources. On this basis, the second objective of this thesis was to understand the complexities around the delivery of a fall prevention exercise programme in the complex context of ARC.

Methods

A programme that combined Cognitive Stimulation Therapy and physical fall prevention exercises (CogEx) was developed along with training manuals to support programme delivery. Physical exercises were incorporated into the CST. Existing CST facilitators were trained to deliver the physical exercise as part of CogEx. A feasibility randomised controlled trial was used to evaluate the CogEx in two ARC facilities. The plan was to undertake a fully powered randomised controlled trial to test the effectiveness of CogEx in decreasing fall in people living with dementia in ARC. However, the learnings from the CogEx study led us to pivot and explore some of the complexities that impacted the successful implementation of CogEx. To explore these complexities a qualitative sub-study was undertaken on a falls prevention exercise trial that was underway in ARC. This study was a type 1 hybrid effectiveness-implementation design exploring factors influencing the maintenance of a fall prevention programme in ARC as usual practice. For the qualitative component, Interviews and focus groups were held with stakeholders at different levels of ARC organisation (senior management, onsite management, exercise group facilitators) who were involved with the program.

Results

The feasibility study demonstrated that physical exercises could be combined with the CST session to form CogEx; however, the fidelity of the combined programme was poor. Due to the feasibility issues identified a decision was made to stop further work on the CogEx intervention and move to understanding the complexities around delivery of falls prevention in ARC.

The qualitative study identified that the factors influencing the embedding of a falls prevention exercise programme into ARC could be categorised as: the influence of business models and philosophies; requirements for evidence; and valuing the contribution of physiotherapy in falls prevention.

Conclusion

A fall prevention exercise programme was developed that incorporated physical and cognitive exercise for ARC residents (CogEx). However, the fidelity of the programme was poor. The factors that impacted the fidelity of fall prevention exercise programmes and the decision to embed them into routine practice reflected the complex context of ARC.

Any future research into implementing falls prevention in ARC should use co-design with all ARC stakeholders. As they know the contextual minutiae that external researchers do not. This may result in interventions that are sustained beyond the availability of research funding and translate to become part of routine practice.

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Attestation of Authorship

I hereby declare that this submission is my own work and that, to the best of my knowledge and belief, it contains no material previously published or written by another person (except where explicitly defined in the acknowledgements), nor used artificial intelligence tools or generative artificial intelligence tools (unless it is clearly stated, and referenced, along with the purpose of use), nor material which to a substantial extent has been submitted for the award of any other degree or diploma of a university or other institution of higher learning.

Signature Date 16 February 2024

Co-authored Works

The idea for physical exercise to be incorporated into Cognitive Stimulation Programme (CST) came from a comment made by Professor Aimee Spector to Associate Professor Gary Cheung many years ago, that in hindsight she would have included physical exercise in CST. The New Zealand project to incorporate physical exercise into CST was led by Dr Cheung. The proposal brought together a team of experts in CST, medical care of older adults and falls prevention exercise. Funding was received from Brain Research New Zealand. The candidate was involved from the initial meeting in her capacity as an academic physiotherapist with knowledge in falls prevention for older adults.

The original proposal to develop a falls prevention intervention in Aged Residential Care was led by Professor Ngaire Kerse. The proposal brought together a team of experts in older adult health, Aged Residential Care and falls prevention. Funding from ACC in 2008 saw a pilot trial undertaken of the developed multifactorial intervention. The candidate was involved in the exercise programme development and training the physiotherapists to deliver the intervention. The positive results from the pilot study on measures of mobility led to a proposed randomised controlled trial of the strength and balance exercises. Funding was received from the Health Research Council of New Zealand for a randomised controlled trial *Staying UpRight in Residential Aged Care*. The candidate was involved from the initial meeting in her capacity as a team member of the pilot study and her role in developing the strength and balance exercise programme.

Co-Authorship

Chapter 5. Feasibilty study	Binns
Binns, E., Kerse, N., Peri, K., Cheung, G., & Taylor, D. (2020). Combining cognitive stimulation therapy and fall prevention exercise (CogEx) in older adults with mild to moderate dementia: A feasibility randomised controlled trial. *Pilot Feasibility Studies, 6*(1), Article 108. https://doi.org/10.1186/s40814-020-00646-6	Contributed to study design, registered the trial, wrote and submitted ethics approval, trained the CST facilitators and research assistants, supervised data collection, analysed and interpreted the data, wrote the manuscript and responded to journal reviewer feedback.
	Kerse
	Contributed to study design and provided feedback on the manuscript.
	Peri
	Contributed to study design and provided feedback on the manuscript.
	Cheung
	Contributed to study design and provided feedback on the manuscript.
	Taylor
	Contributed to study design, provided supervision, assisted with exercise programme development and interpretation of the data, provided feedback on the manuscript.

Chapter 6. Fidelity challenges in CogEx Binns, E., Kerse, N., Peri, K., Cheung, G., & Taylor, D. (2020). Program fidelity challenges discovered during a feasibility randomized controlled trial of group falls prevention exercises. In Sage Research Methods Cases: Medicine and Health. SAGE Publications, Ltd. https://doi.org/10.4135/9781529742626	Binns Conceived the concept for the manuscript, responded to journal call for papers, wrote the manuscript and responded to journal reviewer feedback. Kerse Provided feedback on the manuscript. Peri Provided feedback on the manuscript. Cheung Provided feedback on the manuscript. Taylor Provided supervision, provided feedback on the manuscript.
Chapter 8. Qualitative study, part of an effectiveness-implementation hybrid type 1 study Binns, E., Bright, F., Parsons, J., Peri, K., Taylor, L., Kerse, N., & Taylor, D. (2023). "It's all about the money": An interpretive description of embedding physical therapy-led falls prevention group exercise in long-term care. *BMC Geriatrics, 23*(1), Article 14. https://doi.org/10.1186/s12877-022-03722-z	Binns Contributed to study concept and design, wrote and submitted ethics amendment and locality applications, oversight of data collection, analysis and interpretation of data, wrote draft manuscript and responded to journal reviewer feedback.

	Bright Analysis and interpretation of data, drafting of manuscript. **Parsons** Contributed to study concept and design, recruitment strategy and data collection, provided feedback on the manuscript. **Peri** Recruitment strategy and data collection, provided feedback on the manuscript. **Taylor** Contributed to study concept and design, provided feedback on the manuscript. **Kerse** Provided feedback on the manuscript. **Taylor** Contributed to study concept and design, provided supervision, analysis and interpretation of data, drafting of manuscript.

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Professor Denise Taylor

Professor Ngaire Kerse

Dr Kathy Peri

Associate Professor Gary Cheung

Associate Professor Felicity Bright

Dr Lynne Taylor

Associate Professor John Parsons

Publications and Presentations

Parts of the work presented in this thesis have been published and/or presented in the following forums:

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CONFERENCE PRESENTATIONS

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CO-AUTHORED PUBLICATIONS

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Parsons, J., Waters, D. L., Binns, E., Burholt, V., Cheung, G., Clare, S., Duncan, R., Fox, C., Gibson, R., Grant, A., Guy, G., Jackson, T., Kerse, N., Logan, R., Peri, K., Petagna, C., Stephens, F., Taylor, D., Teh, R., & Wall, C. (2020). Letter to the editor: Healthy for Life: An innovative and collaborative approach to COVID 19 lockdown in New Zealand. *The Journal of Frailty and Aging*, *10*, 72. https://doi.org/10.14283/jfa.2020.49

Taylor, L. M., Parsons, J., Moyes, S. A., Binns, E., Cavadino, A., Taylor, D., Lord, S., Del Din, S., Klenk, J., Rochester, L., & Kerse, N. (2023). Effects of an exercise program to reduce falls in older people living in long-term care: A randomized controlled trial. *Journal of the American Medical Directors Association.*, *25*(2), 201–208. https://doi.org/10.1016/j.jamda.2023.10.022

OTHER OUTPUTS

Binns, E., & Taylor, D. (2020). Super Seven Exercises.

A home exercise programme developed for frail older adults during the first COVID lockdown in NZ. Hardcopy of this pamphlet was distributed to over 4000 older adults in the Waikato region, and an electronic copy hosted on the websites of the Accident Corporation of New Zealand and Physiotherapy New Zealand. https://www.livestronger.org.nz/assets/Uploads/Exercise-at-home/super-seven-exercises-physiotherapy-nz.pdf

Parsons, J., Waters, D. L., Binns, E., Burholt, V., Cheung, G., Clare, S., Duncan, R., Fox, C., Gibson, R., Grant, A., Guy, G., Jackson, T., Kerse, N., Logan, R., Peri, K., Petagna, C., Stephens, F., Taylor, D., Teh, R., Wall, C., & Harwood, J. (2020, May 2). Healthy for Life [TV programme].

Produced by Tomorrowland and aired on TV1 (TVNZ). A television show of health promotion content anchored on the Super Seven Exercises programme (full programme available archived on TVNZ on demand, promo https://www.youtube.com/watch?v=OKqDSzR70sI). In this multi-agency collaboration lead by John Parsons (Otago University, Auckland University, ACC, Ministry of Health, Age Concern, HQSC, DHBs and others), I led the development and delivery of the exercise segment, was responsible for scripting, blocking and delivered the exercises on camera.

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Ethics Approvals for Studies

Chapter	Study	Ethics approval number	Date
5	Feasibility study	16/NTB/121	23/08/2016
8	Qualitative study	18/NTB/151AM	23/11/2020

Abbreviations

ADAS-Cog	Alzheimer's Disease Assessment Scale Cognition
ARC	Aged residential care
Brief BESTest	Brief Balance Evaluation Systems Test
CogEx	Cognitive and physical exercise fall prevention programme
CST	Cognitive Stimulation Therapy
CI	Confidence interval
FAC	Exercise group facilitator
FICSIT	Frailty and Injuries: Cooperative Studies of Intervention Techniques
fMRI	Functional MRI
GDS-15	Geriatric Depression Scale – 15 items
HDEC	Health and Disability Ethics Committee
I^2	Measure of heterogeneity
IRR	Incidence rate ratio
ID	Interpretive description
interRAI	international Resident Assessment Instrument
LTC	Long-term care
MCI	Mild cognitive impairment
MCID	Minimum clinically important difference
MD	Mean difference
Mgmt	Onsite management

MMSE	Mini-Mental State Examination
MoCA	Montreal Cognitive Assessment
MRI	Magnetic resonance imaging
NICE	National Institute for Health and Clinical Excellence
NZ	New Zealand
PLwD	People living with dementia
ProFaNE	Prevention of Falls Network Europe
QoL-AD	Quality of Life - Alzheimer's Disease Assessment Scale
RAC	Residential aged care
RCT	Randomised controlled trial
RR	Risk ratio
RUG-III	Resource Utilisation Group
SD	Standard deviation
SM	Senior management
SPPB	Short Physical Performance Battery
SRQR	Standards for Reporting Qualitative Research
SUp	Staying UpRight
TIDieR	Template for Intervention Description and Replication

Glossary

Aged Residential Care encompasses and represents, low and high dependency and dementia care residential facilities

Dose is the frequency, intensity, time (session duration and length of programme) and type of exercise

Environmental interventions are assistive technologies or home modifications

Fall is an event which results in a person coming to rest unintentionally on the ground or other lower level, not as a result of a major intrinsic event (such as a stroke) or an overwhelming hazard

Multifactorial programme are two or more interventions that are recommended to address fall risk factors that have been identified after a resident has been assessed

Multicomponent programmes are two or more components provided to all residents for example exercise and staff training

Odds ratio is a measure of association between a fall risk factor and falling

Older adult is a person aged 65 years or older

Rate of falls is the number of falls per person per year and includes that some people fall multiple times,

Rate ratio compares the rate of falls in an intervention group divided by the rate of falls in a comparison group

Risk ratio is used to measure a treatment effect and compares the number of people who fell once or more in the intervention and control groups

Chapter 1 Introduction

1.1 Falls in older adults living in aged residential care

Falls in older adults are a global health problem (Florence et al., 2018; Montero-Odasso et al., 2022; World Health Organization, 2007). Around a third of older adults fall in any one year with this increasing to approximately half those aged over 80 years (Bergen et al., 2016; Fleming et al., 2008; Health Quality and Safety Commission New Zealand, 2014; Iinattiniemi et al., 2009; Rubenstein, 2006). When we consider aged residential care (ARC) these falls statistics are alarming, with residents being 3 times more likely to fall than those living in the community (Public Health England, 2022; Rubenstein, 2006). Two groups of older adults with a high fall risk are those living with dementia (Modarresi et al., 2019) and those living in ARC (I. D. Cameron et al., 2018; Kuhnow et al., 2022). Up to 87% of older adults living in ARC have a level of cognitive dysfunction, creating a high-risk population (Chen et al., 2023; Dyer et al., 2018; Eriksson et al., 2008; Kao et al., 2022). There is strong evidence for the effectiveness of physical exercise preventing falls in community dwelling older adults (Sherrington et al., 2020) and emerging evidence that exercise may be beneficial to prevent falls in ARC (I. D. Cameron et al., 2018; Dyer et al., 2023) but as yet no clear guidance on which programmes are effective.

The key objectives and specific aims of this thesis were:

1. To develop and evaluate a combined cognitive and physical exercise programme in ARC

   Specific aims:

   1.1. To develop a combined cognitive and physical fall prevention exercise programme

   1.2. To test the feasibility for a randomised controlled trial (RCT) evaluating the combined programme

The challenges identified following this first objective led to a change in direction of the thesis. The focus moved from undertaking a fully powered RCT to exploring the complexities around the delivery of fall prevention exercise programmes in ARC.

2. To understand the complexities around the delivery of a fall prevention exercise programme in the complex context of ARC

   Specific aims:

   2.1. To explore the factors that impact ARC providers' decisions to implement fall prevention exercise programmes

1.2 Thesis structure

The following section outlines the content of each chapter and how each chapter relates to the objectives of the thesis. Chapters 2-6 address the first objective and Chapters 7 and 8 address the second objective of the thesis.

Objective 1: To develop and evaluate a combined cognitive and physical exercise programme in ARC

The first section of the thesis (Chapters 2-6) describes the development and testing of the fall prevention exercise programme by: (i) describing the issue of falls in ARC and what is currently known about physical exercise to prevent falls in ARC residents, (ii) summarising the types of cognitive exercise and providing rationale for choosing Cognitive Stimulation Therapy (CST) as the basis for the programme, (iii) outlining the programme development before (iv) testing the feasibility of the developed programme (Binns et al., 2020a, 2020b).

Chapter 2 provides an overview of falls in ARC and the exercise interventions that have been trialled to reduce falls in ARC. This chapter presents the definitions of a fall, ARC and older adults that will be used in this thesis, together with describing why falls in ARC need to be addressed. Within this chapter the fall risk factors of this population are identified and the age-related cognitive and gait changes that contribute to the high fall risk are highlighted. Lastly, a narrative review of the literature on fall prevention exercise in ARC is presented.

Chapter 3 provides the rationale for selecting CST as the type of cognitive exercise to be combined with physical exercise to develop an exercise programme to prevent falls in older adults living with cognitive dysfunction in ARC. This chapter identifies the types of cognitive exercise that have been developed for people living with cognitive dysfunction and presents a literature review of fall prevention studies that have combined cognitive exercise with physical exercise. The literature that demonstrates the benefit of CST on cognitive dysfunction is presented along with potential mechanisms of change that occur following participation in CST. The global dissemination of CST is described along with the availability of CST throughout New Zealand (NZ).

Chapter 4 describes the development of a fall prevention exercise programme that combined physical exercise with CST. This new programme was named CogEx (cognitive and physical exercise). This chapter presents the origin of the idea to combine CST and physical exercise to prevent falls in ARC and the expertise of the team members who contributed to this phase.

Chapter 5 presents the published manuscript of the feasibility of undertaking a RCT to test the effectiveness of CogEx to decrease falls in ARC. A mixed methods feasibility RCT was used to address the objectives of the study (Binns et al., 2020a). Chapter 6 presents triangulation and further analyses of the feasibility study data to develop a deeper understanding of the challenges found (Binns et al., 2020b).

Objective 2: To understand the complexities around the delivery of a fall prevention exercise programme in the complex context of ARC

Chapters 7 and 8 explore factors impacting the delivery of fall prevention exercise programmes in ARC. The learnings from CogEx were used to inform an exploration of the factors that impact a research intervention becoming part of everyday practice in ARC.

Chapter 7 positions ARC as a complex adaptive system (Braithwaite et al., 2018; Plsek & Greenhalgh, 2001; Rouse, 2008) and introduces implementation science as a field of enquiry to study the influences on healthcare professional and organisational behaviours (Bauer & Kirchner, 2020; Handley et al., 2016; Kirchner et al., 2020). This chapter presents an overview of the field of implementation science and hybrid effectiveness-implementation designs that enable both effectiveness and implementation outcomes within a study (Curran et al., 2012; Landes et al., 2019; Skivington et al., 2021b).

Chapter 8 presents a qualitative study associated with a type 1 hybrid effectiveness-implementation study that explored the factors influencing programme sustainability (Binns et al., 2023). Chapter 9 presents the major findings and discusses the limitations of the thesis, as well as implications for practice and future research into fall prevention exercise programmes for older adults living in ARC.

Chapter 2 Background

This chapter describes the problem of falls in older adults living in aged residential care (ARC). The reasons why an older adult may fall and the ageing changes in the brain that contribute to the high falls rate in this population are discussed (Büchele et al., 2014; Kuhnow et al., 2022; Rubenstein & Josephson, 2002). The connection between cognitive impairment and falls in people living in ARC is explored. Cognitive ability is important to consider in ARC as up to 87% of the people living in ARC have been diagnosed with some type of cognitive impairment (Bartfay et al., 2013; Chen et al., 2023) and there is limited literature pertaining to falls in ARC that considers cognitive function (I. D. Cameron et al., 2018; Dyer et al., 2023; Gulka et al., 2020). Fall prevention exercise programmes for this population will then be explored. There is strong evidence for effective fall prevention exercise programmes for community dwelling older adults (Sherrington et al., 2020) but the same cannot be said for older adults living in ARC (I. D. Cameron et al., 2018; Dyer et al., 2023; Gulka et al., 2020). The different fall risk factors for older adults living in ARC (Deandrea et al., 2013; Kuhnow et al., 2022) are important to consider when designing fall prevention interventions for older adults living in ARC.

First, the definitions of falls, ARC, older adults and fall risk factors that will be used in this thesis are discussed (Section 1), followed by a narrative review of the ageing brain (Section 2) and finally a narrative review that was undertaken to identify the effectiveness of exercise interventions to reduce falls in older adults living in ARC (Section 3).

2.1 Section 1. Falls in aged residential care

This section will discuss key terms and definitions that are important to consider when discussing falls in older adults living in ARC, and then describe the health issue of falls in this population that needs to be addressed.

Definition of a fall

Falls are defined differently by older adults, health professionals and researchers. Older adults and people living with chronic disease when asked to define a fall tend to describe the mechanism that caused a fall such as a slip trip, or stumble (Kim & Foucher, 2022; Matsuda & Hoffman, 2022; O'Malley et al., 2022; Zecevic et al., 2006). Health care professionals often describe the consequences of a fall such as how a person landed or whether an injury occurred (Matsuda & Hoffman, 2022; Zecevic et al., 2006). Despite these differences, all included ending up on the ground as a descriptor of a fall (Hauer et al., 2006; Matsuda & Hoffman, 2022; Zecevic et al., 2006).This difference in language may reflect older adults wanting to diminish the seriousness of a fall and may also contribute to falls being under reported by older adults to health professionals (Hoffman et al., 2018; Stevens et al., 2012). The focus of health professionals knowing the consequences of a fall is because they use this information to direct patient management and treatment of a fall (Zecevic et al., 2006). Researchers define what a fall is to measure them or ask research participants about them (Lamb et al., 2005; Zecevic et al., 2006). The definition of a fall is important for interpretation of research findings, direct comparisons of research trials and for meta-analysis (Buchner et al., 1993; Lamb et al., 2005; World Health Organization, 2007).

A definition of a fall to be used in research was proposed in 1987 by the Kellogg International Work Group on the Prevention of Falls by the Elderly (1987) as:

> an event which results in a person coming to rest inadvertently on the ground or other lower level and other than as a consequence of the following: sustaining a violent blow, loss of consciousness, sudden onset of paralysis, as in a stroke, an epileptic seizure. (p. 4)

One of the first clinical studies to use this definition modified it slightly to be “not as a result of a major intrinsic event (such as a stroke) or an overwhelming hazard” (Tinetti et al., 1988, p. 1702); however, other definitions continued to be used. Nevitt et al. (1991) used “falling all the way down to the floor or ground, or falling and hitting an object like a chair or stair” (p. M164), while the Frailty and Injuries: Cooperative Studies of Intervention Techniques (FICSIT) used “unintentionally coming to a rest on the floor or other lower level; excludes coming to rest against furniture, wall or other structure" (Buchner et al., 1993, p. 301). Despite the eight FICSIT trials establishing an operational definition of a fall, study centres interpreted it differently with some centres also modifying the definition. The FICSIT tai chi study was impacted by the changing interpretation of the definition, as when the original definition was used falls were significantly reduced but when a modified definition (narrowed to exclude stumbles) was used there was not a reduction in falls (Masud & Morris, 2001; Wolf et al., 1996). This illustrates the importance of a shared understanding and application of the definition of a fall. In another attempt to create a universally accepted definition of a fall, the Prevention of Falls Network Europe (ProFaNE) group used expert consensus and literature reviews to develop and recommended a simplified definition of "an unexpected event in which the participants come to rest on the ground, floor, or lower level" (Lamb et al., 2005, p. 1619). Despite this falls definition being promoted and used widely, a variety of falls definitions are still used in research, or no definition stated at all (I. D. Cameron et al., 2018). The World Health Organization (2007) uses an expanded version of the ProFaNE definition that also includes "excluding intentional change in position to rest in furniture, wall or other object" (p. 1). This addition complicates the definition by stating the obvious rather than providing further clarity. We explicitly chose to use the ProFaNE definition in earlier research to enable direct comparisons with other studies (Taylor et al., 2012). However, our most recent falls prevention research in ARC measured falls through an audit of facility incident reports of participants and therefore a fall definition was not stated in the publication (Taylor et al., 2020). This method is reliant on ARC staff being taught the definition of a fall used by the facility and applying it when completing incident reports. In ARC the majority of falls are not witnessed, rather staff discover residents on the ground and a fall is assumed (Brett et al., 2021; Büchele et al., 2014; Rapp et al., 2012) or if a resident recovers themselves they may not report the fall, so it is difficult to ascertain the mechanism of the fall.

In fall prevention studies, falls are typically counted over a period to compare how many falls occurred before and after an intervention (Dyer et al., 2023; Hauer et al., 2006). However, falls and measures of falls can be reported in numerous ways in the literature. The following are a selection of the most commonly used:

- Number of falls is a count of the number of falls that occurred and can include falls requiring medical attention, injurious falls, falls resulting in fracture, falls requiring hospital admission (Hauer et al., 2006), as well as falls that don't require medical attention
- Number of participants that have fallen is a count of the number of participants that fell. Can include falls requiring medical attention, injurious falls, falls resulting in fracture, falling two or more times (Hauer et al., 2006)
- Recurrent faller is a person who fallen more than once in a year (Jehu et al., 2021)
- Fall risk is the probability that a future fall will occur (World Health Organization, 2002). The greater the number of risk factors that a person has the higher the risk is that they will fall in the future (Nandy et al., 2004; Tinetti et al., 1988; Whitney et al., 2012)
- Fall rate is the number of falls per person and may also include a denominator of time. Fall rate can be the mean number of falls/participant, fall rate/person/year, rate/1000 person years, fall/unit of person time that falls were monitored (I. D. Cameron et al., 2018; Hauer et al., 2006)
- Rate ratio compares the rate of falls in an intervention group divided by the rate of falls in a comparison group (Dettori et al., 2021)
- Relative risk ratio is used to measure a treatment effect and compares the number of people who fell once or more in the intervention and control groups (I. D. Cameron et al., 2018; Tenny & Hoffman, 2023)

The variation of fall definitions and measures is important to consider when comparing studies and synthesising the data, as it can affect study findings (Hauer et al., 2006; Wolf et al., 1996). For example, if the number of falls is reported, a few individuals with many falls might influence the study results and an intervention may be assessed as not effective, whereas if the fall rate is reported the results may look quite different and the intervention assessed as effective (Wolf et al., 1997). To assist in improving the comparability of future studies, a common outcome dataset to be used in fall prevention studies was recommended by ProFaNE to the research community. The dataset included:

- The definition of a fall to be used
- Number of falls
- Number of fallers
- Fall rate
- Time to first fall (Hauer et al., 2006; Lamb et al., 2005).

However, despite these recommendations, variability in the reporting of fall prevention studies remains (I. D. Cameron et al., 2018).

Definition of aged residential care

Aged residential care (ARC) is an umbrella term which covers all the levels of residential care available for older adults. Terminology for describing the various levels of care differ across countries. Terms include: private hospital and geriatric hospital care, (for those with high dependency or 24-hour nursing care needs); rest homes, nursing homes, hostels and residential care homes, (for those with low dependency care needs) and dementia care and psychogeriatric care. In this thesis, the term ARC is used to encompass and represent, low and high dependency and dementia care residential facilities.

To be admitted into ARC in NZ, an older adult is assessed as no longer able to live independently at home (Jorgensen et al., 2009; New Zealand Government, 2021). The International Resident Assessment Instrument (interRAI) Home Care is a mandated component of this assessment and determines what level of care is needed (Goodhew, 2012). A national contract (Age-Related Residential Care Services Agreement (Ministry of Health, 2013a)) between the national health authority (NZ Ministry of Health) and ARC facilities defines the Government funded care services provided to a resident. Government funding varies for residents assessed as requiring low dependency, high dependency and dementia level care. Services covered by the agreement include an individualized care plan based on the interRAI LTC facilities assessment. Means testing is used to determine the amount of government subsidy paid to an ARC facility for a person's residency. Most residents receive a form of subsidy (Ministry of Health, 2020).

Definition of an older adult

An older adult is defined by governments as a person aged 65 years or older and the age at which funded services become available (Associate Minister of Health, 2016; Centers for Disease Control and Prevention, 2023; National Institutes of Health, 2022; NHS England, n.d.), and that is the definition used in this thesis. In research, like the definition of a fall, defining an older adult enables studies to be compared. It also defines the population that the research can be generalised to but of course, not all older adults are the same. For example, a 65-year-old may be retired and living in ARC, while a 75-year-old may be driving, in paid employment and living in their own home.

2.1.1 The heterogeneity of older adults

Fall statistics reflect the heterogeneity in the older adult population. Increased age is related to an increase in falls (Haagsma et al., 2020), with approximately 30% of people over 65 years old falling in a year (Bergen et al., 2016; Health Quality and Safety Commission New Zealand, 2014; Rubenstein, 2006) and approximately 50% of people over 80 years old (Fleming et al., 2008; Iinattiniemi et al., 2009; National Institute for Health and Care Excellence, 2013; Zhou et al., 2017). However, variation has been found across countries and regions of the world with 14-20% of Japanese older adults falling in a year (Dsouza et al., 2014; World Health Organization, 2007), 6-31% of Chinese older adults and 21% of older adults living in Barbados (World Health Organization, 2007). In European countries, Greece had the lowest rate of older adults seeking medical treatment following a fall (7,594 per 100,000 older adults) and Norway had the highest rate (19,796 per 100,000) (Haagsma et al., 2020). However, the low fall rate in Greece may be due to a lack of systemic reporting (Lytras et al., 2022). The Oceania region has been found to have the highest prevalence of older adult falls in the world with 34.4%, followed by America (27.9%) (Salari et al., 2022). This rate may be due to the meta-analysis only including 6 Oceania studies ($N = 2{,}044$). The authors had observed that with increasing sample sizes the prevalence of falls decreased, so the Oceania finding could be due to the small number of studies. Residential settings are associated with an increase in falls, with ARC residents being 3 times more likely to fall each year than community dwellers (Public Health England, 2022; Rubenstein, 2006). Medical conditions are also associated with increased falls, for example 35-90% of people living with Parkinson's disease will fall in a year (Allen et al., 2013; Pickering et al., 2007), as will 37-73% of people living with stroke (Batchelor et al., 2012; Kerse, Parag, et al., 2008; Xu et al., 2018) and people living with dementia (PLwD) have 1.1 to 6.4 times the fall risk of a community dwelling older adult (Asada et al., 1996; de Carle & Kohn, 2001; Kallin et al., 2004; Myers et al., 1991; Tinetti et al., 1988; Van Doorn et al., 2003) and are 3 times more likely to fracture a hip if they fall (Melton et al., 1994; Suttanon et al., 2010). These arbitrary groupings of older adults for recording falls are by no means exclusive and a person can be in more than one category such as being 80 years old living with dementia and residing in ARC. However, identifying why different groups of older adults fall is important to prevent further falls.

2.1.2 Why it is important to address falls in aged residential care

Falls in older adults are a major global public health issue. The personal impact of a fall can be severe, with falls resulting in injury, disability, or death (Ambrose et al., 2013; Rubenstein, 2006; Salari et al., 2022). Half of older adults who have an injurious fall continue to need assistance with activities of daily living 6 months after their fall (Spinks & Wasiak, 2009). Up to 75% of older adults who fall and fracture a hip are unable to walk independently again or don't regain their previous level of independence and 15-20% will move from their home into ARC (Barnea et al., 2018; Gill et al., 2013; Magaziner et al., 2003). Falls have been identified as a contributing factor in 40-74% of admissions of older adults into ARC (Ambrose et al., 2013; Prabhakaran et al., 2020). This then creates a population of older adults living in ARC that are at a high risk of future falls, as a previous fall is strongly associated with falling again (Deandrea et al., 2013; Dhargave & Sendhilkumar, 2016; Kiely et al., 1998).

There are also substantial financial costs associated with falls. In developed countries falls account for 0.85 to 1.5% of total healthcare expenditure (Heinrich et al., 2010; Stewart Williams et al., 2015). In 2015 the costs of fatal and non-fatal falls in America was $50 billion (Florence et al., 2018), Australia's costs are expected to rise to $1.4 billion by 2051 (Australia and New Zealand Falls Prevention Society, 2023) and in New Zealand (NZ) they are forecast to cost between $296 and $418 million annually by 2025 (Barry & Kaye, 2016). As the proportion of older adults increases globally so does the number of older adults falling and the concomitant health care costs (Florence et al., 2018; Montero-Odasso et al., 2022; World Health Organization, 2007).

2.1.3 Risk factors for falls in people living in ARC

Falls are multifactorial and hundreds of fall risk factors have been identified (Kwan et al., 2011; Masud & Morris, 2001). Falls should not be explained away as a natural part of ageing (Ambrose et al., 2013) but rather recognised as a marker of frailty or a mobility impairment that is indicative of an acute or chronic health impairment in an older adult and warrants further investigation (Berg & Cassells, 1992; Brown et al., 2009; Martin et al., 2013; Sattin, 1992; Todd & Skelton, 2004). Identifying and understanding the fall risk factors for the groupings of older adults with high incidences of falls is crucial for developing effective fall prevention interventions. Residents living in ARC are a group of older adults with one of the highest incidences of falls, with 50-70% of residents falling in a year (E. J. Cameron et al., 2018; Kiely et al., 1998; Kuhnow et al., 2022). The world guidelines for falls prevention in older adults recommend that all ARC residents are considered at high risk of falls (Montero-Odasso et al., 2022).

A number of fall risk factors for older adults living in ARC have been identified (E. J. Cameron et al., 2018; Deandrea et al., 2013; Dhargave & Sendhilkumar, 2016; Kiely et al., 1998; Kuhnow et al., 2022; Rubenstein et al., 1994) (see Table 2.1). A history of a fall has been identified as the risk factor most strongly associated with a fall (Deandrea et al., 2013; Dhargave & Sendhilkumar, 2016; Kiely et al., 1998). It is unclear how strongly associated cognitive impairment or dementia is to fall risk as neither have been consistently defined or systematically assessed (E. J. Cameron et al., 2018; Dhargave & Sendhilkumar, 2016; Kiely et al., 1998; Kuhnow et al., 2022). However, looking across the factors, some such as wandering and moderately impaired cognitive skills

(Kiely et al., 1998; Kuhnow et al., 2022), suggest cognitive factors are noticeably associated with fall risk. The physical fall risk factors included use of a walking aid, unsteady gait, impaired balance, and partial support for standing balance (Deandrea et al., 2013; Dhargave & Sendhilkumar, 2016; Kiely et al., 1998; Kuhnow et al., 2022). Terminology makes it difficult to understand what some risk factors represent, such as moderate disability as this could be used to categorise cognitive or physical limitations (Deandrea et al., 2013). The evidence for gender as a risk factor is unclear as some studies identified being male as a risk factor (E. J. Cameron et al., 2018; Kiely et al., 1998), one identified being female (Dhargave & Sendhilkumar, 2016) and others did not identify gender as a risk factor (Deandrea et al., 2013; Kuhnow et al., 2022).

Table 2.1

Fall risk factors for residents in ARC

Study	Risk factor	Odds ratio	95% CI
Deandrea et al. (2013)#			
	History of a fall	3.06	2.12-4.42
	Use of a walking aid	2.08	1.88-2.31
	Moderate disability	2.08	1.88-2.31
Kiely et al. (2015)*			
	History of a fall	3.41	3.18-3.66
	Wandering	1.84	1.65-2.05
	Transfer independence	1.49	1.34-1.61
	Use of a walking aid	1.44	1.34-1.55
	Wheelchair independence	1.39	1.28-1.52
	ADL deterioration	1.21	1.11-1.31
	Age $\geq$87	1.16	1.08-1.24
	Male gender	1.14	1.05-1.22
	Unsteady gait	1.13	1.05-1.22
Dhargave & Sendhikumar (2016)			
	History of a fall	5.66	NR
	Impaired Balance	3.11	NR
	Vertigo	2.24	NR
	Use of a walking aid	2.14	NR
	Vision impairment	1.85	NR
	Chronic conditions	1.63	NR
	Female gender	1.58	NR
Kuhnow et al. (2022)^			
	Other fractures	3.64	3.27-4.05
	Hip fractures	3.58	3.27-3.93
	Moderately impaired cognitive skills	2.45	2.28-2.64
	Partial support to balance standing	2.44	2.30-2.57
	Wandering daily	2.31	2.18-2.44

Note. CI = Confidence interval; NR = Not reported.
Pooled odds ratio. *Multivariate logistic regression-based odds ratio.
^Adjusted odds ratio.

Often falls are the result of the interaction of more than one fall risk factor and the more risk factors an older adult has the greater their risk of falling (Nandy et al., 2004; Tinetti et al., 1988; Whitney et al., 2012). ARC residents tend to have multiple morbidities, cognitive and physical impairments and are highly likely to have multiple fall risk factors, reflecting their reasons for admission into ARC (Gaugler et al., 2007; Gill et al., 2013; Mor et al., 2018; Prabhakaran et al., 2020).

Dementia is a significant fall risk factor to consider given the prevalence of dementia in ARC residents. In NZ more than 48% of ARC residents have a diagnosis of dementia (Ma'u et al., 2021). Similarly high percentages of dementia are reported for ARC residents in Australia (52%), Canada (61.5%), Switzerland (66%), England (50-80%) and the United States of America (50.4%), in contrast is Japan with only 21.4% of residents diagnosed with dementia (Jain et al., 2019). It is possible that the incidence of dementia may be higher in any of these countries given that there is evidence that dementia is under diagnosed (Maslow & Fortinsky, 2018; Nygaard & Ruths, 2003; van den Dungen et al., 2012).

Dementia is a medical diagnosis and an umbrella term for several neurological diseases that impair one or more cognitive domains and impair independence in activities of daily living (Hugo & Ganguli, 2014; Scott & Barrett, 2007; World Health Organization, 2017). The fall risks of wandering, deterioration in activities of daily living and moderately impaired cognitive skills identified in ARC residents (see Table 2.1), could be common behaviours that are associated with dementia or cognitive impairment (Algase et al., 2007; Cipriani et al., 2014; Hugo & Ganguli, 2014; Petersen et al., 2009). The fall risk for older adults living with dementia has been identified as 2-3 times higher than that of older adults not living with dementia (Modarresi et al., 2019; Suttanon et al., 2010).

Older adults who are living in ARC and living with dementia, create a group of older adults who are at a high risk of falling (Kröpelin et al., 2013). With modifiable risk factors identified in the ARC population of older adults, the next step is to determine what interventions are effective in addressing these risk factors with the aim of reducing falls.

2.1.4 Gaps and limitations in determining fall risk in ARC

Dementia was not strongly identified as a fall risk factor in the literature discussed above (see Table 2.1). However, this is a good example of methodological issues making direct comparison of study findings challenging. The following section outlines key methodological issues to be considered in interpreting the falls prevention literature.

Methodological issue of study assessments

Research findings are shaped by the outcomes that have been selected to evaluate the research questions. With fall risk factors numbering in the hundreds (Kwan et al., 2011; Masud & Morris, 2001), it is beyond the scope of a single study to measure them all. Therefore, published research can only report on those risk factors that the study investigated. Risk factor studies have also used the government mandated ARC assessments of the health and functional capabilities of residents to create large data sets that have then been used for research (Kiely et al., 1998; Kuhnow et al., 2022). When conducting secondary analysis of these datasets it is critical to remember that this data was collected for healthcare and not research purposes. It is possible that there is variation in the data, the personnel and level of training received to complete the assessments, and therefore the overall quality of the information cannot be known. The categories used in these assessments can also be challenging to interpret without the assessment manual to aid in understanding how categories are completed and scored. For example, because of the structure of the categories in the Resident Assessment Instrument–Minimum Data Set (2.0) form (Hirdes et al., 2008), falls resulting in a fracture could be identified as a fracture rather than a fall event, thereby reducing the reporting of a fall. This resulted in Kuhnow et al. (2022) identifying 'other fracture' or 'hip fracture' as fall risks factors and not a history of a fall as had other studies (Deandrea et al., 2013; Dhargave & Sendhilkumar, 2016; Kiely et al., 1998). The nuances of assessment tools used in studies can impact the conclusions if not understood.

Methodological issue of the terminology used in a study

The terminology used can make it difficult to understand study findings, such as ‘moderate disability’ (Deandrea et al., 2013). In Deandrea et al.’s study a definition was not provided, and it was unclear whether physical or cognitive disability was being referred to, or the ability to perform activities of daily living, which incorporates both physical and cognitive capacity. Terminology can also be challenging when different terms are used to describe aspects of the same condition. For example, delirium, change in cognitive status, behavioural symptoms, moderately impaired cognitive skills, wandering and wandering behaviour could all be used to describe cognitive dysfunction (Kiely et al., 1998; Kuhnow et al., 2022; Morris et al., 1997). When the definition of a term used in study is not provided, interpretation is left open to assumptions made by the reader which can create a lack of clarity and understanding of study findings.

Methodological issue of study parameters

The inclusion criteria varied across the studies. Studies included people as young as 60 years old (Dhargave & Sendhilkumar, 2016) or did not state an age criteria instead relying on the place of residence as a proxy for old age (Deandrea et al., 2013). Not specifying an age and using a proxy can be problematic as admission criteria and the level of nursing care provided to and needed by the residents ARC varies between countries and healthcare systems (Becker & Rapp, 2010; Brett et al., 2021; Deandrea et al., 2013; Jain et al., 2019).

Methodological issue of the diagnosis of dementia

Dementia and cognitive impairment were not clearly identified or measured across the studies. Not all of the mandated assessments used in ARC include identification or an assessment of dementia (Kuhnow et al., 2022), resulting in ‘cognitive impairment’ being used as an all-encompassing term in the absence of a cognitive assessment or diagnosis of dementia. There were factors identified that suggest cognitive factors contribute to fall risk such as wandering (Kiely et al., 1998; Kuhnow et al., 2022); however, at this point it remains unclear.

2.1.5 Cognition of aged residential care residents

One of the main reasons for older adults moving into ARC, is that they are no longer able to manage at home due to physical or cognitive impairments (Chen et al., 2023; New Zealand Government, 2021). The cognitive ability in ARC residents is mixed, with a prevalence of mild cognitive impairment (MCI) ranging from 4-87% (Chen et al., 2023; Dyer et al., 2018) and the prevalence of dementia ranging from 16-85% (Dyer et al., 2018; Kao et al., 2022). It is also possible that a person's level of cognitive impairment can be unknown due to a lack of formal assessment and diagnosis (Bartfay et al., 2013; Binns et al., 2020b; Lang et al., 2017; Maslow & Fortinsky, 2018). In NZ, the government-mandated assessment (international Resident Assessment Instrument (interRAI)) determines whether a person should be admitted into ARC, what level of care they need and is repeated every 6 months with ARC residents (Goodhew, 2012; interRAI New Zealand, 2023). In 2021/22 71,000 assessments were completed in 673 ARC facilities, reporting 88% of residents as cognitively impaired, 49% had a diagnosis of dementia including Alzheimer's disease, and approximately 15% of resident's cognitive ability had worsened since their last assessment (interRAI New Zealand, 2022; Ma'u et al., 2021).

Cognitive decline is a part of the normal ageing process; however, it can also be secondary to medication side effects or health issues such as depression (Dharmarajan, 2021; Lang et al., 2017; Martinez-Ruiz et al., 2020; Marvanova, 2016). MCI is when cognitive decline is greater than expected for a person's age and doesn't interfere with activities of daily living but greater effort is needed to complete them (Hugo & Ganguli, 2014; Petersen et al., 2009). MCI may be a transitional stage between the expected cognitive decline of normal ageing and the more serious decline of dementia (Alzheimer's Association, 2022; Gauthier et al., 2021; Pandya et al., 2016); however, only 5-15% of people with MCI go on to develop dementia each year, and one third will develop dementia in 5 years (Alzheimer's Association, 2022; Pandya et al., 2016). People with MCI can also remain stable and there are higher rates of reversion to normal cognition (30-50%) than there is progression to dementia (Pandya et al., 2016).

Dementia is an umbrella term for several neurodegenerative diseases in which there is deterioration in memory, personality, thinking, impaired reasoning, the ability to perform everyday activities and emotional and behavioural changes, and due to structural changes in the brain (Dementia Australia, 2022; Gauthier et al., 2021; Scott & Barrett, 2007; World Health Organization, 2017). It is possible to get dementia at any age however, the chance of developing dementia increases with age and is more common in people over 65 years old (Scott & Barrett, 2007). While dementia mainly affects older adults, it is not a normal part of ageing (Brown & Ridderinkhof, 2009). In dementia, there is a loss of synaptic connections, gliosis, inflammation and cell death (Elahi & Miller, 2017). Magnetic resonance imaging has found white matter hyperintensities, atrophy of hippocampal sub-regions and a decrease in the frontal cortex grey matter associated with dementia (Launer, 2005) however, each neurodegenerative disease affects the structure of the brain differently (Elahi & Miller, 2017).

There are many classifications of dementia and up to 30% of people are misdiagnosed (Gauthier et al., 2021). Alzheimer's disease is the most common cause of dementia in older adults but other dementia types include vascular dementia, dementia with Lewy bodies, frontotemporal dementia and mixed dementia (Gauthier et al., 2021). Dementia is a progressive disorder and the diagnosis is given when there is substantial impairment in one or more cognitive domain which is sufficient to impair autonomy in everyday activities (Hugo & Ganguli, 2014; Scott & Barrett, 2007).

The worldwide number of PLwD is predicted to be 78 million by 2030 and increase to 132 million by 2050, however this is a conservative estimate as dementia is under diagnosed with less than 25% of people globally being diagnosed, and often only in the late stages of the disease (Gauthier et al., 2021; World Health Organization, 2017). The economic cost for dementia to the global economy in 2019 was estimated to be $US1.3 trillion (World Health Organization, 2023). Higher income countries tend to spend a higher percentage of their gross domestic product on dementia care than lower income countries (Pedroza et al., 2022), with annual spends ranging from

US$104 million in Vanuatu, US$195 billion in China, to US$321 billion in the United States of America (Mattap et al., 2022; Skaria, 2022). Dementia is a major cause of disability and dependency for older adults worldwide and fast becoming one of NZ's most significant health and growing healthcare problems (Alzheimers New Zealand, 2021; Livingston et al., 2020). The current number of 70,000 PLwD is estimated to grow to almost 170,000 by 2050 (Alzheimers New Zealand, 2021) and the total cost to the NZ economy will increase from an estimated $2.5 billion in 2016 to $5.9 billion by 2050 (Ma'u et al., 2021).

2.2 Section 2. Ageing

This section considers the complex process of ageing on the brain and the impact on motor performance and cognitive function. A narrative review was undertaken using a structured approach. Scopus, EBSCO Health Database (CINAHL, MEDLINE, SPORTDiscus) were searched for studies that investigated changes in brain structure and function, the association of cognitive impairment with gait and balance and the impact of cognitive impairment on fall risk. All study designs were included. Search terms included ageing, older adult, brain (function and structure), gait, cognition, balance, falls, and fall risk.

Ageing can be defined as a "process of intrinsic deterioration with time" (van Beek et al., 2016, p. 3). Ageing is a natural, physiological process that effects every organ and system in the human body, with a general decline of 1% occurring after the third decade (Dharmarajan, 2021; Duraković, 2013; Navaratnarajah & Jackson, 2017). The ageing process in the brain varies between individuals as chronological and biological ageing do not necessarily match, and many factors may be involved such as genetic background, pathological changes, lifestyle choices and physical activity (Chodzko-Zajko et al., 2009; Dharmarajan, 2021; Mintzer et al., 2019; Mitchell et al., 2019; Navaratnarajah & Jackson, 2017; Stranahan & Mattson, 2012).

Structural changes in the ageing brain

Age-normative structural changes occur in the brain with white matter integrity declining in anterior white matter tracts, which precede decreasing cortical grey matter volumes in the frontal and temporal regions (Bender et al., 2016; Giorgio et al., 2010; Li et al., 2018; Slater et al., 2019; J. A. Taylor et al., 2023). These changes occur over time to many different parts of the brain, impacting areas involved with cognition. The dorsolateral prefrontal cortex and orbitofrontal cortex regions seem to be the most age sensitive and related to an observed decrease in the cognitive functions of working memory, episodic memory encoding and divided attention (Li et al., 2018). These cognitive domains, along with processing speed all decline with age, while vigilance, semantic memory and procedural knowledge do not (Cohen et al., 2016). The cerebellar hemispheres and the hippocampus also demonstrate an accelerated decline (Li et al., 2018).

Functional network changes in the ageing brain

Functional connectivity is the "dynamic of temporal correlations between brain areas" (Edde et al., 2021, p. 236); an organisation of brain networks linked by white matter of areas needed to function together (functional segregation) and areas that need to integrate information for function (functional integration) (Damoiseaux, 2017; Hsu et al., 2014). Ageing changes are observed in the functional connectivity of networks within the brain due to decreased white matter structural integrity (Deery et al., 2023; Hsu et al., 2014; Stumme et al., 2022). In older adults, more brain regions are used for motor control of walking, particularly the prefrontal cortex and basal ganglia networks which are most vulnerable to age-related changes (Seidler et al., 2010). There are many brain networks, for gait there are four large-scale networks of interest; the default mode network, the central executive network, the fronto-parietal network and the primary motor sensory network (Hsu et al., 2014). There is variability between individual brains (Marek & Dosenbach, 2018) but the networks can be generally described:

- The <u>default mode network</u> is anchored in the anterior cingulate cortex and medial prefrontal cortex, the posterior cingulate cortex, the precuneus and retrosplenial cortex and the bilateral parietal lobule, it is involved in internal mentation such as accessing and processing past events for problem solving or future planning, memory consolidation and autobiographical memory and deactivates during goal oriented activity (Hsu et al., 2014).

- The central executive network, involving the dorsolateral and prefrontal cortex and the posterior parietal cortex, is responsible for high-level cognitive function such as attention control and working memory (Hsu et al., 2014). The use of these two networks is dependent on whether the brain is engaged in a task requiring attention (Goulden et al., 2014).
- The fronto-parietal network (includes parts of the lateral prefrontal cortex, the intraparietal sulcus and posterior parietal cortex) (Gratton et al., 2018; Zanto & Gazzaley, 2013) and the primary motor sensory network (includes areas of the primary motor cortex, cerebellum, premotor area and the supplementary area) (Wu et al., 2009) overlap in their anatomy and function with both involved in the top-down control of motor planning and execution (Hsu et al., 2014).

More between-network connectivity and less within-network connectivity has been observed in older adults however, in the default mode network there was lower between-network functional activity, which is linked to worse memory and executive function (Damoiseaux, 2017; Dexter & Ossmy, 2023). While a lack of connectivity between the fronto-parietal and primary motor sensory networks has also been observed (Hsu et al., 2014). While these findings are dissimilar, both studies demonstrate changes in network connectivity with age which resulted in functional consequences. It is the default mode network and central executive network that have been identified as involved in mild cognitive impairment and Alzheimer's disease and represent brain regions initially affected by grey matter atrophy and amyloid deposition in Alzheimer's Disease (Daigle et al., 2022; Grieder et al., 2018; Simic et al., 2014). Disruptions in the networks are theorised as being responsible for changes of general cognition and memory (Liu et al., 2017).

2.2.1 The association of cognitive function with motor performance

Cognitive capacity, specifically executive function, has been shown to be associated with balance changes, slow gait, and falls risk (Li et al., 2018; Taylor et al., 2017; Zhang et al., 2019). Executive function is a cognitive domain that encompasses a range of higher-level cognitive processes which co-ordinate sub-processes such as memory, language and perception, to plan, monitor and execute a sequence of goal-directed complex actions (Collette et al., 2006; Coppin et al., 2006; Guitar et al., 2018; Maldonado et al., 2020; Voss & Bullock, 2004). Executive function is integral to navigating daily life (Brown & Chrastil, 2019). To safely navigate in a complex everyday environment the executive function components of task planning, problem solving, sensory integration, judgement and reasoning are all used, as well as the ability to manipulate and focus attention (Segev-Jacubovski et al., 2011). When it is impaired, many factors involved in movement production are affected, resulting in difficulties with activities of daily living and changes in movement control (Delbaere et al., 2004; Fastame et al., 2022; Li et al., 2018). Executive dysfunction has been related to increased fall rates in cognitively intact and impaired older adults (Chantanachai et al., 2021). In PLwD, executive dysfunction has been found to have a strong association with future falls (Delbaere et al., 2004; Fastame et al., 2022).

2.2.2 Impaired cognition and changes in balance

Balance changes in older age, reflecting the age-related structural and functional decline of the systems involved (Shaffer & Harrison, 2007; Van Humbeeck et al., 2023). Balance involves sensory perception and integration as well as motor planning and muscle activation in a co-ordinated and smooth fashion (Boisgontier et al., 2017; Kiss et al., 2018; Schedler et al., 2021). This process occurs continuously to sense and respond to balance perturbations, forming a closed-loop feedback system (Peterka, 2018). Sensory feedback (visual, auditory, somatosensory and vestibular) is integrated by the central nervous system to create positional awareness and motion perception (Van Humbeeck et al., 2023; Viseux, 2020; Wilczyński et al., 2023; Wittenberg et al., 2017). The system reweights sensory inputs depending on task and environmental demands (de Dieuleveult et al., 2017; Peterka, 2018; Pinto et al., 2021). Sensory input is transformed within the cerebral cortex, cerebellum and brainstem to a motor output which is timely and scaled to provide the appropriate balance response, and planned to meet the movement goal (Mahoney et al., 2018; Peterka, 2018; Takakusaki, 2017; Wittenberg et al., 2017).

Older adults have poorer control of displacements of the centre of mass and increased postural sway relative to their base of support in steady stance and a less effective stepping response compared to young adults (Nieto-Guisado et al., 2022; Osoba et al., 2019; Seidler et al., 2010). A shift from automatic control to a more attentionally demanding movement control strategy occurs with age, with central mechanisms becoming more important in maintaining balance (Ellmers et al., 2020; Heuninckx et al., 2010; Seidler et al., 2010). Increased demand for stability (such as decreased sensory input or uneven terrain) leads to an increase in attentional resources and executive function for balance (Muir-Hunter et al., 2014). A slowed reaction time results in delayed responses to a balance threat, decreasing the chance of successful recovery and a fall may occur (Hauer et al., 2003; Peterka, 2018; Segev-Jacubovski et al., 2011). Dual tasks have been used to demonstrate the interrelationship of the neural processes of balance and cognition. A 'posture first' strategy is a normal response to prioritise the maintenance of balance over other tasks when there is a risk of falling, but in cognitively impaired older adults the inverse is seen, and a 'posture second' strategy is exhibited (Hauer et al., 2003; Montero-Odasso & Speechley, 2018). Prioritising another task over maintaining balance can result in a person falling.

Balance declines with the level of cognitive impairment (Kuan et al., 2021; Liu et al., 2020; Maharani et al., 2018; Mansfield et al., 2007). A decline in sensory inputs used for balance (vision, proprioception and the vestibular system) as part of the ageing process requires more attention resulting in recruitment of frontal regions of the brain (Liu et al., 2020), while impaired processing of peripheral inputs like vision makes navigating the environment difficult (Marshall et al., 2023). Visual attention has been strongly associated with fall risk with fallers displaying reduced ability to observe and avoid hazards (Marshall et al., 2023). With cognitive impairment, the impaired functional networks of the brain disrupt the effective interaction between processing centres, impairing the sensory integration needed for balance (Liu et al., 2020).

2.2.3 Impaired cognition and changes in gait

Changes in gait, particularly gait speed are recognised as early indicators of impaired cognition (Hsu et al., 2014; Ijmker & Lamoth, 2012; Kikkert et al., 2016; Kostic et al., 2022; Mielke et al., 2013; Montero-Odasso et al., 2018; Montero-Odasso et al., 2012; Valkanova & Ebmeier, 2017). Ageing sees changes in muscle mass, strength, joint proprioception, slower processing speed and cognitive performance, which all contribute to biomechanical changes in gait (shorter stride and a wider stance) and a slower gait speed (Cohen et al., 2016; Fastame et al., 2022; Kikkert et al., 2016). However, gait is not purely a motor task but rather a complex activity that requires attention and executive function to successfully interact with the environment, (Amboni et al., 2013; Erickson et al., 2009; Morris et al., 2016). When cognitive impairment affects the sub-domains of attention, sensory integration and motor planning, which are required to walk and navigate the environment, increased demand for cognitive resources results in poorer gait performance (Bohlke et al., 2023; Fastame et al., 2022; Zhang et al., 2019). The interrelationship of gait and cognition is evident during dual tasking, performing a cognitive and physical task concurrently. One of the earliest studies to demonstrate the effect of dual tasking on gait was designed following the observation that some older adults needed to stop walking in order to talk (Lundin-Olsson et al., 1997). Dual tasking creates competition for common neural structures and the demands of the dual task can exceed available resources resulting in poor performance of either or both tasks in some older people, especially those with some cognitive or physical impairments (Ambrose et al., 2013; Li et al., 2018).

Gait changes can be detected before cognitive impairment is detected and are observed clinically as slowness, asymmetry, lack of smoothness or changes in spatiotemporal characteristics (stride variability, increased double support time) (Bahureksa et al., 2017; Cohen et al., 2016; Kikkert et al., 2016; Modarresi et al., 2019; Montero-Odasso & Speechley, 2018). It is impaired executive function that is associated with increased variability in gait particularly decreased gait speed (Amboni et al., 2013; Fastame et al., 2022; Kikkert et al., 2016; Valkanova & Ebmeier, 2017; Zhang et al., 2019). Slow gait can also be viewed as a purposeful adaptation to reduce fall risk as safe walking not only includes gait but balance and navigating the environment (Takakusaki, 2017; van Iersel et al., 2006; Zhang et al., 2019). In PLwD increased double support time and step length variability have been found to be associated with falls (Modarresi et al., 2019).

2.2.4 Impaired cognition and falls

Cognitive impairments are superimposed on those of normal cognitive ageing changes such as a decline in memory, processing speed, attention, visuospatial perception and executive function (Lampit et al., 2015; Liu et al., 2020). This is reflected in the increasing magnitude of fall risk by degree of cognitive impairment (Kuan et al., 2021; Tangen et al., 2014), with older adults with dementia having 2-3 times the fall risk of older adults without dementia (Modarresi et al., 2019; Suttanon et al., 2010). It is the cognitive process of executive function that is consistently associated with increased fall risk (Marshall et al., 2023; Muir et al., 2012; Smith et al., 2023). Cognitive impairment may increase fall risk through impaired balance, impaired gait, and increased risk-taking behaviour secondary to a decreased ability to recognize and avoid hazards (Burton et al., 2015; Kuan et al., 2021; Montero-Odasso & Speechley, 2018; Muir et al., 2012; Zhang et al., 2019).

2.3 Section 3. Fall prevention in aged residential care

This section used a narrative review with a structured approach to explore the evidence of fall prevention interventions with a final focus on exercise-based interventions for older adults living in ARC. Scopus, EBSCO Health Database (CINAHL, MEDLINE, SPORTDiscus) were searched for studies that used exercise as a single intervention to prevent falls, were set in ARC and had a primary outcome measure of falls such as the rate of falls, number of falls or the number of fallers. All study designs were included. Studies were excluded if the exercise intervention was delivered in sitting or if participants were not ARC residents. Search terms included nursing home, residential care, rest home, hostel, falls and exercise. An initial literature search was undertaken prior to the CogEx study development in late 2015. The search was updated in January 2024.

Fall prevention is a global term that encompasses any action taken to prevent a person from falling. Interventions can address extrinsic (environmental) fall risk factors such as floor surfaces, lighting, or intrinsic fall risk factors such as reviewing a person's medication or sight correction (I. D. Cameron et al., 2018; Hill-Westmoreland et al., 2002). Intrinsic risk factors may or may not be modifiable. A history of falls, age and gender are not modifiable, whereas some physical impairments may be, such as the use of a walking aid, moderate disability, impaired balance, and unsteady gait. Cognitive impairment cannot be ignored when considering falls prevention interventions in ARC. The interventions that have been explored in older adults living in the community such as exercise, use of technology, environmental assessment, cannot be translated directly into ARC as the population of older adults who reside in ARC have different fall risk factors to community-dwelling older adults.

2.3.1 The growth of falls prevention research

The first systematic review of falls prevention research in older adults published by the Cochrane Collaboration, "Interventions to reduce falls in the elderly" included 18 randomised controlled trials (Gillespie et al., 1997). The number of trials included in each update grew until in 2009 the systematic review was split by target population (Gillespie, 2013); acknowledging that the characteristics of populations and environments may require different interventions. The resulting two systematic reviews were, "Interventions for preventing falls in older people living in the community" with 111 trials (Gillespie et al., 2009) and "Interventions for preventing falls in older people in nursing care facilities and hospitals" with 41 trials (Cameron et al., 2010). The most recent systematic review published by the Cochrane Collaboration, "Interventions for preventing falls in older people in care facilities and hospitals" included 95 trials, 71 trials in ARC and 24 in hospitals (subacute rehabilitation wards) (I. D. Cameron et al., 2018). An update of this review is currently in progress (Dyer et al., 2023).

2.3.2 Fall prevention interventions

The evidence of the effectiveness of specific interventions for ARC residents is less certain than for community dwelling older adults (I. D. Cameron et al., 2018; Dyer et al., 2023; Gulka et al., 2020; Vlaeyen et al., 2015). In ARC, similar fall prevention interventions that have proven to be effective for community-dwelling older adults have been investigated including:

- exercise programmes which include muscle strengthening and balance retraining (El-Khoury et al., 2013; Finnegan et al., 2019; Hewitt et al., 2018; Sherrington et al., 2020; Sherrington et al., 2019)
- environmental fall-hazard reduction (Clemson et al., 2023)
- prescribing vitamin D (Guirguis-Blake et al., 2018; Kalyani et al., 2010)

Additional interventions specific to ARC have also been investigated including:

- reviewing medications (Dyer et al., 2004; Gulka et al., 2020; Seppala et al., 2022)
- reviewing low height beds (Capezuti et al., 2008)
- using risk assessment tools (Holte et al., 2015; Kerse et al., 2004; Logan et al., 2021)
- education for staff (I. D. Cameron et al., 2018; Dyer et al., 2004; Gulka et al., 2020; Holte et al., 2015; Vlaeyen et al., 2015).

Meta-analyses of the effectiveness of fall prevention interventions in ARC have reported mixed results (I. D. Cameron et al., 2018; Gulka et al., 2020; Vlaeyen et al., 2015). The only intervention that the studies had agreement on was medication review *not* preventing falls (I. D. Cameron et al., 2018; Gulka et al., 2020). For all other included interventions, the findings have been equivocal. Multifactorial fall prevention programmes were reported to reduce the number of recurrent fallers (Vlaeyen et al., 2015) and the number of falls (Gulka et al., 2020; Vlaeyen et al., 2015). However, there was no clear effect on the rate of falls (I. D. Cameron et al., 2018). Staff education has been reported to both reduce (Gulka et al., 2020) and increase falls (Vlaeyen et al., 2015). Similar contrasting findings were found for multicomponent programmes, being to reduce (Gulka et al., 2020) and have no effect on the number of falls (Vlaeyen et al., 2015). Vitamin D supplementation was found to probably reduce the rate of falls but not the risk of falling (I. D. Cameron et al., 2018) but in another meta-analysis had no effect on falls (Gulka et al., 2020). Exercise was found to reduce the number of people falling by 36% and recurrent fallers by 41% (Gulka et al., 2020), but also to have an uncertain effect on the rate of falls and may make no difference to fall risk (I. D. Cameron et al., 2018).

The above reviews shared methodological challenges. The overall quality of the included studies was low. For example, in the Cochrane Collaboration Systematic Review all the studies were categorised as low or very low quality except for studies of Vitamin D, which were of moderate quality (I. D. Cameron et al., 2018). For most interventions there were few studies included in the reviews. In Vlaeyen et al.'s (2015) meta-analysis there was only one exercise intervention study and five multicomponent studies. A difference between the earliest of these reviews (Vlaeyen et al., 2015) and the later two (I. D. Cameron et al., 2018; Gulka et al., 2020), was that the latter had higher numbers of studies which included exercise, reflecting the growth of research into the effectiveness of exercise as a fall prevention intervention for residents living in ARC.

There are meta-analyses that focused on exercise as a fall prevention intervention for residents living in ARC. These have also produced conflicting results. Lee and Kim (2017) in their meta-analysis reported that exercise reduced the rate of falls, with the effect being stronger when exercise was combined with two or more other falls prevention interventions (such as medication review, environmental modification, or staff education). These combined interventions also reduced the *number* of fallers. When considering the type of exercise, Lee and Kim identified that balance training (gait, balance and functional training; or balance and strength exercises) was an important component of the intervention. Similarly, Schoberer and Breimaier (2020) identified balance exercise significantly reduced the number of falls however the quality of evidence was low. There was moderate confidence that exercise interventions should be for longer than 6 months to reduce the number of falls.

Schoberer and Breimaier (2020) considered the effect of frailty on the outcome of falls prevention studies and where studies identified participants as frail there was moderate confidence that exercise interventions *increased* the number of falls. However, this finding was based on three studies and should be interpreted with caution, but it does signal the importance of the different levels of impairment that exist in the ARC population and that careful consideration of an individual's ability is required when prescribing exercise. In contrast to Schoberer and Breimaier (2020) and Lee and Kim's (2017) reviews, Sherrington et al. (2017) reported that there was insufficient evidence to support exercise as a single intervention to prevent falls in older adults living in ARC.

A recently published meta-analysis evaluated fall outcomes at the end of the intervention and at post-intervention follow up (Dyer et al., 2023). They reported that exercise decreased the number of falls and the risk of falling. The positive effect of exercise was not maintained after the intervention stopped, suggesting that falls prevention exercise should be provided as ongoing care for ARC residents who are able to participate. This meta-analysis included slightly more studies than the meta-analysis by (Lee & Kim, 2017) but still found there were insufficient studies to confidently recommend the type of exercise programmes that would be most effective.

As the body of research into falls prevention for ARC residents has grown, these systematic reviews and meta-analyses indicate that exercise has started to emerge as an intervention that may be effective for this population. Currently, the world guidelines for falls prevention in older adults strongly recommend individualised, supervised exercises are offered to those who are willing and able to participate, as a part of a multidomain intervention to prevent falls in ARC (2022).

2.3.3 Exercise interventions to prevent falls in ARC residents

The mixed evidence of exercise as a falls prevention intervention for ARC residents could be due to differences in the ARC populations and levels of care provided in ARC in different countries, the difference in inclusion criteria for the age of study participants, and the variety of exercises and exercise prescription parameters that have been studied.

Numerous types of exercises have been evaluated for reducing falls and risk of falls in ARC (I. D. Cameron et al., 2018; Dyer et al., 2023; Gulka et al., 2020; Schoberer & Breimaier, 2020). Of these, whole body vibration alone or combined with strength and balance exercises (Buckinx et al., 2014; Sitjà-Rabert et al., 2015), chair exercise (Arslan et al., 2023), an activity programme combined with goal setting (Kerse, Peri, et al., 2008), cycling (Varela et al., 2018) and tai chi (Choi et al., 2005; Saravanakumar et al., 2014) did not prevent falls in ARC residents.

Equivocal findings for the Otago Exercise Programme are reported. The Otago Exercise Programme did not decrease falls when performed twice a week for 6 or 12 months (Kovács et al., 2013; Kovács et al., 2012) however, when performed three times a week for 3 months the number of falls did decrease (Jahanpeyma et al., 2021).

It is unclear whether exercise programmes that incorporate strength and balance exercises along with other exercises decrease falls. An exercise programme delivered by occupational therapists that included strength, balance, flexibility and aerobic exercise in a 1 hour session twice a week did not decrease falls (Rolland et al., 2007). Neither did a programme of progressive high intensity functional exercises for 29 sessions over 3 months (Rosendahl et al., 2008). Neither did a high intensity functional exercise programme for 45 minutes, 5 sessions a fortnight for 4 months (Toots et al., 2019). Successful programmes included: a programme of 45 minutes of mobility exercises twice a week with 45 minutes of moderate to light intensity resistance exercise with weight machines three times a week (Serra-Rexach et al., 2011); a programme of individually tailored, progressive balance and strengthening exercises for an hour twice a week with a daily walk (Arrieta et al., 2019); and a programme of strengthening, proprioceptive training, static and dynamic balance and flexibility exercises for 1 hour twice a week for 16 weeks (Toulotte et al., 2003). A programme of progressive daily walks, balance exercise, twice weekly progressive power exercise in a leg press machine and occupational therapy exercise for executive and cognitive functions for 8 weeks reduced the number of falls (Cadore, Moneo, et al., 2014); as did a power training, balance and gait training programme twice a week for 12 weeks (Cadore, Casas-Herrero, et al., 2014). The Sunbeam programme which used a circuit of progressive resistance exercise with weight machines, static and dynamic balance exercises, for 1-hour twice a week for 25 weeks saw a reduction on the rate of falls (Hewitt et al., 2018). A progressive strengthening programme focusing on hip and postural muscle strength twice a week and incorporated a walking programme 20 weeks into the 3-month programme also decreased falls (Tuunainen et al., 2013).

The types of exercise that reduced falls included: ballroom dance for 50 minutes three times a week for 12 weeks (da Silva Borges et al., 2014); Wii Fit for 1 hour three times a week for 6 weeks (Fu et al., 2015); computerized balance training with visual feedback for 4 weeks (length and number of sessions not reported) (Sihvonen et al., 2004); Pilates for 1 hour three times a week for 12 weeks (Irez et al., 2011); short stick exercises performed in sitting for 25 minutes twice a week for 6 months (Yokoi et al., 2015).

Interpreting the findings of these studies is challenging due to methodological issues such as differences in the inclusion criteria (age, level of cognition, history of falls, diagnoses of dementia or Alzheimer's Disease, mobility, level of ARC), and small sample sizes. Many of the above studies were pilot or feasibility studies (Kovács et al., 2012; Saravanakumar et al., 2014; Schoenfelder, 2000), had a small sample (Cadore, Casas-Herrero, et al., 2014; Cadore, Moneo, et al., 2014; Toulotte et al., 2003), a measure of falls was not the primary outcome (Arslan et al., 2023; Buckinx et al., 2014; Rolland et al., 2007; Schoenfelder & Rubenstein, 2004), the study was not powered to detect a significant difference in falls (Arrieta et al., 2019; Choi et al., 2005; da Silva

Borges et al., 2014; Fu et al., 2015; Irez et al., 2011; Serra-Rexach et al., 2011; Sitjà-Rabert et al., 2015) or no rationale for sample size was provided (Rosendahl et al., 2008; Sihvonen et al., 2004; Toots et al., 2019; Tuunainen et al., 2013; Varela et al., 2018). It is also worth noting that no serious adverse events were reported by any of the studies.

Of the studies identified above, only six were powered to detect a significant difference in falls, with three finding a reduction and three finding no effect. The Sunbeam programme of progressive resistance training and balance for 1 hour twice per week for 50 hours, resulted in a reduced rate of falls in the exercise group by 55% (Incidence Rate Ratio = 0.45, 95% CI 0.17-0.74) (Hewitt et al., 2018). The Otago Exercise Programme performed for 45 minutes, 3 days a week and a walking programme on 3 other days of the week for 12 weeks reduced the number of falls ($p<.005$) (Jahanpeyma et al., 2021), however a group exercise programme based on the Otago Exercise Programme twice a week and a supervised walk once a week for 12 months, did not result in any difference in falls (Kovács et al., 2013). A goal setting programme that promoted progressive increases in physical activity plus a tailored activity programme based on activities of daily living that were to be done daily or several times a day for 6 months, did not result in any difference in falls (Kerse, Peri, et al., 2008). A high intensity functional exercise programme performed for 45 minutes, 5 session a fortnight for 4 months did not result in a decreased fall rate (Toots et al., 2019). A seated programme of short stick exercises for 33 minutes, twice a week for 6 months significantly reduced the number of fallers and the time to first fall in the exercise group compared to the control group (mean ± standard deviation (SD), 10.1±3.0 months versus 9.0±4.1 months, $p=.027$) (Yokoi et al., 2015).

These mixed results could be due to the study participant inclusion criteria resulting in participant groups with different characteristics. The level of cognition varied from including only PLwD (Toots et al., 2019), cognitive impairment (<24/30 Mini-Mental State Examination (MMSE)) (Kovács et al., 2013) or being required to remember a goal they set (Kerse, Peri, et al., 2008), to excluding people with insufficient cognition (≤15/30 MMSE) (Hewitt et al., 2018) or PLwD (Jahanpeyma et al., 2021; Yokoi et al., 2015). A high fall risk was used to include (Jahanpeyma et al., 2021) and exclude people (Yokoi et al., 2015). People needed to be able to walk 6m with or without an assistive device (Kovács et al., 2013), stand up from a chair with arm rests with no more than 1 person assisting (Toots et al., 2019), or not have a physical disability which prevented exercise (Jahanpeyma et al., 2021) or be bed or chair bound (Hewitt et al., 2018). All study participants lived in ARC. However, the inclusion criteria used by Yokoi et al. (2015) of a person being able to walk without the use of an assistive device and take care of themselves without assistance, describes a much more independent group of people than those who would be assessed as needing ARC in NZ even though the term “residential care facilities” was used (Yokoi et al., 2015, p. 1269). This is an example of either the same term being used across countries but describing a different level of care for residents, or a difference in translation.

Identifying the type of exercise and dose that is effective in reducing falls in ARC is challenging due to the lack of specificity and level of detail published about the intervention. The Template for Intervention Description and Replication (TIDieR) guide was developed to encourage sufficient detail to be published so that clinicians could implement an intervention that was found to be effective (Hoffmann et al., 2014). Studies published after the development of the TIDieR guide have begun to provide greater detail about the interventions. Hewitt et al. (2018) published their progressive resistance and balance exercise programme, and how they progressed the exercises. Toots et al. (2019) provided the link to website where the High-Intensity Functional Exercise Programme (HIFE) and resources could be accessed. Similarly, the Otago Exercise Programme is a manualised programme that is freely available and was referenced by Jahanpeyma et al. (2021) and Kovács et al. (2013). Yokoi et al. (2015) appended the content of the short stick exercise programme with the number of repetitions and duration of each exercise. Although the reporting of programme details is improving, there are currently too few studies available that have been sufficiently powered and found to be effective, to ascertain what type of exercise and dose is effective or whether exercise is effective at all in reducing falls in ARC.

When considering falls prevention interventions for older adults living in ARC it is vital to think of the complexity and variability of the population. They are complex in terms of physical and cognitive function with differing levels and numbers of impairments (de Souto Barreto et al., 2016; Lynds & Arnold, 2023). This is reflected in the different fall risk factors for older adults living in ARC and may be why falls prevention programmes that are effective for community dwelling older adults may not be effective for ARC residents. In NZ 80% of ARC residents require a mobility device (P. Tang, Senior interRAI Systems Clinician, interRAI New Zealand, email communication, February 14, 2022), which often reflects poor balance and leg weakness, two fall risk factors that are modifiable with exercise (Ambrose et al., 2013). So, an expectation that exercises would make a difference is reasonable, however, other comorbidities of older adults living in ARC and the reason why each person is living in care needs to be considered. Each risk factor a person has adds to their risk of falling so the greater the number of risk factors the greater the fall risk (Lord et al., 2003; Stevens & Lee, 2018; Tinetti et al., 1988).

2.3.4 The core components of a fall prevention exercise programme

The key types of exercise to prevent falls in ARC appear to be strength, balance and functional exercises (Dyer et al., 2023). These are also the components of exercise programmes which have the strongest evidence for reducing the rate of falls in community dwelling older adults (Sherrington et al., 2020; Sherrington et al., 2019). When considering how a person maintains balance, it makes sense that these three exercise types are appropriate to prevent falls for all older adults.

Why is strength important?

Muscle strength in humans is defined as the “maximum force generation capacity of an individual” (Macaluso & De Vito, 2004, p. 450). Muscle strength is related to the cross-sectional area of a muscle, and with age there is a decrease in muscle fibre number and size (Aagaard et al., 2010; Frontera et al., 2000). Muscle mass declines from the age of 30 years old, accelerating after the age of 60 years old and can result in a loss of up to 40% of muscle mass by the age of 80 years (Lexell et al., 1988; Volpi et al., 2004). This physiological change decreases muscle strength and when superimposed on sedentary older adults can result in a decrease of leg muscle strength of up to 60% (Doherty, 2003; Hughes et al., 2001; Marcell et al., 2014). Muscle strength is associated with physical function in older adults (Bårdstu et al., 2022). ARC residents have been identified as physically inactive due to the environment but also staff encouraging residents to stay in sitting to be safe (Barber et al., 2015; Gulka et al., 2020; Kazoglu & Yuruk, 2020; McArthur & Iaboni, 2021), which results in pathophysiological consequences which can include muscle atrophy and impaired balance (Crocker et al., 2013; Enoka, 1997; Lazowski et al., 1999). The ability to strengthen muscles is maintained across the lifespan (Kalapotharakos et al., 2010; Liu & Latham, 2009). In response to a muscle being under load, for example resistance training, strengthening occurs through muscle hypertrophy and neural adaptation such as enhanced neural drive and motor unit recruitment (Arnold & Bautmans, 2014; Borde et al., 2015; Häkkinen et al., 2000).

Increased muscle strength does not necessarily transfer to increased function (Liu et al., 2014; Mohammed et al., 2022; Skelton et al., 1994), with older adults observed to use different movement patterns to optimise the strength that they do have (Schot et al., 2003). This may be because when a muscle is trained in isolation for example the quadriceps with knee extension, it is only strength that is being trained. When the function quadriceps will be used for is sit to stand, it is a complex motor task requiring neuromuscular coordination for elements such as speed of movement, movement sequence, balance and range of motion required (Liu et al., 2014; Reid & Fielding, 2012). If the goal of muscle strengthening is to increase function, specificity of training is important and functional training should be used to improve tasks (Hawley, 2008).

Why is balance important?

Balance is defined as the state of an object when the forces acting on it are zero (Newton's First Law) (Peskir, 2022). When balance is used to describe human upright stance, it is postural control that is being described, which is the ability to control body position in space or maintain a state of balance during an activity such as sit to stand (Ivanenko & Gurfinkel, 2018; Pollock et al., 2000). Balance and postural control are often used synonymously. The exercises prescribed to prevent falls are commonly called balance exercises or balance retraining, so in this thesis the term balance will be used.

Human balance is a complex function and a motor skill, involving multiple sensory inputs and coordinated motor outputs (Horak et al., 1997; Pollock et al., 2000; Yiou et al., 2018). The muscular outputs required to balance come from muscle contractions that are appropriately timed and scaled according to the task and occur in response to changes detected by a variety of sensory systems (Aagaard, 2003; Peterka, 2018; Powers & Howley, 2007; Tresch & Jarc, 2009). Balance worsens with age due to an age-related decline in the sensory receptors (proprioceptive, cutaneous, visual and vestibular systems), slower motor and sensory nerve conduction velocities and response amplitudes (Aagaard et al., 2002; Shaffer & Harrison, 2007), decreased motor neuron firing frequency, reducing motor outputs which lead to a slower reaction time (Nolan et al., 2010; Seidler et al., 2010).

Improving balance requires training that specifically challenges the coordination of these sensory inputs and motor outputs (Horak, 2006), resulting in neuromuscular changes (Rodríguez-Rosell et al., 2018). A balance assessment to identify what impairment is contributing to a person's decreased balance will inform the choice of exercise that meets their needs (Horak, 2006), however a public health approach such as widespread delivery of effective fall prevention interventions such as the Otago Exercise Programme and tai chi are also used to enable widespread accessible and affordable options (Marina et al., 2022; Sleet et al., 2008).

Why is functional exercise important?

The term "functional exercise" appeared in the fall prevention literature to simplify the ProFaNE intervention category that incorporated gait, co-ordination and functional task training (Sherrington et al., 2020; Sherrington et al., 2019). Functional exercises use everyday movements, like standing up from sitting down or stepping up and down a step, with muscles being activated according to the requirements of the task (Tresch & Jarc, 2009; Yiou et al., 2018). Practice of meaningful tasks results in the strengthening of neuromuscular control to perform the task (Kleim & Jones, 2008), and for older adults with changes in strength and sensory inputs, adaptation to moving differently to use the strength they have may also occur (Horak, 2006; Winstein et al., 2014).

Functional exercises can be used as balance and strengthening exercises. Body weight can be used as a load against gravity for strengthening exercises. The exercise principle of overload is applied to the lower limb muscles through weight bearing and progressed by increasing the number of repetitions performed of an exercise (Powers & Howley, 2007). However, the choice of functional exercise, for example sit to stand, can also include a challenge to balance when changing from one position (sitting) to another (standing). Therefore, balance is also improved through practicing the shift of the centre of gravity required to complete sit to stand. In response to repetition, neural (Aagaard, 2003; Enoka, 1997; Sale, 1988) and skeletal muscle adaptation (Aagaard et al., 2002; Gandevia, 1999) occur strengthening the muscles and increasing the neural drive for the task (Aagaard, 2003; Rodríguez-Rosell et al., 2018).

2.3.5 Exercise intervention to prevent falls in PLwD in ARC

Given the high proportion of ARC residents that have dementia, this is a risk factor that warrants special consideration and management. There is a lack of falls prevention research that focusses specifically on PLwD (I. D. Cameron et al., 2018; Dyer et al., 2023; Gulka et al., 2020), despite PLwD being two to three times more likely to fall and twice as likely injure themselves (Kröpelin et al., 2013; Suttanon et al., 2010). The Cochrane Systematic Review of fall prevention interventions for older people in ARC (I. D. Cameron et al., 2018) only identified two, low quality, exercise intervention studies designed for PLwD or cognitive impairment (Kovács et al., 2013; Toulotte et al., 2003). A group exercise programme based on the Otago Exercise Programme for 1 hour twice a week and a supervised walk once a week for 12 months, did not result in any difference in falls for the cognitively impaired older adult participants (Kovács et al., 2013). A programme of supervised strengthening, proprioceptive training, static and dynamic balance and flexibility exercises for 1 hour twice a week for 16 weeks, resulted in no falls in the exercise group during the 16 weeks but once the programme finished falls occurred. This study was small with 20 PLwD with a history of falls participating (Toulotte et al., 2003). The Cochrane Systematic Review identified that future research on interventions specifically designed to prevent falls in PLwD in ARC was needed and recommended authors clearly report the cognitive status of participants in ARC (I. D. Cameron et al., 2018). Rather than identify any exercise intervention studies specifically for PLwD, Gulka et al. (2020) found that many studies of exercise used cognitive impairment as an exclusion criteria, so PLwD were excluded from the research.

Researchers are beginning to evaluate interventions for people with cognitive impairment by including them in research participation opportunities. The Sunbeam trial (Hewitt et al., 2018) reported a subgroup analysis to understand the effect of their programme for trial participants who had been identified as having mild to moderate cognitive impairment or dementia (Mak et al., 2022). The results were significant with a 50% decrease in the rate of falls (95%CI = 0.28-0.89), and a decrease in the risk of falls (Incidence Ratio Rate (IRR) 0.69, 95%CI = 0.53-0.91), multiple falls (IRR 0.60, 95%CI = 0.39-0.89), and injurious falls (IRR 0.56, 95%CI = 0.33-0.95). This finding contrasts others (Brett et al., 2021; Gulka et al., 2020; Toots et al., 2019). Brett et al. (2021) evaluated an intervention designed to investigate the effect of exercise to decreased agitation with an RCT and included the number of falls as a secondary measure. the number of falls was analysed following an exercise programme of balance, strengthening and aerobic exercises for either 45 minutes once a week or 15 minutes three times a week, for 12 weeks. They found no increase in falls in the intervention groups. Toots et al. (2019) investigated the effect of a high intensity functional exercise programme of 45 minutes for 5 sessions a fortnight for 4 months, on PLwD with an RCT. There was no difference between the exercise and control groups for fall rate during the intervention (IRR 1.2, 95% CI 0.8-2.0, $P = 0.398$). Gulka et al. (2020) performed two subgroup analyses to understand whether dementia or cognitive impairment had an effect on the outcome of *all* types of fall prevention interventions in a meta-analysis. They found that cognitive impairment or dementia negatively impacted the effectiveness of an intervention for the number of falls. Importantly, the relative risk of falls increased with a greater prevalence of cognitive impairment amongst participants. When 40-69% of the participants were cognitively impaired, the relative risk of falls was 0.52 (95% CI = 0.41 to 0.66) however when more than >70% of the participants were cognitively impaired, the relative risk increased significantly to 0.86 (95% CI = 0.67 to 1.11) ($P < .001$). This again highlights some of the complexities and uncertainties of the evidence to date.

The lack of inclusion of PLwD or cognitive impairment in studies results in a study sample that is not representative of the population of ARC residents and limits the generalisability of the exercise findings. The challenge of recruiting people living with cognitive impairment into research has been identified as a contributing factor to studies containing small numbers of PLwD as participants (Bartlett et al., 2019; I. D. Cameron et al., 2018). However, it is time that fall prevention research using a truly representative population of ARC is undertaken. Research on exercise interventions specifically designed to prevent falls in people with cognitive dysfunction in ARC is needed.

2.4 Summary

This chapter introduced the problem of falls in older adults in ARC and how the difference in magnitude of fall risk differs in this population compared to community dwelling older adults, by age and diagnosis. The risk factors for falls in the ARC population are, a history of a previous fall, use of a walking aid, unsteady gait, impaired balance, and muscle weakness. Also contributing to falls in this population are the ageing related changes in the brain (Cohen et al., 2016; de Oliveira Silva et al., 2019; Kikkert et al., 2016; Montero-Odasso et al., 2012), due to the interrelated effect on cognitive function and motor performance. Older adults living in ARC with dementia were identified as having the greatest fall risk. To understand how to prevent falls in this population, the literature was reviewed; the results are as yet unclear for residents of ARC and PLwD in ARC. There are only a few exercise intervention studies but these do give some positive indications that exercise may help to prevent falls in ARC. Understanding that cognition contributes to the motor changes observed in the gait and balance of older adults with cognitive dysfunction, leads to the conclusion that falls should not be approached as purely a motor problem (Segev-Jacubovski et al., 2011). Further research is needed to address not only the modifiable risk factors of strength and balance but to also consider addressing the risk factor of cognitive dysfunction.

Chapter 3 Cognitive exercise to improve cognition

This chapter provides the background and rationale for selecting CST as the type of cognitive exercise to be combined with physical exercise to prevent falls in older adults living in ARC. The identification of cognitive dysfunction as a fall risk provides impetus to manage falls as a combined cognitive and motor problem (Kuhnow et al., 2022; Suttanon et al., 2010; Van Doorn et al., 2003). Different types of cognitive exercises have been developed for people living with cognitive dysfunction and will be described below. This will be followed by a literature review of studies that have combined cognitive exercise with physical exercise to address fall risk. Finally, the development of CST and its underpinning mechanisms are discussed, with the rationale for using CST as the choice of cognitive exercise for this research.

3.1 Introduction to cognitive exercise

Cognition-oriented treatments are non-pharmalogical interventions which engage thinking and cognition to improve or maintain cognitive processing and the impact that cognitive impairment has on a person's activities of daily living (Bahar-Fuchs et al., 2019; Gavelin et al., 2020). There are three main types of cognitive exercise that have been used with PLwD and whilst there is some overlap, they differ conceptually and in application (Bahar-Fuchs et al., 2019; Clare & Woods, 2004). They are:

- Cognitive Training aims to improve an individual's performance on a standard set of tasks through guided practice, designed to reflect specific cognitive functions. Tasks may be pen and paper, computer based or activities of daily living (Bahar-Fuchs et al., 2019).
- Cognitive rehabilitation recognises the perspective of the person is of central importance and uses an individual approach to identify goals and devise strategies to improve function in the person's everyday context (Bahar-Fuchs et al., 2013).
- Cognitive stimulation therapy (CST) aims to enhance cognitive and social functioning through a group therapy approach incorporating reality orientation, reminiscing, and actively stimulating PLwD, whilst

providing an optimal learning environment and the social benefits of being part of a group (Woods et al., 2023).

3.2 Combining cognitive exercise and physical exercise to prevent falls

A narrative review was undertaken using a structured approach. Scopus, EBSCO Health Database (CINAHL, MEDLINE, SPORTDiscus) were searched for studies that investigated the effect of cognitive exercise combined with physical exercise to prevent falls in older adults. All study designs were included. Search terms included cognitive exercise, cognitive training, cognitive stimulation therapy, cognitive rehabilitation, physical exercise, falls, mild cognitive impairment, dementia and older adult. The search identified Cognitive Training (guided practice of standard set of tasks) as the cognitive exercise used with physical exercise to investigate the potential to prevent falls in older adults with cognitive dysfunction. No studies were identified that included solely ARC residents, so studies of community dwelling older adults living with cognitive dysfunction are discussed as those findings may inform whether similar investigations should be undertaken in ARC.

The effectiveness of combining Cognitive Training with exercise on reducing fall rate and fall risk for community dwelling older adults living with MCI was evaluated in an RCT (Lipardo & Tsang, 2020). Over a 12-week period, three intervention groups were compared with a waitlist control. The interventions were cognitive training alone, physical exercise alone and cognitive training combined with physical exercise (see Table 3.1). The physical exercise and cognitive training combined with physical exercise groups spent no less than one third of the time on balance training; the combined group used Cognitive Training elements during physical exercise such as sit to stand with orientation training; the cognitive training group had a 60–90-minute session of paper-based Cognitive Training once a week.

Table 3.1

Intervention dose by group

Group	CT session (60-90 minutes)	Ex session (60-90 minutes)	Ex session (60-90 minutes)	Ex session (60-90 minutes)	Total dose over 12 weeks (hours)
CT					12-18
Ex					36-54
CT + Ex					48-72

Note. Grey shaded area = intervention received; CT = Cognitive Training; Ex = physical exercise.

No significant difference was found between the groups for fall rate after 12 weeks (p=0.152) or after 36 week follow up (p=0.954), or for fall risk. This lack of difference between groups may be due to methodological issues with the study; attendance was low, with a high percentage of participants not attaining the number of supervised participation hours set for each intervention (48% cognitive exercise combined with physical exercise, 57% physical exercise and 74% cognitive exercise). It is also unclear how attendance was measured, for example if a participant attended the class but did not exercise was that time considered participation or not (L. M. Taylor et al., 2023).Taking a binary position of a participant needing to attend 100% of the classes was a study weakness, as in everyday life very few people attend 100% of classes offered (Freiberger et al., 2012; Hewitt et al., 2018; Hughes et al., 2019; Taylor et al., 2020; Williams et al., 2014). A preferred research method for analysing an acceptable level of attendance is to establish a priori criteria for attendance, between 50-70% is commonly used in exercise studies (Candy et al., 2020; Lin et al., 2018; L. M. Taylor et al., 2023; Williams et al., 2014). The interventions were not dose matched, as the authors used the recommended number of hours of falls prevention exercise for the exercise group (40 hours) and the optimal duration of Cognitive Training for the cognitive training group (22 hours) (see Table 3.1). The dropout rate of 20% and 28% at 12 and 36 weeks respectively resulted in the study being underpowered. The study reported fall rates were fall per month, rather than the fall per year recommended by ProFaNE (Lamb et al., 2005). Measuring falls over less than a year is problematic as a fall may not occur over a short period of time. Lastly, different forms of Cognitive Training were used by the cognitive training and the cognitive training with physical exercise group, and this could be a reason for differing results if they practiced different tasks targeting different cognitive functions.

Another RCT evaluated the effectiveness of supplementing strength and balance exercises with Cognitive Training on cognitive function, physical function, fear of falling and fall rate, in older adults living in "homes for the aged" and community dwelling older adults living nearby (van het Reve & de Bruin, 2014, p. 3). All participants took part in a 30-minute progressive resistance (strength) programme on machines and a 10-minute balance programme, twice a week for 12-weeks. The strength and balance supplemented with cognitive training group also took part in a 10-minute computer-based Cognitive Training programme, three times a week over the 12-weeks. The addition of Cognitive Training to a strength and balance programme was not more effective in decreasing falls than the physical exercise (control) programme alone. The fall rate decreased significantly and similarly in both groups compared to the previous 6 month's falls (strength and balance supplemented with Cognitive Training decreased 83%, control group 81%). These are very large decreases in fall rates however, it is difficult to unpack the statistical analysis as not enough statistical information was provided. There are three issues affecting the quality of the study:

- Four participants were reallocated to a group they were not randomised to due to vision problems but were then analysed as part of the group they were originally randomised to.
- Outliers were trimmed from analysis yet an intention to treat approach was used, which is contradictory to using a trimming method.
- Missing data was imputed but it is unclear how much.

At 12 months follow-up the fall rate was 46% and 58% respectively. Fear of falling also decreased significantly for all participants, with no between group differences. Dual task costs of gait, gait initiation and measures of divided attention skills, improved significantly in the strength and balance supplemented with cognitive exercise group. Although the improvement in these cognitive skills did not translate to a different fall rate between the groups, it demonstrated that there is potential to decrease cognitive fall risk factors with targeted cognitive exercise. However, the authors commented that three dimensions of attention (alertness, selective and divided) were addressed with Cognitive Training, making it difficult to know which one resulted in the observed changes. This is also a potential weakness of Cognitive Training, practicing set tasks that reflect specific cognitive functions, may not be transferrable to daily activities. It is difficult to have confidence in these findings given the low quality of the study.

Other studies have investigated combining Cognitive Training with physical exercise but did not include a measure of falls (Barban et al., 2017; Gschwind et al., 2015; Hagovská & Olekszyová, 2016; Schoene et al., 2015). An RCT evaluating Cognitive Training combined with physical exercise for the effect on cognition and mobility in community dwelling older adults living with MCI, recorded falls as an adverse event (Shimada et al., 2018). Over a 40-week period the cognitive training with exercise group had a weekly 90-minute session consisting of a 10-minute warm up, followed by 20-minute strength and balance training, 25-minute dual task training e.g. playing a word game while stepping, a 5-minute break then 25-minute aerobic exercise followed by a 5-minute cool down. Over the same period, the control group attended three 90-minute health promotion classes, were sent pamphlets, and telephoned 2-3 times to promote adherence to the education programme. Falls were recorded however the method was not reported. Eleven exercise group participants and 13 control group participants reported a fall, it is not known if a person fell more than once however, there was no between-group differences in falls ($p=0.811$).

Lipardo and Tsang (2020) and Shimada et al. (2018) used simultaneous training (performing Cognitive Training and physical exercise concurrently using a dual-task paradigm), and van het Reve and de Bruin (2014) used sequential training (Cognitive Training and physical exercise delivered separately on separate days). Simultaneous training may not be the best approach for people living with cognitive impairment as the increased demand for cortical resources may be too great and negatively affect the quality of performance on both tasks (Phirom et al., 2020; Sánchez-Sánchez et al., 2022). When performing a motor and a cognitive task at the same time, dual-tasking interference is the percentage change observed in the quality of one or both tasks (Leone et al., 2017). Lipardo and Tsang (2020) discussed the increase in cognitive demand as a possible explanation for standalone exercise protocols having a significant positive effect on executive function but not simultaneous exercise programmes of physical and cognitive exercise.

The choice of Cognitive Training as the type of cognitive exercise to be combined with physical exercise to prevent falls is an interesting one given that the NICE dementia guidelines recommend *not* offering Cognitive Training as a treatment to people living with mild to moderate Alzheimer's disease (National Institute for Health and Care Excellence, 2018). The practicalities of implementing computer-based Cognitive Training may make it an attractive choice for researchers compared to other cognition-oriented treatments that are more resource intensive. A commercially available, standardised computer-based Cognitive Training product is resource and time effective, as it uses algorithms to determine and progress task difficulty and monitor cognitive performance in real time, and it does not necessarily require a trained health professional to run the programme and therefore less researcher input is required (Gates & Valenzuela, 2010; Gavelin et al., 2021). However, the utility of computer-based Cognitive Training is limited to people living with cognitive impairment who can follow tasks on a computer screen and should be considered after assessing whether a person is appropriate for the intervention (van het Reve & de Bruin, 2014).

Many of the studies in this section do not report falls as an outcome. Of those that did, two studies reported that Cognitive Training had no effect of fall (Lipardo & Tsang, 2020; Shimada et al., 2018). van het Reve and De Bruin (2014) reported a large effect on falls however concerns with the methodological studies limits the confidence in these findings. The NICE dementia guidelines (National Institute for Health and Care Excellence, 2018) recommended CST as the non-pharmacological intervention of choice for people living with mild to moderate dementia.

3.3 Cognitive Stimulation Therapy (CST)

CST was developed using the beneficial elements of effective non-pharmacological therapeutic approaches commonly used in dementia care at the end of the 20th century (Neal & Briggs, 2000; Spector et al., 1998; Spector et al., 2001; Stott & Spector, 2011). It is a structured and manualised group treatment specifically developed for people living with mild to moderate dementia. The programme is 7 weeks long and involves a 45-minute group activity session twice weekly, to actively stimulate and engage PLwD and promote executive function and language use (T. Liu et al., 2021; Spector et al., 2006). It was developed following a rigorous research process and is supported by a growing body of evidence (Spector et al., 2006; University College London, 2014; Woods et al., 2023; Yates et al., 2017).

CST results in small, short-term cognitive benefits in people living with mild to moderate dementia as well as clinically meaningful improvements in communication and social interaction (Spector et al., 2003; Woods et al., 2012; Woods et al., 2023). Larger cognitive improvements are possible when the severity of dementia is milder rather than moderate (Woods et al., 2023). CST is the only evidence-based treatment recommended for people living with mild to moderate dementia in the NICE dementia guidelines as an intervention to promote cognition, independence and wellbeing (National Institute for Health and Care Excellence, 2018). Similarly, Alzheimer's Disease International recommends that CST programmes should be offered to people in the early stages of dementia (Prince et al., 2011). In NZ, the Dementia Care Framework recommends CST as one of the two specific treatments considered as good practice for PLwD (Ministry of Health, 2013).

Further development of CST has seen cultural adaptations (Alvares-Pereira et al., 2021; Bertrand et al., 2019; Capotosto et al., 2017; Marinho et al., 2021; Olakehinde et al., 2019; Paddick et al., 2017; Wong et al., 2018; Yamanaka et al., 2013) and different delivery formats developed and investigated in response to different environments, needs and funding models. A maintenance programme of CST (MCST) was developed to evaluate whether cognitive and quality of life improvements gained from CST participation could be maintained over time (Orrell et al., 2005). Individual CST (iCST) was developed to deliver CST to PLwD in their own home by a caregiver so that people who were not suitable to be a part of a group or had transport difficulties could access CST (Yates et al., 2015). In response to the COVID-19 pandemic, virtual iCST was developed and offered to continue to deliver CST safely to PLwD while complying with a country's isolation lockdown orders (Hui et al., 2022; Peri et al., 2022).

3.4 Evidence to support CST

Studies that have been undertaken to understand how CST works can be categorised by what aspect of cognition and structural aspect of the brain they assessed for change. These are:

- Psychological processes and strategies
- Changes in cognitive domains
- Structural brain changes

The following sections discuss the research in these three categories.

3.4.1 Psychological processes and strategies

CST is not a domain-specific cognitive intervention. Unlike Cognitive Training that aims to develop working memory through the practice of a standard set of tasks, CST works across multiple modalities to produce cognitive gains that are generalisable and transferrable (Liu et al., 2017; Woods et al., 2023). The following processes and strategies are described in Spector et al.'s early work underpinning CST:

- use of implicit memory
- integration of reminiscence and multi-sensory stimulation
- socialisation through group participation
- a group learning environment
- the use of a reality orientation board as an external cue
- and game-like activities (Spector et al., 2001; Spector et al., 2003).

Repetition is also used for familiarity rather than explicit learning, and is a strategy taken from the reality orientation approach that informed CST (Rai et al., 2018). More recently, the emphasis on being person-centred and stimulating the use of language has been identified as key to the approaches used in CST (T. Liu et al., 2021; Woods et al., 2023). Contributing to this understanding may be the development of assessments that are able to measure specific cognitive domains.

3.4.2 Changes in cognitive domains

The Cochrane Systematic Review identified improvement in general cognition as well as positive changes in communication and social interaction following participation in CST (Woods et al., 2023). Most CST studies included several measures of cognitive function however, the MMSE and the Alzheimer's Disease Assessment Scale-Cognitive (ADAS-Cog) were the most commonly used measures (25 and 21 of 34 studies, respectively) (Woods et al., 2023). These two measures assess different and multiple cognitive domains.

The MMSE is a standard outcome measure used in research and clinically with older adults to screen for cognitive impairment, assess the severity of cognitive impairment and monitor change (Arevalo-Rodriguez et al., 2021; Folstein et al., 1975; Nieuwenhuis-Mark, 2010; Shigemori et al., 2010). It uses 11 subtests to evaluate the cognitive domains of orientation, registration (immediate memory), attention and calculation, recall (short-term memory), language and copying (constructional praxis) (Nieuwenhuis-Mark, 2010; Shigemori et al., 2010). Scored out of 30, a lower score on the MMSE indicates cognitive impairment (Creavin et al., 2016). The original work of Folstein et al. (1975) used a cut-off score of $\geq$ 24 to indicate normal cognition and $\leq$ 20 to likely indicate dementia. Since then, various cut-off scores have been used to categorise mild cognitive impairment, borderline impairment, severe cognitive impairment, or normal cognition (Arevalo-Rodriguez et al., 2021; Creavin et al., 2016; Monroe & Carter, 2012). The total MMSE score is reported in CST studies to indicate change in general cognition after completing a CST programme rather than the on sub-tests scores to identify change in specific cognitive domains (Woods et al., 2023).

ADAS-Cog is a standard outcome measure used in clinical trials with people living with mild to moderate Alzheimer's Disease (Rosen et al., 1984; Schrag et al., 2012). It uses 11 tasks to assess the cognitive domains of language, praxis and memory and the total score out of 70 is used to indicate cognitive dysfunction with a higher score indicating greater dysfunction (Balsis et al., 2015). The sub-scales can be analysed separately to identify dysfunction in specific cognitive domains (Balsis et al., 2015; Benge et al., 2009). Several CST studies have analysed the ADAS-Cog subscales to identify the specific cognitive domains that are amenable to CST. Spector et al. (2010) revisited their 2003 CST RCT data and analysed the ADAS-Cog subscales and found a statistically significant difference between the CST and control groups on the commands and spoken language tasks (p<.05). Further analysis of the cognitive domains of language, praxis and memory, demonstrated a significant improvement only on language (p=.01), however all tasks showed less deterioration or improvement than the control group. Some pilot studies of cultural adaptations of CST have also analysed sub-scales of ADAS-Cog (Alvares-Pereira et al., 2021; Capotosto et al., 2017; Olakehinde et al., 2019; Paddick et al., 2017). The Italian adaptation of CST found a significant difference in the narrative language domain of the CST treatment group (p<.001) (Capotosto et al., 2017) as did the Nigerian adaptation (p<.01) (Olakehinde et al., 2019); the Portuguese adaptation found significant differences in language and praxis (Alvares-Pereira et al., 2021) while the Tanzanian adaptation found a significant improvement in language (p<.001), memory (p<.001) and praxis (p<.001) (Paddick et al., 2017).

To investigate other cognitive domains, Hall et al. (2013) selected a battery of neuropsychological measures including, Wechsler memory Scale 3rd edition, Token test, Boston naming test 2, Delis-Kaplan executive function system verbal fluency and Trail making test A and B to specifically assess change in orientation, attention/working memory, memory (verbal and non-verbal), language (expression and comprehension), executive function, and praxis. Significant improvements were found on delayed verbal recall (p<.030), visual memory (p<.028), orientation (p<.003) and auditory comprehension (p<.007) but no other measures.

These findings demonstrated that it is predominantly aspects of cognition involved with language that improve. This perhaps reflects that during CST verbal communication is encouraged and frequent. CST groups stimulate conversation and provide the opportunity for participants to contribute to group discussions without the fear of being judged as right or wrong, thereby preserving communicative capabilities (Capotosto et al., 2017; Hall et al., 2013; Woods et al., 2023) and enabling interaction-based learning through social interactions (Shamay-Tsoory, 2022)

3.4.3 Structural brain changes

Identification of the cognitive domains that respond positively to CST has led to investigations into what areas or networks of the brain are stimulated by CST. Several theoretical mechanisms of neural plasticity have been suggested as underpinning CST (Cespón et al., 2018; Chen et al., 2019; Hall et al., 2013; Liu et al., 2017). Firstly, that CST results in activity-dependent firing of neurons which maintains synapses and neuronal function (Chen et al., 2019; Fields, 2015; Hall et al., 2013; Liu et al., 2017; McFarlan et al., 2023). Secondly, that CST promotes alternative neuronal pathways to perform a function (Barulli & Stern, 2013; Cramer, 2008; Hall et al., 2013; Liu et al., 2017; Stern, 2002). Thirdly, CST increases efficient use of existing networks (Bamidis et al., 2014; Cespón et al., 2018; Hall et al., 2013; Liu et al., 2017; Wenger & Lövdén, 2016).

The development of neuroimaging techniques particularly magnetic resonance imaging (MRI), has enabled the testing of theories of brain function through the measurement of brain volume and observation of neural activity (Maclaren et al., 2014; Raichle, 2003; Raichle, 2015; Raichle & Mintun, 2006). Studies that measured change in cognition and brain function following CST participation found improved measures of cognition and equivocal changes in brain structure (Behfar et al., 2023; Liu et al., 2017; T. Liu et al., 2021). Decreased grey matter was measured in some studies (Liu et al., 2017; T. Liu et al., 2021) with no significant change in total brain volume reported in others (Behfar et al., 2023; T. Liu et al., 2021). Functionally, default mode network connectivity was observed to both decrease (Liu et al., 2017) and increase (Behfar et al., 2023; T. Liu et al., 2021); while no change was observed in the central executive network (Liu et al., 2017; T. Liu et al., 2021) or the language network (T. Liu et al., 2021). A significant increase in the functional connectivity between the memory-related hippocampus with a learning and memory related region of the postcentral gyrus was observed (Behfar et al., 2023). Similar findings are promising for CST utility as the studies used slightly different populations (mild dementia (Liu et al., 2017; T. Liu et al., 2021); mild to moderate Alzheimer's disease dementia (Behfar et al., 2023)) and formats of CST (Chinese adaptation of the CST published manual, twice weekly 45 minute sessions for 7 weeks (Liu et al., 2017; T. Liu et al., 2021; Spector et al., 2006); Cognitive Training programme (*NEUROvitalis*) adapted to CST (*NEUROvitalis senseful*) for people living with Alzheimer's disease, twice weekly 60 minutes for 8 weeks (Behfar et al., 2023)).

The length of the CST interventions (7 and 8 weeks) could have been too short to see structural changes, as it has been suggested that structural changes may take months or years to occur (Cespón et al., 2018). That studies measured no decrease in brain volume is a promising indication of the benefit of CST participation, as in populations where progressive decline is expected, maintenance should be considered a positive outcome (Behfar et al., 2023; T. Liu et al., 2021). The changes observed in brain connectivity associated with internal mentation, cognition (Behfar et al., 2023; T. Liu et al., 2021) and memory (Behfar et al., 2023) suggest that activity-dependent neuroplasticity occurred (Fields, 2015; McFarlan et al., 2023) despite participants' brains being affected by a progressive neuropathology. The findings need to be interpreted with caution as given the small number of participants that completed post-CST scans (n=16 (Liu et al., 2017; T. Liu et al., 2021) and n=13 (Behfar et al., 2023)), there is limited statistical power. While the precise mechanism for changes measured post-CST are yet unclear, these studies provide preliminary evidence of changes that occurred.

Another potential mechanism for change is the recent hypothesis that the reversal of MCI to normal cognition may be possible through emotional and social behaviour effects on the extracellular accumulation of *amyloid*-β peptide pathology associated with Alzheimer's disease (Ávila-Villanueva et al., 2022;

Colavitta et al., 2023). Given the socialisation encouraged in the group environment of CST, this is potentially another mechanism to explain how CST works.

Understanding how CST works is limited by our understanding of the brain itself. While neuroanatomy is known and neural connections are beginning to be understood, how information is processed is still not explicitly known (Lam, 2016). The methodological constraints of imaging techniques, analysis and interpretation of this data limits discovery (Gilmore et al., 2021). From early medical discovery relying on autopsy to visualise changes in brain structure, now it is possible to use non-invasive neuroimaging techniques to understand the form and function of the brain (American Psychological Association, 2014; Noble et al., 2019). In the last 10 years, the science behind imaging has progressed at a rate reflective of the Information Age of the world (Gordon et al., 2017). As these tools continue to develop and the field of cognitive neuroscience progresses, the opportunity to better understand and identify the mechanisms of action that create the change in people observed following CST participation will continue.

3.5 CST in ARC

The Cochrane Systematic Review (Woods et al., 2023) included an analysis of CST studies by dwelling and identified 10 studies that only included ARC residents as participants (Baldelli et al., 2002; Baldelli et al., 1993; Capotosto et al., 2017; Coen et al., 2011; Gibbor et al., 2021; Graessel et al., 2011; Lin et al., 2018; Mapelli et al., 2013; Middelstädt et al., 2016; Tanaka et al., 2021). The intervention used in these studies varied by: the length of time that CST was delivered from 4 weeks (Baldelli et al., 1993) through to 1 year (Graessel et al., 2011); the programme format, individual (described as reality orientation) (Gibbor et al., 2021), following the 14-session CST programme in the published manual (Capotosto et al., 2017; Coen et al., 2011) or based on the manual (Lin et al., 2018); and some included other activities such as seated exercise (Tanaka et al., 2021) and practising activities of daily living (Graessel et al., 2011). This heterogeneity reflects the broad criteria for a CST programme, that the intervention targets cognitive and social functioning and if multicomponent, that more than 50% of the time was spent on cognitive stimulation activities (Clare & Woods, 2004; Woods et al., 2023).

Many of these studies had small sample sizes and a used variety of assessment tools, measuring cognition, quality of life, depression, mood and behaviour. An overall positive effect was found for cognition (Standard Mean Difference SMD): 0.60, 95% CI: -0.01 to 1.20, 9 studies) with large heterogeneity between studies ($Chi^2 = 60.46$, degrees of freedom (DF) = 8 ($P < .00001$); $I^2 = 87\%$). A subgroup analyses found no difference in cognition effect sizes for setting (community versus ARC; $Chi^2 = 0.03$, df = 1. P = .86, $I^2 = 0\%$) (Woods et al., 2023).

The studies that delivered CST using the published "Making a Difference" manual (Spector et al., 2006) (including cultural adaptations) are discussed. There are three ARC intervention studies (Capotosto et al., 2017; Coen et al., 2011; Lin et al., 2018) that evaluated the effectiveness of CST on cognition and quality of life. One of these was a small study that compared CST (n=14) to a dose matched, usual care control group of ARC residents (n=13) (Coen et al., 2011). Eligible residents had mild to moderate dementia (MMSE of 10-23/30) and were randomised to group. The CST group improved on MMSE (small statistically significant) and Quality of Life – Alzheimer's disease, but not on the ADAS-Cog or measures of global functioning, depression, behaviour, or anxiety. The CST group MMSE mean change was 0.8 points (standard deviation (SD) $\pm$ 3.6). Another way to interpret the results is to consider whether the change would be considered clinically meaningful (Garg et al., 2022). Using the minimum clinically important difference (MCID) of a measure, considers whether patients and clinicians would have perceived a change (Copay et al., 2007; Jaeschke et al., 1989). An MCID for the MMSE, developed from a distribution-based approach using 51 RCTs with 12, 449 patients, is 1.6-2 points (Watt et al., 2021). Therefore, a clinical interpretation of the MMSE mean change in this study would be that cognition was maintained rather than improved. The lack of change on ADAS-Cog may be due to lack of responsiveness of this measure for people living with mild dementia (Chiu et al., 2023; Garg et al., 2022; Rentz et al., 2021), or that the total score remained the same but subscale scores may have increased or decreased (Balsis et al., 2015). An MCID for Quality of Life – Alzheimer's disease has not yet been established (Kahle-Wrobleski et al., 2017).

Similarly, a small study of an Italian adaptation of CST compared CST (n=20) to a dose matched control group doing general activities (n=19) (Capotosto et al., 2017). Eligible residents had mild to moderate dementia (Alzheimer's disease, vascular or mixed; MMSE $\geq$ 14) and were randomised to group. The CST group maintained their MMSE score (change in group score median = 0.18) and small significant improvements on the ADAS-Cog (change in group score median = -0.9), narrative language test, the Cornell scale for depression in dementia, the social and emotional loneliness scale and the Quality of Life – Alzheimer's Disease, but not on a measure of short-term memory (the backward digit span). The maintenance of MMSE score over time could be interpreted as a clinically positive outcome, as participants' cognition could be expected to deteriorate overtime due to the progressive neuropathology of dementia. Interpreting the ADAS-Cog measured change using an MCID of 4-5 points (Watt et al., 2021) also suggests that cognition was maintained.

Another study was of a Taiwanese adaptation of CST, which compared dose matched CST (*n*=30) and reminiscence therapy (*n*=43) to a usual care control group (*n*=32) (Lin et al., 2018). The CST programme was based on the published CST manual but modified to weekly, 50-minute sessions for 10 weeks. The adaptation was described as 'culturally appropriate' without an explanation of why this modification was culturally appropriate for Taiwanese participants. Eligible residents had mild to moderate dementia (MMSE< 17 with below senior high school education, or <24 if above senior high school) and were randomised to group. Data was analysed for participants who had $\geq$ 70% attendance (CST *n*=25, reminiscence therapy *n*=40), and group participants were categorised by their behavioural and psychological dementia symptoms (dispute, return and dissociate). This resulted in group sizes that ranged from 2 to 26). Overall, CST and reminiscence therapy had positive effects on MMSE (CST mean score changes (SD) in the three symptom groups were 3.50 (3.57), -1.62 (2.90) and 3.00 (4.24) points; reminiscence therapy were -0.22 (3.41), 1.5 (2.59) and 0.14 (2.91) points)). Interpreting these score changes with the MMSE MCID (1.6-2 points), a clinically meaningful improvement of cognition would have been seen for 2 of the CST groups, and maintenance (no change) of cognition for reminiscence therapy. However, it is not known if the MCID is the same for the Chinese MMSE. CST had a greater effect on quality of life than reminiscence therapy with CST change scores ranging from 10.62-15.9 points, and reminiscence therapy 1.70-2.91 points.

While these three studies shared the methodological issues of small sample sizes and not being powered to detect a statistically significant difference, participants were randomised and two of the studies used blinded assessors and dose matched control groups (Capotosto et al., 2017; Coen et al., 2011) to improve study quality. All participants had a diagnosis of dementia however different MMSE cut off scores were used for mild or moderate dementia, Lin et al. (2018) only used an upper score cutoff resulting in the inclusion of two participants with severe dementia and Capotosto et al. (2017) included Alzheimer's disease, vascular or mixed type dementia (which was not stated by the other studies).

There are challenges to using MCIDs as the measures themselves may be affected by methodological issues (Tahira et al., 2021; Watt et al., 2021). There are two main approaches to determine MCID. The anchor based method uses expert opinion or patient perceptions to determine the MCID, and the distribution based method uses a standard deviation of 0.4 or 0.5 of the baseline or mean change standard deviations (Cohen et al., 2022; Copay et al., 2007; Tahira et al., 2021; Tanaka & Yamagami, 2023; Watt et al., 2021). The MCID may also not be generalisable to other populations. Predominantly the interest in the ADAS-Cog score has been driven by establishing if clinical trials of disease modifying Alzheimer's disease interventions were beneficial and so are not appropriate for people with non-Alzheimer's disease dementia (Andrews et al., 2019; K. Y. Liu et al., 2021; Watt et al., 2021). Similarly, the MCID for MMSE have been developed from community dwelling rather than ARC populations (Burback et al., 1999; Howard et al., 2011; Watt et al., 2021).

Three additional studies delivered CST as per the published manual with a mixed sample of PLwD in ARC and in the community (Alvares-Pereira et al., 2021; Wong et al., 2018; Zubatsky et al., 2023). A feasibility study exploring a Hong Kong Chinese CST adaptation for cultural appropriateness included 5

ARC participants in their sample of 30 (Wong et al., 2018). The number of ARC residents in two studies exploring if CST outcomes were different for PLwD in ARC or in their own homes, was also small (Alvares-Pereira et al., 2021). In a Portuguese adaptation of CST, residential participants lived in a nursing home (n=23), psychogeriatric centre (n=32) and rehabilitation centre (n=11); and community dwellers were outpatients (n=14) or attended a day centre (n=25) (Alvares-Pereira et al., 2021). After randomisation to intervention or control groups, 12 ARC residents received CST. A study in Missouri, America compared the effect of where a person lived and the healthcare setting where CST was delivered (academic clinics and hospital based) (Zubatsky et al., 2023). Of the 173 participants, 22 were ARC residents and included in the community sample of 85 participants. These two studies found CST was beneficial regardless of where a person lived however the proportion of ARC residents in these studies was small.

Overall, the findings from these early studies suggest that CST may be beneficial for cognition in ARC residents with mild to moderate dementia and is likely due to more than the social interaction of group activities. Many of these early studies are small and care needs to be taken in interpretation of their findings. A definitive clinical trial is needed that evaluates the effectiveness of CST in ARC residents.

3.6 The worldwide dissemination of CST

A CST group is available in at least 38 countries and on every continent except Antarctica (University College London, 2023). The global availability of the CST programme is due to the accessibility of CST manuals and a CST resource website. The CST training manual for group leaders was published following the RCT (Spector et al., 2003). There are now three CST manuals: “Making a Difference”, the original CST format (Spector et al., 2006); “Making a Difference 2”, maintenance CST including a training DVD (Aguirre et al., 2012); “Making a Difference 3”, individual CST (Yates et al., 2014). Versions have been published in Chinese, Danish, German, Italian and Norwegian. A website holds CST resources, including links to purchase manuals, guidelines for cultural adaptations (Aguirre et al., 2014), a standardised implementation plan (Stoner et al., 2020) and notices of upcoming conferences (https://www.ucl.ac.uk/international-cognitive-stimulation-therapy/). There is an international CST groups page for CST providers from outside the UK to upload the details of their country's CST groups. Each country page contains the key contact details, enabling CST providers to easily link with the CST network in their country. These pages also contain a mixture of information about CST training, CST provision in that country and research projects.

3.7 The implementation of CST in Aotearoa New Zealand

The first CST programme was set up in the Hawke's Bay, NZ after a doctor bought knowledge back from a 2009 conference in the UK (Cheung & Peri, 2014). Four years later CST was still only available to PLwD in the Hawkes Bay (Cheung & Peri, 2017) however, the National Dementia Care Framework (Ministry of Health, 2013b) included CST as one of two specific treatments recommended as good practice for PLwD. This Framework provides guidance to funders, planners and deliverers of dementia care services and so the inclusion of CST in this document was a critical step for high level support and growth of CST in NZ.

A small pilot (n=18) of a NZ adaptation of CST found improvements in participants' depression, cognition and quality of life, and that content or contextual modifications were not needed to deliver the programme in NZ (Cheung & Peri, 2014). Recommendations made from the successful pilot were: development of a CST training and accreditation programme in NZ; inclusion of CST as a treatment option in District Hospital Board Dementia Care Pathways; development of maintenance CST programmes (Cheung & Peri, 2014).

The implementation of CST throughout NZ was due to the commitment of the two health professionals (Gary Cheung and Kathy Peri) who had piloted CST. They secured funding to develop and deliver one-day training workshops and between May 2015 to December 2016 trained 150 CST facilitators around NZ, further funding enabled another 245 facilitators to be trained (Cheung & Peri, 2017). The range of healthcare providers trained to deliver CST included nurses, occupational therapists, diversional therapists, healthcare assistants and activities co-ordinators/assistants. Their place of work also varied: ARC, Alzheimer's/dementia societies, District Hospital Boards, non-government organisations, charitable trust programmes and educational institutions (Cheung & Peri, 2019). These organisations could now offer CST to PLwD. The ongoing work of Cheung and Peri as key trainers has enabled them to continue to grow a network of trained CST facilitators throughout NZ. A part of this work has been the development of a Māori adaptation of CST which was launched on 1 March, 2023 (Triponel, 2023).

3.8 CST as a vehicle for delivering fall prevention exercises

The interrelatedness of cognitive function and motor performance underpins the fall risk factors for PLwD in ARC (Li et al., 2018; Taylor et al., 2017; Zhang et al., 2019). Fall prevention approaches need to consider this and address not only physical fall risk factors but also the fall risk of cognitive dysfunction in this population (Segev-Jacubovski et al., 2011). Fall risk could be reduced by improving cognition with cognitive exercise as well as strengthening lower limbs and retraining balance using a top-down (cognitive) and a bottom-up (physical) approach. With early CST evidence suggesting cognition is maintained or improved in PLwD in ARC (Woods et al., 2023), CST could be the cognitive exercise that is combined with physical exercises to develop a fall prevention exercise programme for ARC residents.

The cognitive benefit for PLwD in ARC is the dominant driver for using CST. However, there are features of the CST programme that lend it to being the cognitive exercise type of choice for the delivery of physical fall prevention exercises. These are:

- The structure of the CST programme (Spector et al., 2006). The CST programme is highly structured with each sessions' theme and activities outlined in the published manual with their time allocation. Each 45-minute session is divided into an introduction (10 minutes), main activity (25 minutes), summary and farewell (10 minutes). Repetitions of exercise could be easily added into this structure.

- An existing workforce of trained CST facilitators (Cheung & Peri, 2019). NZ has trained CST facilitators delivering CST in ARC. These facilitators are ARC staff who are skilled at delivering group activities and have an existing relationship with residents.
- CST is already in the ARC programme of resident activities. There would be no additional use of health resource as CST is already in the work plan of ARC activities staff.
- A one-off training cost. The CST facilitators would require training in the safe delivery of strength and balance exercises. This would be best delivered by a physiotherapist who traditionally deliver falls prevention exercises (Sherrington & Tiedemann, 2015). There would be no ongoing running costs as CST is already being delivered.
- Easy dissemination of programme updates. The network of CST providers around NZ and globally enables any development or changes to CST to be disseminated quickly through already established channels.

3.9 Summary

This chapter introduced cognitive exercise as a non-pharmalogical treatment to maintain or improve cognition for people with cognitive dysfunction. Of the three types of cognitive exercise, reviewing the literature identified Cognitive Training as the one that has been combined with physical exercise and investigated to prevent falls in older adults. However, following the current guidelines for treatment of people living with mild to moderate dementia, CST was chosen as the cognitive exercise to be combined with physical exercise to address the first objective of the thesis.

Numerous studies have shown that CST improves cognition, with improvements also demonstrated in communication, behaviour and activities of daily living. There is a small but growing number of studies that successfully delivered CST to ARC residents and improvements were seen similar to those found in community dwelling older adults living with dementia. Combining the key elements of a fall prevention exercise programme (strength, balance and functional exercises) with CST may result in an effective falls prevention exercise programme for ARC residents. With a national network of trained CST facilitators working in ARC in NZ, this workforce could be trained to deliver a such a programme.

Chapter 4 Development of the CogEx programme

This chapter describes the development of a falls prevention programme that addresses the fall risk factors associated with cognitive dysfunction (Marshall et al., 2023; Muir et al., 2012; Smith et al., 2023) and the most common physical fall risk factors for older adults (decreased muscle strength and balance) (Close & Lord, 2022; Tinetti et al., 1988). CST (Woods et al., 2012; Woods et al., 2023) was combined with the critical components of fall prevention exercise programmes for older adults (Sherrington et al., 2020). Combining progressive balance and physical functional exercises with CST, into a programme called CogEx (cognitive and exercise), addressed these modifiable falls risk factors.

The idea to develop a fall prevention programme combining cognitive and physical exercise grew from the clinical problem of increased falls in ARC, particularly in PLwD. In addition, published research around fall risk factors and knowledge of the lack of effective fall prevention interventions for older adults living with dementia in ARC contributed to the development of the fall prevention programme. A team of academic clinicians with experience in CST (Drs Gary Cheung and Kathy Peri), fall prevention exercise programmes (Dr Denise Taylor and Elizabeth Binns) and medical care of older adults living in ARC (Dr Ngaire Kerse), drew on their respective expertise to combine progressive balance and functional training exercises with CST to develop the CogEx programme. CogEx aimed to reduce fall risk by improving cognition with cognitive exercise as well as strengthening lower limbs and retraining balance.

CogEx used the *twice weekly, 45 minute session for 7-weeks* structure of the CST programme (Spector et al., 2006). Physical exercises based on balance and functional training which have shown benefit in reducing falls in older adults living in ARC (Gulka et al., 2020), were embedded into CST sessions by manipulating the timing of activities within the programme. The following evidence-based principles underpinned CogEx programme development (see Chapter 2 and Chapter 3 for details):

- The critical components of a fall prevention exercise programme in older adults are balance and functional exercises
- Strength and balance can be improved in older adults
- CST improves cognition in PLwD

The development of the strength and balance exercise component of CogEx programme was informed by clinical experience, previous fall prevention research (Binns & Taylor, 2011; Kerse et al., 2009; Taylor et al., 2020; L. M. Taylor et al., 2023), an understanding of the physiological systems of balance and the principles of rehabilitation. This included:

- Task specificity – muscles are activated according to task (Hawley, 2008; Tresch & Jarc, 2009; Yiou et al., 2018) and this task specificity is one of the neural principles underlying plasticity and motor learning (Kleim & Jones, 2008). Exercise specificity is crucial, and exercises were selected that were functional i.e. in weightbearing and were linked to everyday movements that participants would be familiar with.
- Overload – the body responds to a physiological stimulus over and above what it normally experiences (Arnold & Bautmans, 2014; Borde et al., 2015; Häkkinen et al., 2000; Powers & Howley, 2007) so to improve balance it must be challenged (Berg & Kairy, 2002). Different options of hand support for an exercise were provided, (2 hands, 1 hand or no hands), and provided a way to safely challenge each participant's balance at an individual level.
- Progression – as the physiological balance systems adapt in response to the overload, functional improvements create a new normal state. Therefore, exercises need to be progressed for overload to continue to be applied (Becker et al., 2003; Powers & Howley, 2007). Exercises were progressed by changing the speed or amplitude of the movement as well as changing the base of support, or the amount of hand support used.
- Balance is the result of integrating multiple sensorimotor systems – somatosensory, visual, auditory and vestibular inputs all contribute to the maintenance of balance (Boisgontier et al., 2017; Kiss et al., 2018; Massion, 1994; Schedler et al., 2021) and sensory exercises were included

in the selected exercises to ensure integration of sensory inputs during balance.

Exercises were designed to be in standing, incorporate movement and target major muscle groups of the lower limb, and integrate sensory inputs important for balance. Exercises could be individually tailored by decreasing the amount of hand support, encouraging more repetitions of an exercise, and altering the speed or the amplitude of the movement. The exception was the spinal flexion exercise which was to be completed in sitting for safety. Strengthening exercises were selected that incorporated balance, for example, standing and flexing the knee to bring the heel toward the bottom strengthens the hamstrings but also decreases the person's base of support and challenges balance due to standing on one leg. Body weight was used for resistance.

The key principles of the physical exercises in the CogEx programme were:

- Safety
- Fun
- Challenging
- Effortful
- 30 second bouts

To keep the total session time to no more than an hour, exercises in standing were to be performed during the routine CST welcome and farewell songs and a 10-minute exercise session was included (see Table 4.1). Rethinking the delivery of the CST activities was encouraged to maximise movement and weightbearing opportunities, for example, encouraging people to stand to reach across the table for an item or to walk over to write on the whiteboard.

Table 4.1

CogEx physical components.

Welcome & farewell song exercises 30s of each exercise	Sit to stand	Use both hands to push up Push up with one hand No hand support
	Sideways walking	Support No support
	Calf raises	Support No support
	Standing with feet together	Support No support
	Standing heel to bottom	Support No support
Head Nod up/down Turn side/side	Sitting Standing (support or no support)	10x each in time to the music. Rotate thru movements for 30s
Focus eyes on own fingertip Move head from side to side Move head up/down	Sitting Standing (support or no support)	As above
Look at own finger pointing to corner of the room then diagonally to point at the floor	Sitting Standing (support or no support)	Big slow movements for 30s
Elbow to opposite knee	Sitting Standing (support or no support)	30s
Bend to touch the ground (all in sitting)	To your toes To the one side then the other To the opposite foot	10x each movement rotate thru movements for 30s
Backwards chair bends	Sitting arms crossed over chest Standing arms crossed over chest	Sit up tall as you lift your arms, when arms can go no higher gently lean back
Pass object to neighbour Clockwise Anticlockwise	Sitting Standing (support or no support)	15s one way 15s the other way
Write name on ground with toe	Sitting Standing (support or no support)	30s

The exercise routine for the welcome song used five exercises which were repeated during the farewell song. Exercises were performed in standing with a chair close by for hand support, if required. Each exercise was completed continuously for 30 seconds. The run time of the song (typically 3 minutes) encouraged continuous movement and aimed to provide aerobic exercise and increase the person's heart rate, as well as challenge balance and increase strength. The 10-minute exercise routine included eight exercises selected to challenge and improve balance, be performed in standing, and progressed by decreasing hand support, increasing movement amplitude and speed. Basic vestibular exercises were also included. Each person was encouraged to do as many repetitions as they possibly could in the 30 second bout. The exercises were the same for every session so participants could become familiar with the routine through repetition (Rai et al., 2018) and enable balance self-efficacy to increase as the exercises felt easier to perform and progressions were made within each exercise (Soh et al., 2021).

The maximal physical exercise dose achieved by CogEx is less than the 2-3 hours per week recommended for fall prevention in community older adults (Lesinski et al., 2015; Sherrington et al., 2020) however, for older adults living in ARC there is no recommended exercise dose. For ARC there is a general recommendation to promote exercise as part of a multidomain fall prevention intervention (Montero-Odasso et al., 2022). Older adults living in ARC are typically inactive and may be sedentary for up to 79% of their day (Kong et al., 2023; Sedentary Behaviour Research Network, 2012), so doing any fall prevention exercise could be considered better than doing none. To allow for a gradual accumulation of exercise dose, the focus in CogEx was on the time spent doing an exercise rather than number of repetitions performed and enabled each person to do more as they felt able. Physical exercise was interspersed with cognitive exercise to incorporate rest periods. Completing the CST elements of CogEx in standing (for example standing around the table rather than sitting, asking the participant to walk up to the white board and write on it instead of the facilitator) was also to be encouraged to increase the amount of time participants spent weightbearing in standing through incidental activity.

A CogEx programme manual was developed to support the delivery of CogEx (Appendix A CogEx facilitator manual). It contained the principles of CogEx, the session structure, photographs of each exercise with instructions and progressions and a one-page exercise sheet to be used for planning and recording the exercises for each session. The manual was used as the basis of a 1-hour training session, which also included practicing the exercises and progressions, familiarisation with the 30-second interval timer and how to use the exercises record sheets for planning and recording. This training format had been used by Taylor and Binns in previous fall prevention research (Kerse et al., 2009; L. M. Taylor et al., 2023).

The national training programme of CST facilitators had created a pool of health professionals trained to deliver CST (nurses, occupational therapists, diversional therapists, healthcare assistants, activities co-ordinators/assistants) (Cheung & Peri, 2014, 2019) who could be given further training and support to deliver the additional physical fall prevention exercises. There were several advantages to using this existing workforce: the facilitators were already experienced in working with PLwD; they knew the CST programme; and other than training specifically to deliver CogEx, there were no additional delivery costs to the fall prevention component as the CST programmes were already being delivered in ARC.

This chapter described how the idea to develop a fall prevention programme that combined cognitive and physical exercises grew from a clinical problem. The programme that was developed, CogEx, drew on the clinical knowledge of a multidisciplinary team and combined CST and physical exercise. Underpinning the choice of physical exercises were the principles of motor learning, exercise prescription, rehabilitation and current fall prevention guidelines. Following the development of the CogEx programme, a feasibility study was planned to ascertain whether a fully powered RCT to test the effectiveness of CogEx to decrease falls in ARC was warranted.

Chapter 5 The CogEx feasibility study

This chapter comprises the following manuscript:

Binns, E., Kerse, N., Peri, K., Cheung, G., & Taylor, D. (2020). Combining cognitive stimulation therapy and fall prevention exercise (CogEx) in older adults with mild to moderate dementia: A feasibility randomised controlled trial. *Pilot and Feasibility Studies, 6*(1), Article 108. https://doi.org/10.1186/s40814-020-00646-6

To maintain consistency of style throughout the thesis, the manuscript is presented here in a format that differs slightly from the published manuscript. In this publication we have used the term residential aged care (RAC), rather than ARC, to be consistent with the terminology used by other manuscripts published in the journal.

5.1 Prelude

A fall prevention exercise programme that addresses cognition as well as physical fall risk factors is novel for PLwD in ARC. Following the development of the CogEx programme, a feasibility study was undertaken to assess the acceptability of the programme, refine research processes and to determine if a fully powered RCT should be undertaken.

5.1.1 The importance of a feasibility study

The RCT methodology provides rigorous testing of an intervention and has been described as the gold standard of health research (Jones & Podolsky, 2015). In the hierarchy of the levels of evidence, systematic reviews of RCTs and RCTs are ranked the highest for therapeutic research (1A and 1B respectively) (OCEBM Levels of Evidence Working Group, 2011), as they are designed to be unbiased, have less systematic errors and the observed effects are easier to attribute to the treatment (Barton, 2000; Burns et al., 2011). However, there are more unknowns in an RCT than whether the intervention being tested is effective or not.

Conducting a feasibility study prior to undertaking an RCT is an important step in the development process of therapeutic intervention research and can enhance the success of the main study (Eldridge et al., 2016). While the objective of an RCT is to evaluate the effectiveness of an intervention, a feasibility study aims to determine the feasibility of the methods and procedures planned to be used in an RCT, whether further refinement of the intervention is needed and whether a fully powered RCT should be undertaken (Abbade et al., 2018; Abbott, 2014; Sim, 2019; Yardley et al., 2015). A feasibility study has five distinctive objectives, they are:

- Evaluation of recruitment capability and the resulting sample characteristics
- Evaluation and refinement of data collection procedures and outcome measures
- Evaluation of intervention acceptability and suitability and study procedures
- Evaluation of resources and ability to manage and implement the study and intervention
- Preliminary evaluation of participant responses to the intervention (Orsmond & Cohn, 2015)

Determining the success of a feasibility study is based on the criteria set for each feasibility objective by the researchers, rather than achieving a statistically significant result like an RCT (Abbade et al., 2018). Qualitative or quantitative methods may be appropriate depending on the objective being evaluated and it is common to use a mix of methods (O'Cathain et al., 2015). For example, to evaluate if enough participants can be recruited, a count of the number of people invited and those agreeing to participate in a study is taken, a percentage calculated for the recruitment rate and then compared to a rate determined from similar studies (quantitative) (Walters et al., 2017); or to understand participants' experience of an intervention a focus group is used and data analysed to generate themes about the acceptability of the intervention (qualitative) (Yardley et al., 2015).

Given the investment of time and money needed to complete an RCT (Morgan et al., 2018), and in the case of falls prevention studies, the large number of participants required to achieve adequate statistical power (Schwenk et al., 2012), a well-planned feasibility study was essential to determine if a fully powered RCT to evaluate the effectiveness of the CogEx programme to prevent falls in PLwD in ARC study was feasible to undertake (Tickle-Degnen, 2013).

The specific feasibility questions that would contribute to refinement of the CogEx programme were:

1. Will the CogEx programme work as planned?

   Did the physical exercises combine with the CST structure?
   Was the manual fit for purpose?
   Was the facilitator training adequate?
   Did the class record sheet accurately capture the exercises that were delivered?

2. Was CogEx an acceptable programme?

   Was the CogEx programme acceptable to group participants?
   Was the CogEx programme acceptable to the group facilitators?
   What did the facilitators think about the training to deliver CogEx?
   Was it possible to deliver the programme as presented in the manual?
   what helped or hindered the running of the group?

To refine the research processes for an RCT, the questions were:

3. Is the recruitment strategy right?

   What is the recruitment rate?
   What are the characteristics of the PLwD who choose to participate?

4. What secondary measures should be used to assess participant characteristics to understand the mechanism of change/impact observed?

Establishing the feasibility of collecting fall data as the primary outcome measure was not an aim of the study as the researchers had an established process for collecting accurate falls data for participants from auditing ARC incident reports (Taylor et al., 2020).

To answer these questions, a mixed-methods feasibility randomised controlled trial (RCT) was undertaken.

5.1.2 Supporting documents

Supporting documents associated with this chapter can be found in Appendices B–G. They are:

Appendix B CogEx HDEC ethical approval
Appendix C CogEx Participant Information Sheet
Appendix D CogEx Consent Form
Appendix E CogEx assessments
Appendix F CogEx Guiding questions
Appendix G CogEx feasibility study published manuscript

Supplementary information was included with this publication and can be found in Appendices H–L:

Appendix H CogEx Additional file 1 (TIDier checklist)
Appendix I CogEx Additional file 2 (CogEx exercises and muscles and physiological systems targeted)
Appendix J CogEx Additional file 3 (Exercise recording sheets)

Appendix K CogEx Additional file 4 (CogEx participants' change on each outcome measure)

Appendix L CogEx Additional file 5 (CST participants' change on each outcome measure)

Published manuscript begins below the line.

5.2 Introduction

Dementia is a neurodegenerative disorder in which there is deterioration in memory, thinking, behaviour and the ability to perform everyday activities (Scott & Barrett, 2007). It mainly affects older adults, although it is not considered a normal part of ageing (Scott & Barrett, 2007). Globally it is estimated there are 47.5 million people living with dementia (PLwD) and 7.7 million new cases diagnosed every year. It is predicted that the worldwide number of PLwD is likely to rise to over 75.6 million by 2030, and almost triple to 135.5 million by 2050 (World Health Organization, 2016).

Cognitive stimulation therapy (CST) is a treatment developed for people with mild to moderate dementia. CST aims to enhance cognitive and social functioning using group therapy incorporating reality orientation, reminiscing, socialising and actively stimulating PLwD, whilst providing an optimal learning environment and the social benefits of a group. The therapy is standardised into a published manual (Spector et al., 2006) and guides the CST facilitator through set topics of engagement while allowing the group participants to choose the specific content. The 7-week programme is comprised of a 1-hour group activity session twice a week. CST is the only evidence based treatment recommended for people with mild to moderate dementia in the NICE dementia guidelines (National Institute for Health and Clinical Excellence, 2006) based on the evidence that it can improve cognition in people with mild to moderate dementia over and above any medication effects (Kim et al., 2017; Woods et al., 2012). The Dementia Care Framework (Ministry of Health, 2013b) in Aotearoa New Zealand, recommends CST as one of only two specific treatments considered as *good practice* for PLwD. To support this recommendation one-day CST programme training of group facilitators occurred nationally (Cheung & Peri, 2019), and CST is now available through community-based (CB) programmes and in residential aged care (RAC) facilities.

The incident rate for falls in community dwelling older adults is 0.65 falls per person-year and for older adults living in RAC this increases to 1.7 falls per person-year (Rubenstein, 2006). Dementia is an independent risk factor for falls and PLwD are twice as likely to fall and sustain an injury than those without dementia (Suttanon et al., 2010). With the rise in prevalence of dementia, falls in older adults with dementia is an area of serious concern in health care.

Falls in PLwD are multi-factorial (Shaw, 2007), as they are in older adults (Ambrose et al., 2013). Superimposed on the risk factors for falls in older adults are specific clinical features in PLwD that contribute to falls, the two most commonly recognised being cognitive impairments and gait abnormalities (Amboni et al., 2013). Cognitive impairments and gait abnormalities have been found to be interrelated (Montero-Odasso et al., 2012) reflecting that gait is no longer considered a purely motor task but an activity that requires interaction with the environment, attention and executive function (Amboni et al., 2013; Erickson et al., 2009; Morris et al., 2016). In PLwD these abnormalities can be observed as impaired judgment, decreased walking ability, lack of visual-spatial perception, and a loss of ability to recognise and avoid hazards (Burton et al., 2015).

Strengthening and balance exercises are the critical components in falls prevention interventions for community dwelling older adults (Sherrington et al., 2011) and are highly associated with falls (Franciulli et al., 2019). However, fall prevention interventions that work in healthy older adults may not work in PLwD. A meta-analysis identified only three randomised controlled trials assessing the effectiveness of exercise programmes to reduce falls in community dwelling older adults with dementia. While all three studies included strength and balance exercises and the results looked promising, more research is required to ascertain these are important components to include in falls prevention interventions for PLwD (2015).

This leads us to ask whether effective falls prevention for PLwD can be developed that incorporates physical and cognitive exercise? Is it possible to reduce falls risk by improving cognition with cognitive exercise as well as strengthening lower limbs and retraining balance in PLwD using a top down (cognitive) and a bottom up (physical) approach? CST is a programme that can improve global cognition in PLwD over and above the effect of medication and is available through a widespread, trained workforce in Aotearoa New Zealand. The highly structured CST programme lends itself to easily incorporating physical exercise without becoming complex thereby using the existing workforce and not increasing the use of health resource to deliver falls prevention to this at-risk population. We hypothesise that combining falls prevention exercises with CST (CogEx) can deliver falls prevention to PLwD through already established dementia care providers nationally. Prior to embarking on a full-scale clinical trial there are several feasibility issues to address.

Aim

The aim of this study was to assess the feasibility of undertaking a full scale randomised controlled trial to test the effectiveness of CogEx in decreasing falls in PLwD. For the full scale RCT the primary outcome is falls. This study will explore which secondary outcome measures are appropriate to measure the other potential benefits of CogEx and add important information for statistical modelling in the future RCT.

The specific objectives were:

1. To test recruitment strategy of facilities and individuals, percentage recruited and the resultant characteristics of PLwD who participated

2. To test the appropriateness of data collection procedures and select secondary outcome measures

3. To test combining falls prevention exercise into CST

4. To test training of CST facilitators to deliver CogEx

5. To test intervention fidelity of CogEx delivered by facilitators

6. To explore the facilitators perceptions of delivering CogEx

7. To explore the participants' experience of CogEx

Establishing the feasibility of collecting falls data was not a study objective. The research team have a feasible and accurate method of recording falls which involves blinded assessors auditing the incident reports at an RAC facility for falls over a specified date range. We are currently using this method in another falls prevention study being conducted in RAC facilities (Taylor et al., 2020).

5.3 Methods

Design

A mixed methods study design was used to evaluate the feasibility issues in two settings (Residential Aged Care and Community Based) (Creswell & Hirose, 2019). This included quantitative outcome measures in a randomised controlled study comparing CST (control group) with CogEx (intervention group) and qualitative evaluation of the experience of study participants, group facilitators and blinded assessors. Ethical approval was given from the New Zealand Health and Disability Ethics Committee (16/NTB/121).

Setting

The Residential Aged Care (RAC) facility had a mixture of residents living in rest home and private hospital level care. For the Community Based (CB) setting, a regional non-government organisation (NGO) supporting PLwD and their family/whanau delivering CST in the community had agreed to take part.

Recruitment of individual participants

The initial inclusion and exclusion criteria for participants are listed in Table 5.1. The RAC clinical manager used their knowledge of the residents and applied the inclusion and exclusion criteria to screen all residents and identify those who may be eligible to participate in the study. The clinical manager then explained the research to individual residents and invited them to participate as well as contacting the Next of Kin (NoK) to explain the research and their relative's potential involvement. If agreeable to participating in the study, the participant and their NoK's names and contact details were forwarded to the primary researcher who then gave resident contact details to a research assistant (RA).

Table 5.1

Eligibility Criteria

Inclusion criteria	1. Aged 65 years or older
	2. Living in their own home or residential aged care
	3. A diagnosis of mild to moderate dementia
	4. Mobile with or without an assistive device
	5. A MoCA score between 15-26 out of 30
	6. Able to have a meaningful conversation
	7. Able to hear well enough to take part in small group discussion
	8. Able to see well enough to see pictures
	9. Likely to remain in a group for 1 hour
Exclusion criteria	1. A recent significant medical illness
	2. Unable to participate due to severe visual or hearing impairment
	3. Wheelchair/bed bound or unable to walk
	4. Receiving terminal or palliative care.

Note. MoCA = Montreal Cognitive Assessment (0-30, a higher score = better cognition)

Potential CB participants and their NoK were informed about the study by an NGO keyworker and given the study information. The keyworker followed up by phone a week later. If agreeable to participating in the study, the participant and their NoK's names and contact details were given to the primary researcher who then gave resident contact details to a research assistant (RA).

Participants were asked to give verbal and written consent by the RA before completing the baseline assessments, and the NoK were asked to give verbal or written assent by the clinical manager or the primary researcher.

Procedures

The participants were enrolled by the RA prior to baseline assessment. At baseline assessment demographic information, medical conditions including history of falls, current medication and use of walking device were recorded for each participant as well as asking if they had experienced pain or fatigue over the past few days (Kerse, Peri, et al., 2008). Outcome measures were also completed. The RA assessors were blinded and remained blinded throughout the study. It was not possible to blind the staff facilitating the groups or participants to group allocation.

Randomisation and allocation

The primary researcher created a computer-generated sequence and used this to randomise participants. The primary researcher allocated participants to a group within the setting where they lived and then sent the group lists to the staff who were facilitating the groups.

As this was a feasibility study, no sample size was statistically calculated. The intended sample size of 32 participants was based pragmatically on the usual size of a CST group being 8-10 participants and the feasibility study using two CogEx groups and two CST groups.

Interventions

The group facilitators were staff who already ran group exercises and activities, had completed the one-day CST training and were asked by their manager to facilitate the groups for the study. None of the facilitators had run CST prior to the study. The facilitators completed CogEx training in small groups. The training sessions were an hour long and included working through the CogEx manual (available on request), discussing the principles of the programme (safety, fun, session activities, challenge, effort, 30 second bouts of exercise, safety), practicing the 3-minute exercises to a song, practicing the strength and balance exercises and the progressions, discussing the attendance and exercise record sheet and practicing with the 30 second interval timer. The facilitators were asked to check with participants at the start of each session if they had any pain. The TIDiER Checklist is an additional file (see Appendix H CogEx Additional file 1 (TIDier checklist)).

Cognitive Stimulation Therapy (control group)

CST was delivered as per the CST manual for group leaders (Spector et al., 2006) which was a group session for 1 hour twice a week for 7 weeks, with each of the 14 sessions having a different theme.

CogEx (intervention group)

CogEx was CST (as above) with aerobic and progressive strength and balance exercises embedded. As socialisation and engagement are key elements of CST it was important to keep both groups the same length of time; otherwise if CogEx was longer, those participants would receive longer contact time and therefore more socialisation and engagement. To keep the CogEx sessions the same length of time as CST, 3 minutes of aerobic exercise was included during the welcome and the farewell song (6 minutes in total) and 10 minutes of strengthening and balance exercises occurred in the body of the session.

The aerobic exercises were continuous for 3 minutes and included 30 seconds bouts of exercises in standing (walking on the spot, stepping side to side, washing machines, turning to tap your neighbour, washing machines repeated). The strength and balance exercises were informed by clinical experience, previous falls prevention research (Binns & Taylor, 2011; Taylor et al., 2020) and an understanding of the physiological systems of balance and rehabilitation principles. This included:

- *Motor control* muscles are turned on according to task (Tresch & Jarc, 2009; Yiou et al., 2018) and underpins specificity of exercises therefore exercises were functional i.e. in weight bearing and incorporated everyday movement.

- *Overload* the body responds to a stimulus over and above what it normally experiences (Powers & Howley, 2007) so to improve balance it must be challenged.
- *Balance is multisystem* exercises included muscle strengthening, vestibular adaptation and balance strategy retraining.

The exercises targeted major muscle groups, range of motion, physiological systems and were designed to be in weight bearing (see Appendix I CogEx Additional file 2 (CogEx exercises and muscles and physiological systems targeted)). The exception was the vestibular ocular reflex exercises which were in sitting. Strengthening exercises were chosen that incorporated balance for example standing and flexing the knee to bring the heel toward the bottom strengthens hamstrings but also decreases the base of support with standing on one leg. Each exercise was completed for a period of 30 seconds.

The exercises were the same at each session so that the repetition might result in participants becoming familiar with the exercises and their balance self-efficacy increasing. Exercises were progressed individually according to ability by decreasing hand support and encouraging more repetitions within the 30 seconds.

CogEx was manualised and included the programme principles, session structure, photographs of exercises with instructions and progressions and a one-page exercise sheet for each session that could be used to plan and record the exercises (see Appendix J CogEx Additional file 3 (Exercise recording sheets)).

All sessions (CST and CogEx) were run by two facilitators as per usual CST practice (Aguirre et al., 2014). The 1-hour sessions were on days and times decided by the RAC and NGO.

Data Collection

Quantitative and qualitative methods were used to answer the study objectives.

Outcome measures

Outcome measures were chosen that were widely used with older adults or PLwD; however, it was necessary to assess the appropriateness of the measures for this particular population of older adults as well as how long it took to complete all the outcome measures (study objectives 1 and 2). The MoCA score (to assess cognition) was completed first to screen participants for study eligibility (Nasreddine et al., 2005). Then depression assessed with the 15 item Geriatric Depression Scale (GDS) (Yesavage & Sheikh, 1986), quality of life with the Quality of Life-Alzheimer's Disease (QOL-AD) – Version for the person with dementia (Logsdon et al., 1999), cognition with Alzheimer's Disease Assessment Scale – Cognitive (ADAS-Cog11) (Littbrand et al., 2011), balance with the Brief Balance Evaluation Systems Test (Brief BESTest) (Padgett et al., 2012) and functional mobility with the Short Physical Performance Battery (SPPB) (Guralnik et al., 1994).

An attendance sheet documented participants' attendance at each session and a record sheet of each CogEx session was kept documenting the level of the strength and balance exercises completed (study objectives 3 and 4) (see Appendix J CogEx Additional file 3 (Exercise recording sheets)).

Adverse events were monitored by the facilitator asking each resident at the start of each session how they were. All outcome measures were reassessed the week following completion of the 7-week programme.

Qualitative evaluation

Focus groups were used to generate information about participants' experiences of CogEx sessions; they were facilitated by the primary researcher immediately after the final CogEx session (study objective 7). The participants were asked what they liked or did not like about the sessions, what they thought about the exercises and any changes they would like to see. The focus groups were audio-recorded and transcribed verbatim.

Semi-structured interviews were used to generate information about the facilitator's experience of running the groups (study objective 6). The primary researcher interviewed each facilitator after completion of the last group session. The interview was at a time that suited the facilitator and sought to ascertain their thoughts about the programme, the structure, the length of the session and the exercises. The interviews were audio-recorded and transcribed verbatim.

Semi-structured interviews were used to generate information about the assessor's experience of assessing the participants (study objective 2). The primary researcher interviewed each assessor after completion of the post-intervention assessments. The interview was at a time that suited each assessor and sought to ascertain their thoughts about using the outcome measures with the participants and how long each assessment took. The interviews were audio-recorded and transcribed verbatim.

A video camera was set up by a facilitator for each session. The camera was on a tripod in the corner of the room and recorded participant interactions and engagement (CST and CogEx) as well as how participants transitioned from one task to the other.

Data analysis

Descriptive statistics were used to describe the number of residents recruited (percentage), the group demographics at baseline, pre- and post-intervention outcome measures (means, standard deviations), change in outcome measures (difference, 95% Confidence Intervals) (objectives 1 and 2), session attendance (percentage) (objective 5), exercise session content (minutes in sitting and standing) (objectives 3-5).

Qualitative analysis of the focus groups and semi-structured interviews (facilitators and assessors) used a conventional approach to content analysis informed by Hsieh and Shannon (2005). Common ideas were identified within and across the transcripts, then grouped into themes. The qualitative data were used to examine and the assessor's perception of the data collection (objective 2), identify acceptability of the session to the participants and to examine facilitator perception of session delivery (objectives 6 and 7). The video of sessions was viewed to observe how the participants engaged with the exercises and transitioned from one task to another.

5.4 Results

There were changes to the original protocol after commencement of the study.

Setting

The research groups first ran at the RAC. When the NGO went to identify CST groups for the trial, they discovered they were unable to provide any groups in the required timeframe. They found that three CST groups per geographical area per year met their current demand. No groups were scheduled to start until after the study funding had expired. Therefore, a second RAC facility (RAC2) was recruited to participate in the study. RAC2 was a facility providing a mix of assisted living, rest home and private hospital level care.

Recruitment of individual participants

Changes in the study settings resulted in alterations to some of the initial eligibility criteria (Table 5.1):

Inclusion criteria 2: Due to the NGO no longer taking part in the study this was modified to “living in residential aged care”.

Inclusion criteria 3: Staff at RAC1 explained that if cognitive decline developed after admission to RAC, a resident may not be formally diagnosed with dementia. On this information, inclusion criteria were expanded to include “staff identified cognitive problems”. In RAC2 staff only knew an assisted living (apartment with nursing services provided) residents’ diagnosis if the person chose to share their medical history with care staff. Therefore, the study was advertised as seeking people to participate who felt they may have memory problems as well as inviting people with mild to moderate dementia or staff identified cognitive problems. Inclusion criteria and information sheets for participants and families were modified to include “self-identified memory problems”.

Inclusion criteria 5: The eligibility cut off score of >15/30 on the MoCA had been used previously by the research team members in community-based CST research. However, of the first four residents assessed in RAC1, only one had a MoCA >15/30. In discussion with the research team the cut off MoCA score was lowered to >10/30 to screen residents as eligible to participate in the study.

Recruitment at RAC2 involved the clinical manager inviting residents, as well as the research being advertised in the village flyer and a talk and information sheets given to interested residents.

The trial concluded as planned with all groups completing their 7-week programme and post group assessments. No adverse events were reported throughout the trial.

The flow of participants through the study can be seen in Figure 5.1. At RAC1 recruitment from 94 residents occurred from January - March 2018. Of the 20 residents identified by the clinical manager as appropriate to participate in the study, 19 volunteered to participate and of those 12 were eligible. The recruitment for RAC1 was 13% (12/94); of those who were invited and eligible, all took part (100%). At RAC2 recruitment from 52 residents occurred from May – July 2018. Of the 29 residents self-identified or identified by the clinical manager as appropriate to participate in the study, 17 volunteered to participate and of those 11 were eligible. The recruitment rate for RAC1 was 21% (11/52). Of those who were invited and eligible, all took part (100%).

Of the nine residents who did not meet the inclusion criteria three had a MoCA score >26/30, four had a MoCA score <10/30, one was awaiting a lower limb prosthetic and unable to stand, one was visually impaired and unable to do the pen and paper tests; the other reasons were one resident became distressed during the assessment so it was stopped and one resident could not stay on topic long enough to complete any of the tests.

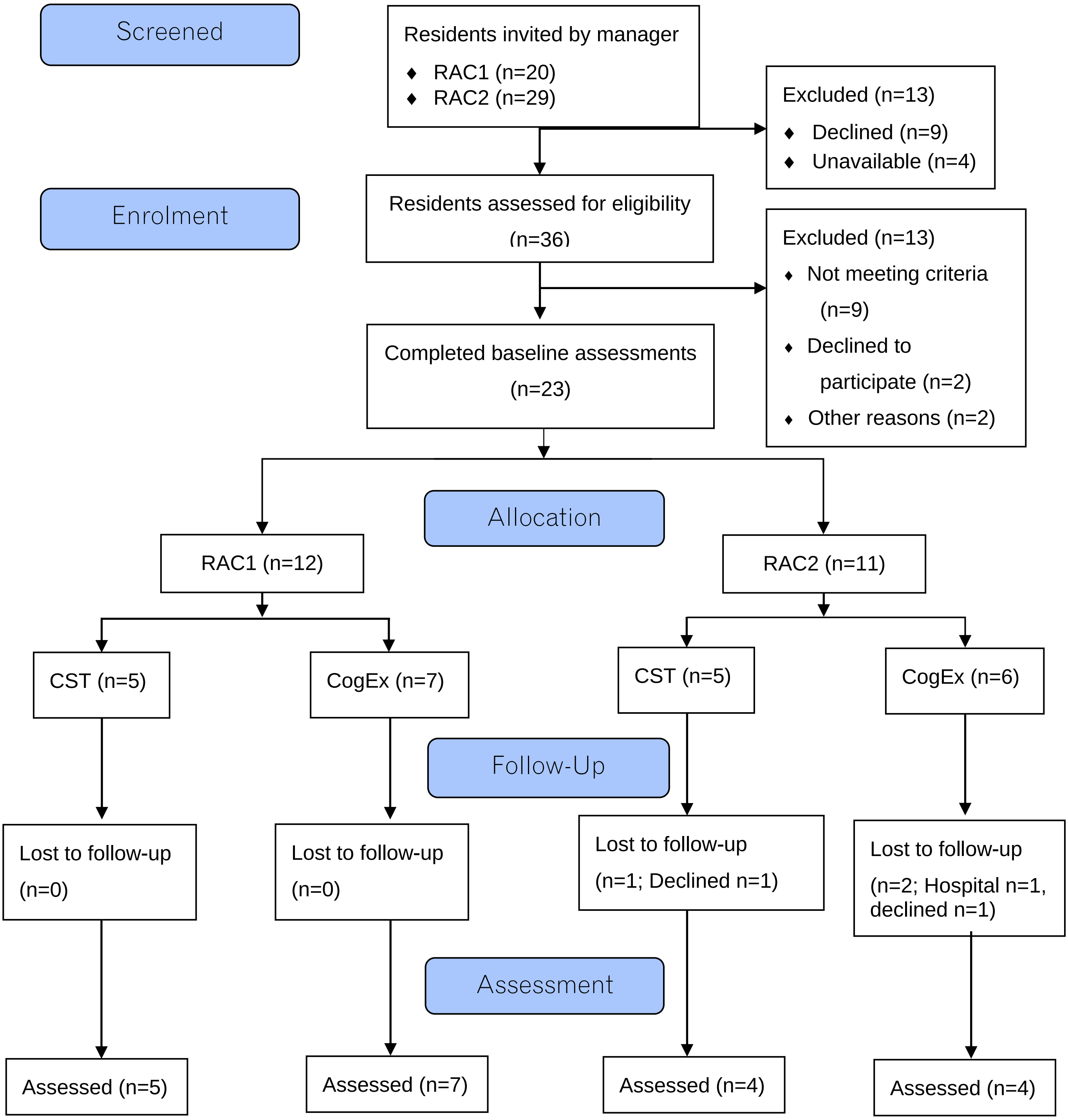
No participants were lost to follow up at RAC1 and three were lost to follow up at RAC2 (one was in hospital, one had stopped going to sessions and declined reassessment, one was emotionally unwell, could not complete the MoCA and the assessment was stopped). Of those lost to follow up one was in the CST group and two were in the CogEx group.

Randomisation and allocation

At RAC1 CST ran first followed by the CogEx group. This was a pragmatic decision by management due to staff availability and allowed the facilitators to experience running a CST group before running CogEx. The research team were concerned that if all participants completed baseline assessments in the same week that those waiting 7 weeks for their group to start might deteriorate. For this reason, once residents and their NoK agreed to participate in the study, they were randomised and then assessed in the week prior to their group starting. At RAC2 CST and CogEx groups were run in parallel therefore participants were randomised following baseline assessment.

Figure 5.1

Flow of participants through the trial



5.4.1 Quantitative evaluation

Participants

The baseline group demographics in Table 5.2 demonstrate that the groups were similar except for the MoCA, ADAS-Cog 11 and mobility. On the MoCA the CogEx group lower mean of 16.0 (SD 4.2) falls into the moderate cognitive impairment band of 10-17 while the CST mean of 18.0 (SD 5.6) is in the mild cognitive impairment band (2019) however the 2-point difference is smaller than the 4-point minimum detectable change to be sure the difference is not due to measurement error (Feeney et al., 2016) Similarly, on the ADAS-Cog 11 the CogEx group had a lower mean ADAS-Cog 11 score of 17.4 (SD 5.9) compared to the CST mean of 15.0 (SD 10.4); however, a definitive cut off score for dementia has not been established. If a score of ≥17 for dementia (Monllau et al., 2007) is used then the CogEx group is classed as having dementia but if >18 (Rockwood et al., 2007) is used then both groups have a worse score than 5 (being normal (Graham et al., 2004) but not classified as dementia. More participants in CogEx used an assistive device when walking.

Table 5.2

Baseline group characteristics and outcome measures at baseline and reassessment

	Baseline		Reassessment	
	CST	CogEx	CST	CogEx
Number of residents randomised	10	13	9	11
Mean age in years, (range)	83.6 (71-95)	87.5 (81-95)	-	-
Female, *n* (%)	8 (80)	9 (69)	-	-
Uses a walking device, *n* (%)	4 (40)	9 (69)	-	-
Medication, mean (SD)	5.2 (2.5)	6.8 (3.6)	-	-
MoCA, mean (SD)	18.0 (5.6)	16.0 (4.2)	18.3 (6.9)	14.6 (3.3)
GDS-15, mean (SD)	3.8 (3.4)	2.9 (2.8)	4.3 (5.1)	2.6 (2.0)
QoL: AD, mean (SD)	37.7 (5.8)	37.2 (6.4)	37.2 (5.7)	37.6 (4.8)
ADAS-Cog 11, mean (SD)	15.0 (10.4)	17.4 (5.9)	14.9 (9.5)	18.4 (5.5)
Brief BESTest, mean (SD)	8.5 (5.5)	9.0 (6.0)	10.3 (5.2)	8.2 (5.1)
SPPB				
Balance score, mean (SD)	2.4 (1.4)	2.4 (1.6)	3.0 (1.0)	2.3 (1.3)
Gait score, mean (SD)	2.3 (1.4)	2.6 (1.2)	2.0 (1.0)	2.2 (1.3)
Chair stand score, mean (SD)	0.8 (0.4)	1.3 (1.3)	1.2 (1.1)	0.9 (0.9)
Total score, mean (SD)	5.5 (2.1)	6.3 (3.8)	6.2 (2.2)	5.4 (2.9)

Note. MoCA = Montreal Cognitive Assessment (0-30, a higher score = better cognition); GDS-15 = Geriatric Depression Scale – 15 (0 – 15, A score of >5 = likely to have depression); QoL: AD = Quality of Life: Alzheimer's Disease (13-52, a higher the score = better the quality of life); ADAS-Cog 11 – Alzheimer's Disease Assessment Scale – Cognitive 11 (0-70, a lower score = better cognition); Brief BESTest = Brief Balance Evaluation Systems Test (0-30, a higher score = better balance performance); SPPB = Short Form Physical Performance Battery (item score 0-4, total score 0-12, a higher score indicates better performance).

All participants were reassessed in the week following the last session (Table 5.2). For RAC1 CST post group assessments occurred 14-18 May 2018 and CogEx 3-7 July 2018; and for RAC2 both group post group assessments occurred 29 - 30 August 2018.

The difference in group baseline and reassessments measures in Table 5.3 illustrate that no clinically meaningful change was observed in any outcome measure for either group. Additional files show the individual participant change scores by group (see

Appendix K CogEx Additional file 4 (CogEx participants' change on each outcome measure) and Appendix L CogEx Additional file 5 (CST participants' change on each outcome measure)).

Table 5.3

Change in group outcome measures after intervention (with 95% confidence intervals)

	CST *n* = 9	CogEx *n* = 11
MoCA	1.2 (-1.0, 3.5)	-0.6 (-2.2, 0.9)
GDS-15	0.1 (-2.2, 2.5)	-0.3 (-1.8, 1.3)
QoL: AD	0 (-2.4, 2.4)	0.5 (-2.1, 3.0)
ADAS-Cog 11	-1.1 (-6.7, 4.6)	-0.3 (-2.7, 2.2)
Brief BESTest	1.3 (-1.5, 4.2)	1.0 (-1.1, 3.1)
SPPB		
Balance score	0.4 (-1.0, 1.8)	0.1 (-0.5, 0.7)
Gait score	-0.3 (-1.4, 0.7)	-0.2 (-0.6, 0.2)
Chair stand score	0.4 (-0.2, 1.1)	-0.1 (-0.6, 0.4)
Total score	0.6 (-0.9, 2.0)	-0.2 (-1.0, 0.6)

Note. MoCA = Montreal Cognitive Assessment (positive difference = improvement); GDS-15 = Geriatric Depression Scale – 15 (a negative difference = improvement); QoL: AD = Quality of Life: Alzheimer's Disease (a positive difference = improvement); ADAS-Cog 11 – Alzheimer's Disease Assessment Scale – Cognitive 11 (a negative difference = improvement); Brief BESTest = Brief Balance Evaluation Systems Test (a positive difference = improvement); SPPB = Short Form Physical Performance Battery (a positive difference = improvement).

Interventions

Ten facilitators trained to deliver CogEx (RAC1 n=5, RAC2 n=5). RAC1 CST was delivered 26 March – 9 May 2018 and CogEx 14 May - 29 June 2018; RAC2 CST and CogEx were delivered 16 July – 29 August 2018. Three of the four group sessions were held in lounges or activity rooms with participants sat at tables except for RAC2 CST where the group sat in a semi-circle in lounge chairs.

Attendance

RAC1 kept attendance sheets for all CST and CogEx sessions. RAC2 kept attendance sheets for 12/14 CogEx sessions and no CST sessions. The percentage of attendance was calculated as the number of participants attending the total number of available group sessions; participant attendance rate per session was also calculated. CST (n=5) average session attendance was 92% (80-100%) and CogEx (n=13) attendance rate was 55% (17-100%).

Class record sheets

The CogEx facilitators recorded the level of strength and balance exercises performed in the 10-minute block; the 3-minutes of aerobic exercise (continuous movement) during the welcome and the farewell song was not recorded as these exercises were set and did not change over the 7-weeks of the programme. The RAC1 facilitators kept and returned the record sheets, the RAC2 facilitators did not. Exercises were performed in bouts of 30 seconds. Table 5.4 illustrates the time spent and number of exercises completed in standing at each session. Not all participants performed calf raises in standing. Sit to stand and calf raises were two of the five exercises performed at the start and end of the 10-minute block therefor each bout of an exercise was counted individually.

Table 5.4

RAC1 CogEx standing exercises completed at each session

Week	Session	Standing exercises (n/16)	Total time in standing (minutes)
1	1	2	1
	2	2	1
2	3	Not recorded on sheet	-
	4	Not recorded on sheet	-
3	5	2	1
	6	2	1
4	7	Public holiday No session	-
	8	2	1
5	9	2	1
	10	2	1
6	11	4	2
	12	2	1
7	13	2	1
	14	2	1

5.4.2 Qualitative evaluation

Only the CogEx qualitative results are presented here to answer study objectives 6 and 7.

Participant focus groups

Both facilities had a culture of resident inclusiveness which meant a resident could take part in any activity that was on offer if they wanted to. Therefore, residents who were not research participants attended the sessions. This inclusiveness resulted in everyone at the last CogEx sessions being invited to participate in the focus group; they were shown the recorder and it was explained that what they said would be recorded, transcribed but not with names and this would be used for research purposes only. They were given the opportunity to leave however, everyone stayed, and this resulted in a mix of participants and non-research participant residents take part in the RAC1 and RAC2 focus groups. It was not possible to remove non-research participant comments from the analysis as transcriptions were anonymised. The Ethics committee who had approved the study were notified of the protocol violation and gave further approval.

Seven residents took part in the RAC1 focus group (participants n=4 and non-research participant residents n=3) and six residents in the RAC2 focus group. At RAC2 the mix of RAC2 participants and non-research participants was unknown as there was no attendance sheet for the final CogEx session. The answers given by RAC1 participants tended to be briefer than those given by RAC2 participants.

The two main topics discussed at the focus groups were the group and the exercises.

Overall the participants enjoyed being a part of the group, what they did in the sessions and wanted the sessions to continue. They enjoyed doing the sessions together and took pleasure in that. They experienced a feeling of being known and knowing as a result of the discussion topics that were used in the CST structure:

> Just the fact that somebody knows that you are (name)…all of us in a way have got to know each other better (female, RAC2)
>
> …we have the questions, we play the games whatever and it means you can beat (others)…that it's not just sitting here nattering to another bunch of old people (female, RAC2)

The participant's comments on the exercises were mixed. There was also discussion at RAC2 of using music to make exercise more enjoyable:

> Oh, that was quite good, gets the whole body moving (male, RAC2)

> I've been doing them in my chair and quite happy (female, RAC2)
>
> I would have liked to have been able to do them better (male, RAC1)
>
> I remember not being able to do some of them, balancing and things. Some of them were very hard (female, RAC2)

One participant declined reassessment as she had stopped attending after session 2 or 3. She was not part of the focus group but wanted her thoughts known as she found the sessions didn't make sense, didn't help and didn't find the topics enjoyable.

Semi-structured interviews

The RAC1 CogEx facilitators were invited to be interviewed and two accepted (n=2/5). They were interviewed individually at the facility at a time that suited them following completion of CogEx. The RAC2 Manager offered to talk about CogEx and asked for the facilitators not to be interviewed as the exercise component of CogEx had been discontinued from the sessions in week 2 or 3.

Facilitators

The main topics of the facilitators' comments were time, engagement, improvement and exercises.

<u>Time:</u> Facilitators combined exercises into the welcome and farewell group song and used the 30 second interval timer for each exercise as planned. To keep the sessions to an hour long and the same length as CST, the facilitators removed the newspaper reading component of CST. They felt that not everyone could see the newspaper to read it, not everyone had an opinion on the news and the group was split when only a few participants gave their opinion whereas the exercises were all inclusive.

<u>Engagement:</u> The facilitators described participants engaging more as the weeks progressed, with participants enjoying singing along with the songs and doing the movements:

> They start (singing) "It's a long way to Tipperary" so you know they are really enjoying it, I think it's great, even the heads are going from left to right, nobody's complaining this is sore (Facilitator 1)

> One lady in the wheelchair was unable to try but her feet were moving so she was aware that something should be happening…engaging her feet (Facilitator 2)

The facilitators also felt that when participants physically touched each other during a trunk rotation exercise (when they reached their arm across their body to tap their neighbour on the shoulder) this increased their engagement with others in the group:

> …they touch and they said o that is nice you gave me your hand (Facilitator 2)

> I noticed one or two of them who weren't quite sure what they were doing, the other residents actually engaged with them (Facilitator 2)

There was also a sense of teamwork with participants copying each other and helping each other out during the group activities and exercises:

Other residents helping those who were slightly hesitant to stand up (Facilitator 2)

<u>Improvement:</u> The facilitators described that as the weeks progressed the participants became more familiar with the exercises, required less prompting and remembered that the session started with a song and movement. The facilitators could see the participants getting better at the exercises:

> …they are getting even lower you know bending…they have been here twice a week touching the ground, they are really touching the ground (Facilitator 1)

> …some of them now are standing up (Facilitator 1)

> One lady in particular made full use of her 30 seconds whereas another couple of people would just be able to do one or two (Facilitator 2)

> Most of the sitting ones are very good (Facilitator 1)

Exercises: The facilitators described doing almost all the exercises in sitting. The two standing exercises that were performed were sit to stand and calf raises. A variety of reasons were given including the setup of the room, safety and it not mattering as long as participants moved:

> I am scared that they will fall because they are standing up now…that's fine and then they want to sit back so yeah go and sit back so the most sitting ones are very good (Facilitator 1)

> Not many of them stood…most of them preferred to remain seated most of the time (Facilitator 2)

> I am happy with the exercises, only the standing ones we didn't really do that, maybe if we had another time only the standing ones, practice a lot on that you know, like sideways walking. Now we have seven but sometimes you have 11 and that's too many then to look after especially because everybody is a bit frail (Facilitator 1)

> …standing up and tip toes was fine… everything we do it in the chair…it doesn't matter as long as they move (Facilitator 1)

The facilitator interviews description of performing almost all exercises in sitting was supported by video and the time spent standing in each session taken from the class record sheets (Table 5.4).

Manager

The RAC2 Manager recalled asking the facilitators how the groups were going and finding out that the exercises had been discontinued from CogEx in week 2 or 3. The Manager described an aged care industry dynamic of staff not wanting someone to feel left out of an activity and so if one person couldn't do something then whatever it was would be discontinued:

> …she said well we have got a couple of people who can't do them (the exercises) so didn't think it was very fair on the others that they

> couldn't do them…people do this all the time in aged care they feel sorry for the person who can't do it so therefore nobody else can take part and that's an interesting dynamic of this industry

The Manager felt if there had been overall supervision of the groups by management that this may have kept the groups on track however it was not their role and maybe if they had a diversional therapist then they would have overseen and been in charge of the project. Another suggestion was a visit by the researcher to check on the groups and if this had occurred the exercises could have been restarted:

> …I think it would have been good to have someone with the research or someone just come back 2 or 3 weeks into it and just remind us how it's going and just having a review just a couple of weeks into it…I think that would have been good (and) got them back on track very quickly

The Manager described the difference in ages, personalities and experience of the staff who trained to be facilitators. Some staff were new to diversional or recreational therapy, so CST had been viewed as a structured way to train staff:

> …I wanted them to do CST so that they don't get into the traditional method of activities or social interaction but start to think about residents and their needs and to get the most out of them and that's what the spin off for us has been that the other staff are very much more engaged

Other factors that the Manager felt affected the CogEx group was morning being a challenging time of day to run a group due to the staff being busy and if someone called in sick it was hard to find cover; that the small room CogEx was run in was harder for participants to move in and participants having to walk through a part of the facility where residents were in hospital level care may have been off putting for participants attending the CogEx group.

Assessors

All assessors (n=3) were interviewed individually at a time that suited them at the University. As this was a small number of people, repetitive comments around topics are presented rather than themes. The assessor's main comments related to time, repetition and not feeling comfortable.

<u>Time:</u> The six outcome measures took between 45 - 90 minutes to complete. The assessors recalled the assessments took longer at RAC1 as the participants were cognitively slower, needed to be redirected to answer questions and motivated to continue. Assessments were often interrupted at RAC1 by staff giving medication or a cup of tea. The assessors recalled a few of RAC1 participants commenting on the number of questions they had to answer with some becoming bored, agitated or emotional when answering questions about marriage and family. The assessors felt that RAC2 participants were more independent and appeared to enjoy the challenge of the tests.

<u>Repetition:</u> The assessors identified repetition of items of the MoCA and ADAS-Cog 11 and described participants also being aware of this:

> ...they are familiar with the question and they might do better just like for example the drawing of the cube…several of them mentioned that "I have done this before "and it's "I know I can't do this, it is difficult for me and it's there again" (Assessor 2)

The assessors felt that some participants looked a little confused being asked the same questions during the assessment such as the orientation questions of date, month, year, day and place.

<u>Not feeling comfortable:</u> The assessors felt uncomfortable with the level of challenge of some balance tests with all three assessors commenting on Brief BESTest items 5 and 6 that elicit a compensatory stepping strategy. They felt uncomfortable doing these tests and gave a variety of reasons such as the age of participants, the restricted space if assessing a participant in their room and

not feeling it was very safe to do this test. One assessor also commented on testing one leg standing in the SPPB, saying that the participants didn't like it:

> A bit tricky like to stand on one leg, they would go "I don't do that usually why would I do that, why are you testing something that I am not even trying to do?" (Assessor 3)

Video

All the video footage was observed to analyse participants' engagement and transitions from one activity to another. The video captured most participants however, as they were sat around a table less than half participants' faces were visible. It was not possible to analyse facial expression or body language for level of engagement at each session.

There were smooth transitions from one task to another such as from the welcome song to the exercises and the video supported the facilitators' semi-structured interviews and documentation of doing almost all exercises in sitting.

5.5 Discussion

The results of the CogEx feasibility study demonstrated that while falls prevention exercises can be incorporated into the CST schedule, the fidelity of the combined programme was poor, and other components of the study design need further consideration before evaluation using an RCT would be feasible.

Objective 1. To test recruitment strategy, percentage recruited and the resultant characteristics of PLwD who participated

An ideal recruitment rate was not set prior to the study. Recruitment of PLwD into research trials has been acknowledged as a problem in many countries (Bartlett et al., 2019) so the results from this study results were to inform recruitment rates for a future study. When designing the study, the numbers of PLwD registered with the NGO was known but not the number of residents with dementia living in the RAC. Recruiting from the community was problematic due to the limited number of CST groups the NGO planned to run annually. Similarly, in RAC all potentially eligible residents were invited by the manager yet after screening less than the 16 were eligible at each facility. Lowering the MoCA score to that used in other CST studies (Lobbia et al., 2018) was appropriate for RAC and contributed to a higher number of residents being recruited however, the percentage recruited at both RAC1 (13%) and RAC2 (21%) was low.

A fully powered fall prevention study requires hundreds of participants (Kalula et al., 2017; Robertson et al., 2002; Schwenk et al., 2012). To recruit a large enough sample of participants for an RCT, all CST deliverers in Auckland (whether community based or RAC) would need to be recruited or a multi-centre trial undertaken.

Objective 2. To test the appropriateness of data collection procedures and select secondary outcome measures

The outcome measures used in this study were based on those in Spector et al.'s original pilot study and RCT (2001; 2003) with the addition of two balance and lower limb measures. However, the MoCA was used instead of the Mini-Mental Scale Evaluation (MMSE) to screen cognition firstly due to the MMSE being no longer freely available (Seshadri & Mazi-Kotwal, 2012) and secondly recent work has identified the MoCA as more sensitive to older adults with mild cognitive impairment (Damian et al., 2011; Lam et al., 2013) and can measure change over time (Gluhm et al., 2013; Krishnan et al., 2017). The assessors and participants noted the repetition between the MoCA and the constructional praxis and orientation sections of the ADAS-Cog-11 and this may have impacted on some participant's performance and agitation with the tests. The MoCA took less time than the ADAS-Cog 11 to administer and needed only the paper copy of the test and a pen while the ADAS-Cog 11 required a large kit of equipment. The MoCA also has banded scores to describe a person's level of cognitive impairment (MoCA Cognition, 2019) while the ADAS-Cog 11 has a normal score established for healthy older adults but a definitive cut off score for dementia is still being debated as to what constitutes a meaningful clinical change (Karin et al., 2014). Of these two tests the MOCA is currently the better choice to ascertain a person's level of cognitive impairment for use in future studies unless more detail was required as to the type of cognition being impacted.

The outcome measures did not show change after taking part in CogEx; however, given that only 1 minute of exercise in standing was completed this could be expected. The number of participants was also too small for inferential analysis or statistical modelling to be undertaken.

The Brief BESTest was chosen to assess balance as it assesses six subcategories that contribute to the maintenance of balance (Padgett et al., 2012) and therefore provides more insight as to why balance is decreased; this version is also the quickest to complete of all BESTest versions (Duncan et al., 2013). The assessors felt uncomfortable with the more challenging balance tests (reactive postural response) despite having trained to do the outcome measures and practicing them on each other. The assessors also felt uncomfortable assessing the one leg stand component of the SPPB because of some participants' reaction to being asked to do something they said they never do.

Assessing balance in frail, elderly older adults who perform fewer incidental activities of daily living in RAC is challenging as in that environment the population is not homogeneous. Our knowledge of physical tests has not kept up with the global population increase of older adults. There is a lack of normative values in outcome measures for older adults living in RAC as most work to date has been on healthy older adults living in the community (Soubra et al., 2019). An example of this is of the outcome measures used in this study only three have had a minimal detectable change identified: MoCA 4 points (Feeney et al., 2016); Brief BESTest 4 points (Viveiro et al., 2018); SPPB total 1 point (Perera et al., 2006), however only the Brief BESTest established this for a population of older adults living in RAC. Consideration should be given to this when selecting measures for future studies.

The battery of assessments took too long and some participants became fatigued or agitated. With the growing evidence of the benefit of CST on cognition and quality of life (Kim et al., 2017) the number of tests could be reduced to focus purely on changes in physical performance in response to CogEx.

The class record and attendance sheets captured the desired information however asking the facilitators to return them weekly would have given the research team oversight of the level of exercises being delivered and created the opportunity to discuss with the facilitators their choices and possibly intervene.

The focus groups were challenging due to research non-participants taking part. The RAC facilities were offering CST as part of their resident activity programme and agreed for the groups to be used for research. As the RACs hosted the research they retained control of the groups and applied their inclusiveness ethos, which resulted in non-research participants taking part in the groups. This also created an ethical issue as these residents had not given written informed consent.

Focus groups were held immediately after the last session to accommodate for cognitive impairment so that participants knew what group activity and exercises the questions related to. Before the focus groups took place, the researcher explained what questions were going to be asked and why, the use of the voice recorder was explained and the opportunity to leave and not take part was given. Focus groups had been chosen when designing the study in order to generate discussion between participants however some focus group participants had poor hearing, and this made their participation in the focus group challenging. The focus group transcription was anonymised making removal of non-research participant comments impossible. Individual interviews with research participants would address the above problems but remove creation of information that occurs when participants talk between each other.

Objective 3. To test combining falls prevention exercise into CST

The RAC1 facilitators successfully incorporated the additional exercises and kept the CogEx sessions the same length as CST (1 hour). They achieved this by firstly, removing the discussion of topics from the newspaper as they found the group did not engage with this. And secondly, by socialising with morning tea after the session rather than as a form of welcome to the group as CST in the community does. In RAC morning tea is a part of the daily routine so having morning tea after the session helped CogEx to run within the RAC normal schedule.

Objective 4. To test training of CST facilitators to deliver CogEx

The additional exercise time was scheduled into the CST structure however, almost no standing exercises were performed. This could be due to CogEx facilitator training being insufficient. Training was a 1-hour session working through the manual, discussing the principles of the programme, practicing the different levels of the exercises and practicing using the timer. This pragmatic approach had been used by the research team previously (Taylor et al., 2012) and was how implementation was envisaged in order to prevent training costs being a barrier. Removing any picture or option of sitting exercises from the manual could act to prompt the facilitators to focus on the importance of exercising in standing to improve the participants' balance. One facilitator's comment that it didn't matter what the participants did as long as they were moving suggests that the difference between fall prevention exercise and activity was not understood.

The lack of standing exercise could also be due to the industry dynamic referred to by the manager of making sure everyone does the same thing, alluding to accepted cultural norms within a facility. It could be that this group of health care workers are very well trained to err on the side of safety and comfort versus physiotherapists who are trained to encourage people to work to their limits and know challenging balance is important in order to stimulate physiological change. The exercise programme whilst appearing straight forward requires a skill set that is not an inherent quality of health care workers in RAC who routinely lead activities with large groups of residents in sitting.

Ongoing training such as a physiotherapist attending one session a week to support the facilitator may have helped to grow the confidence and understanding of the facilitators in encouraging participants to stand and progressing the exercises. Increasing the time the physiotherapist is involved with delivering CogEx training and implementation also increases the implementation costs of the programme, but this would be beneficial if the facilitators gained confidence, knowledge and long-term skills to deliver future CogEx programmes independently.

Objective 5. To test intervention fidelity of CogEx delivered by facilitators

This study contained measures of delivery and engagement as categorised by Walton, Spector, Tombor and Richie that when triangulated provided a description of the fidelity of the intervention (Walton et al., 2017). Fidelity measures of delivery were the class record sheets (session content) and the facilitator and manager semi-structured interviews all which illustrated that standing exercise content was minimal. While video of sessions was recorded, ethical approval was for the video to be used to observe participant engagement and transition from one task to another, not to observe the content of the session or the facilitators. The active ingredient of the intervention (weight bearing exercise to improve lower limb strengthening and balance) was not delivered as intended and the fidelity of the intervention was poor.

Objective 6. To explore the facilitators perceptions of delivering CogEx

The facilitators described participants getting more familiar with the programme over time and could see changes in the participants engagement and ability to stand; they understood that standing was important but were not comfortable encouraging people to stand. One facilitator would have preferred a session of only standing exercises. The large number of residents that attended the sessions also contributed to the facilitators not encouraging more people to stand. The sessions should have had no more than eight participants however, due to the RAC inclusiveness ethos residents that were not research participants took part. One of the facilitators described 11 people attending one session; with only two staff to supervise that many people balancing exercises may not have been a safe.

Objective 7. To explore the participants' experience of CogEx

Participant engagement was measured by their choice to attend and satisfaction with content (Rixon et al., 2016). Class attendance was higher for CST than CogEx and participant focus groups revealed mixed thoughts about the exercises.

While exercises that are challenging can be experienced as hard that is not an ideal starting point. With a more sedentary population such as that in RAC, starting gradually and building confidence and strength over time may be a better approach. What is not known from the study is how the exercises were presented to the participants i.e. what the facilitators told them or how they encouraged them. The attendance rates were much higher for CST than CogEx. This could be due to participants not liking the exercises although very few standing exercises were performed, or it could be due to time of day of the session or the room size as suggested by the RAC2 facility manager.

5.5.1 Limitations

There were several limitations to this study. While this study sought to upskill and then utilise a healthcare workforce already in place in RAC there was not additional funding to pay for the programme delivery. The RACs allowed the research to occur with groups that were planned and as such the RACs retained control of the groups. Both RACs had an inclusion policy so if a resident wanted to take part in an offered activity they could. This resulted in residents who were not research participants taking part in both the CST and CogEx groups and in most cases these residents had not been eligible to participate in the research due to being wheelchair bound, hard of hearing or having a MoCA <10/30. The non-participant residents' physical capabilities or lack thereof contributed to the facilitators not delivering CogEx as intended (in standing) as they delivered the exercises to the lowest level of physical ability of the group (in sitting).

The outcome measures used were also a limitation. The study initially aimed to test the feasibility of CogEx in community dwelling and RAC populations and evaluate the appropriateness of the secondary outcome measures. Only one of the outcome measures (Brief BESTest) had normative values for older adults living in RAC, and this poses a challenge for researchers to be able to be confident changes can be reliably measured and interpreted in this population. The small sample size was too small for inferential analysis or statistical modelling to be undertaken and so appropriate secondary outcome measures that can be used in the analysis of a larger study remain unknown. However, we found it was reasonably practical to collect a battery of secondary outcome measures in this feasibility study.

A key challenge was the culture of the facilitators to err on the side of caution and not be able to modify the exercise for each individual so that everyone could participate albeit with a variation of the same exercise.

5.6 Conclusion

It was not feasible to deliver CogEx (falls prevention exercises embedded in CST) in the way originally conceived for this trial with the workforce currently delivering CST in Aotearoa New Zealand. The RAC environment is complex and while the CogEx programme appears simple implementation was not. Based on the findings from this study future research needs to firstly explore either modifying the CogEx training package to give the facilitators more support to develop their skills throughout the 7-weeks of the programme or using a different workforce (e.g. physiotherapist) to deliver the falls prevention component of CogEx with a CST facilitator. Importantly greater understanding of the complexity of the RAC setting is needed. Each RAC facility is driven by organisational level factors such as organisational priorities, culture, staffing and workflow pressures but must also deliver on obligations to funders and expectations of resident's and their families; all of which combine to make each RAC facility a unique environment. Identification and consideration of these factors are needed for successful intervention implementation.

End of published manuscript.

The attention given to collecting detailed fidelity information in this study provided a rich source of data that is seldom found in fall prevention research literature. This significantly contributed to the decision to change the planned pathway from a fully powered RCT to further investigating issues around fidelity.

Chapter 6 The CogEx fidelity study

This chapter comprises the following manuscript:

Binns, E., Kerse, N., Peri, K., Cheung, G., & Taylor, D. (2020). *Program fidelity challenges discovered during a feasibility randomized controlled trial of group falls prevention exercises*. SAGE. https://doi.org/10.4135/9781529742626

To maintain consistency of style throughout the thesis, the manuscript is presented here in a format that differs slightly to the published manuscript. In this publication we have used the term residential aged care (RAC), rather than ARC, to be consistent with the terminology used by other manuscripts published in the journal.

6.1 Prelude

One objective of the feasibility study was to test the intervention fidelity delivered by the programme facilitators (Binns et al., 2020a). Finding that CogEx was not delivered as designed by the CST facilitators was significant. A more nuanced interpretation of the fidelity data was undertaken to better understand what refinements to the CogEx programme would be needed. The qualitative data from the CogEx facilitator interviews combined with the class exercise record sheets provided a rich source of information about *how* sessions were delivered and the CogEx intervention fidelity.

Intervention fidelity is predominantly based on implementation fidelity and the guidance work from the UK Medical Research Council for conducting process evaluations of complex interventions (Rixon et al., 2016). Currently there is a lack of consensus on the terminology and these terms are used interchangeably as well as the term treatment fidelity (Borrelli et al., 2005; McGee et al., 2018; Toomey et al., 2020). The definition of intervention fidelity used in this chapter is the extent to which an intervention was delivered as designed and intended by the developers (Carroll et al., 2007; Hansen, 2014; McGee et al., 2018; Toomey et al., 2020; Walton et al., 2017).

A number of models of fidelity have been developed, mostly in health behaviour change research (Rixon et al., 2016). While conceptualisations vary, they include dimensions of:

- Study design (Bellg et al., 2004; Borrelli et al., 2005)
- Training of providers (Bellg et al., 2004; Borrelli et al., 2005)
- Delivery of treatment (Bellg et al., 2004; Borrelli et al., 2005)
- Adherence (Bellg et al., 2004; Borrelli et al., 2005; Carroll et al., 2007; Hansen, 2014)
- Dosage (Bellg et al., 2004; Carroll et al., 2007; Durlak & DuPre, 2008; Hansen, 2014)
- Engagement (Carroll et al., 2007; Durlak & DuPre, 2008; Hansen, 2014)
- Quality of delivery (Borrelli et al., 2005; Carroll et al., 2007; Durlak & DuPre, 2008; Hansen, 2014)
- Adaptation (Carroll et al., 2007; Durlak & DuPre, 2008; Hansen, 2014)
- Treatment receipt (Bellg et al., 2004; Borrelli et al., 2005)
- Participant enactment of skills learnt from the intervention (Bellg et al., 2004; Borrelli et al., 2005)
- Programme differentiation (Bellg et al., 2004; Borrelli et al., 2005; Carroll et al., 2007; Durlak & DuPre, 2008; Hansen, 2014)

Not all dimensions of fidelity may be applicable to a health intervention, for example CogEx aimed to increase participant balance rather than change a health behaviour therefore treatment receipt in the form of knowledge received was not applicable. A challenge for physiotherapy researchers has been the lack of guidelines for assessing and reporting fidelity (Toomey & Hardeman, 2017). It has been suggested that to support translation of research findings to clinical practice, the intervention fidelity dimensions to measure are:

- Adherence
- Dosage
- Quality of delivery
- Participant responsiveness
- Programme differentiation (An et al., 2020).

Given the variety of health interventions researched by physiotherapists, increasing knowledge of the dimensions of fidelity relevant to the research being undertaken and choosing intervention-specific measures and methods (qualitative and quantitative) to assess fidelity would strengthen study findings (An et al., 2020; Toomey & Hardeman, 2017).

Intervention fidelity is integral to accurately interpreting intervention outcomes as it increases the internal validity of the trial; that the observed outcomes can be attributed to the programme as described (McGee et al., 2018; O'Shea et al., 2016; Rixon et al., 2016). Measures of intervention fidelity provide information to understand *how* and *why* an intervention succeeded or not in achieving the desired outcome. For example, if an intervention is found to be ineffective it could be incorrectly considered due to the intervention components rather than inconsistent delivery or the trial design; this has been described as a Type III error (Dobson & Cook, 1980). This is particularly important when considering evidence-based practice is based on the published outcomes achieved with an intervention and assumes the intervention was delivered as written (Carroll et al., 2007).

This article focusses on evaluating fidelity of the CogEx intervention through data triangulation.

6.1.1 Supporting documents

The supporting document associated with this chapter can be found in Appendix M CogEx fidelity published manuscript.

Published manuscript begins below the line.

6.2 Introduction

A global health problem that is growing with our ageing population is falls. The incident rate for falls in community dwelling older adults is 0.65 falls per person-year and for older adults living in residential aged care (RAC) this increases to 1.7 falls per person-year (Rubenstein, 2006). Dementia is an independent risk factor for falls and older people living with dementia (PLwD) are twice as likely to fall and sustain an injury than those without dementia (Suttanon et al., 2010). With the growing proportion of RAC residents living with cognitive impairment (Boyd et al., 2011), falls in PLwD in RAC is an area of serious concern in health care. In Aotearoa New Zealand (NZ) physiotherapy is typically only funded for a RAC resident following a doctor or nurse referral therefore the opportunity for physiotherapists to deliver falls prevention in RAC is limited.

Cognitive Stimulation Therapy (CST) is the only evidence based treatment recommended for people with mild to moderate dementia in the NICE dementia guidelines (National Institute for Health and Clinical Excellence, 2006) based on evidence that it can improve cognition in people with mild to moderate dementia over and above any medication effects (Kim et al., 2017; Woods et al., 2012). The Dementia Care Framework (Ministry of Health, 2013b) in NZ recommends CST as one of only two specific treatments considered as good practice for PLwD. To support this recommendation a one-day CST programme facilitator training was rolled out and CST is now available nationwide delivered by trained facilitators (Cheung & Peri, 2019).

We designed a mixed methods feasibility randomised controlled trial to explore whether falls prevention exercises could be embedded and delivered in the CST programme structure in order to establish feasibility for undertaking a full scale randomised controlled trial (RCT) to test the effectiveness of CogEx, the combined exercise and CST programme, in decreasing falls in PLwD. The rationale underpinning this study was that training a pre-existing workforce delivering activity programmes (activities staff) in RAC to also deliver falls prevention exercises embedded in the CST structure (CogEx) would address a health need without increasing costs. This article focuses on how study outcome measures when triangulated demonstrated fidelity of the CogEx intervention.

Section summary

- Falls in older adults is a global problem
- Staff who do not traditionally deliver falls prevention exercise were trained to do so

6.3 Research design

The research team was multidisciplinary (physiotherapists, doctors and a nurse) with expertise in falls prevention exercise, CST training and delivery, caring for people with dementia and running trials in RAC. A pragmatic approach was taken when designing the trial; this approach values real-world practical considerations as much as theoretical concepts and in this trial the potential participants and complex environment the programme was going to be delivered in were important considerations (Frampton, 2018). The specific objectives of the feasibility study were:

1. To test recruitment strategy, percentage recruited and the resultant characteristics of PLwD who participate

2. To test the appropriateness of data collection procedures and the outcome measures

3. To test combining falls prevention exercise into CST

4. To test training of CST facilitators to deliver CogEx

5. To test intervention fidelity of CogEx delivered by facilitators

6. To explore the facilitators' perceptions of delivering CogEx

7. To explore the participants' experience of CogEx

Participants and setting

The study was conducted at two RAC facilities. The residents invited to take part in this study met the criteria of: being 65 years or older; diagnosed with mild to moderate dementia; mobile with or without an assistive device; a Montreal Cognitive Assessment (MOCA) score between 15-26 out of 30; able to hear and see well enough to take part in the group discussion; and likely to remain in a group for 1 hour. The inclusion criteria were based on those used in previous CST studies and aimed to be as inclusive as possible of the RAC population in NZ.

Residents gave consent and their next of kin gave assent. Participants were randomised to take part in the CST or CogEx group within their facility. All participants completed baseline and post-intervention assessments.

CogEx training

Activities staff who had completed the one day master class CST training (Cheung & Peri, 2019) were invited by their manager to train and deliver the CogEx programme. CogEx was CST (Spector et al., 2006) with aerobic and progressive strength and balance exercises embedded and followed the CST structure of an hour long group session twice a week for 7 weeks . The falls prevention exercises were designed to challenge and improve balance, be done in standing and progressed by decreasing hand support. They were progressive in nature incorporating increasing movement amplitude and speeds as well as including basic vestibular exercises. Progressions were based on an individual's ability. A seated option was available for each exercise so that everyone could participate. A CogEx manual was developed and included the programme principles, session structure, photos of exercises with instructions and progressions and a one-page exercise sheet for each session that could be used to plan and record the exercises for each session. Groups of facilitators were trained as their work schedules allowed and this involved theory and practice: working through the manual; doing each exercise and progression; practicing with the interval timer; doing a 3-minute exercise sequence that was part of the programme. The trainer (EB) was available for ongoing support during the 7 weeks of the programme via telephone or email. We had used a similar training structure previously with physiotherapists in an earlier fall prevention trial. Both groups were to run to the CST format of 1 hour of group activity run by a facilitator and an assistant, twice a week for seven weeks (Spector et al., 2006).

Outcome measures and Data collection

There was concern within the research team that participants may not be able to transition between activities in the CogEx group. Video was chosen as a tool to observe how participants managed the transitions as well as their engagement with the programme in both CogEx and CST groups i.e. were they awake, engaged with the activity or other group members; and so was used to explore the participants' experience of CogEx (Objective 7).

When designing the study Objective 5 was explicitly regarding fidelity however, after completion of the study we realised that only Objectives 1 and 2 didn't contribute to measuring fidelity. Therefore, all study outcome measures and forms of data collection by Objective are listed below:

Objective 1: Descriptive statistics to describe the number of residents recruited and group demographics at baseline.

Objective 2: Pre- and post-intervention clinical measures and change in outcome measures (MOCA, Geriatric Depression Scale – 15, Quality of Life: Alzheimer's Disease, Alzheimer's Disease Assessment Scale – Cognitive 11, Brief Balance Evaluation Systems Test, Short Form Physical Performance Battery). Semi-structured interviews with assessors.

Objectives 3-5: Length of each class. Record of class content.

Objective 6: Semi-structured interviews with facilitators. Length of each class.

Objective 7: Video. Participant semi-structured group feedback immediately following the last group. Class attendance sheets.

<u>Fidelity measures</u>

Measures used for Objectives 3-7 contributed to assessing intervention fidelity and can be categorised as measures of delivery and engagement (Walton et al., 2017). Fidelity measures of delivery were the session content, attendance sheets (intervention records) and the facilitator semi-structured interviews. While video (observation) of sessions was recorded, the intent was to observe how the participants engaged with the exercises and transitioned from one task to another, not to observe the content of the session. Therefore, participant engagement was measured by attendance and focus groups (participant experience) (Bartlett et al., 2019).

Section summary

- A pragmatic approach to study design and intervention delivery was taken in order to confidently answer the question of feasibility
- Measures of fidelity are specific to the trial being undertaken
- Fidelity measures can be categorised and this study used measures of delivery and engagement

Research Practicalities

When doing research in a real life setting there is a lot that is outside of your control. This is compounded when you only have funding for the blinded assessors and your research relies on goodwill and professional networks and relationships. However, everyone involved in this project had the shared passion of working for the residents. This was not the first study we had conducted within RAC, so the practicalities encountered and reflected on below are a mix of earlier learnings being reinforced as well as some new learnings.

You are a guest

The RAC facilities generously hosted the research and were not paid. Both facilities planned to offer CST in their resident activity programme and agreed for the groups to be used for research. The day to day running of the groups (day, time, location) were decided by the facility with only the group content set by the researchers. Residents who wanted to take part in the research gave informed consent however, the facilities had an ethos of inclusiveness so if a resident wanted to participate in an offered activity they could. This resulted in residents who were not research participants participating in the CST and CogEx groups and in most cases these residents were excluded from the research due to being wheelchair bound or having a MOCA <10/30.

Your research is not part of their job

Knowing that nobody enjoys paperwork we designed study forms to be minimal. The attendance sheet was one page and the facilitator had to enter the date, session number, attendees' names and whether they attended or not. A session sheet for each class (14 in total) was in the manual and the facilitator had to date the sheet and tick which exercises and what level were performed. These forms were all paper.

How to use video

The video camera was on a tripod in the corner of the room so there was not another person present that might change the group dynamic; and for the camera to be as unobtrusive as possible. It was impractical for the researcher to set up the camera for each class, so the facilitators were asked to do this.

In a pragmatic trial does diagnosis matter?

We learnt that residents may have cognitive impairment or dementia but not be formally assessed and diagnosed if this developed after admission to RAC, as in this environment it would not necessarily change their treatment or management. The study criteria were expanded to include "staff identified cognitive problems" and "self-identified memory problems".

Section summary

- Funding may dictate what you can control in your study
- Great relationships with all research stakeholders (participants, staff, host institutions, assessors…) is vital

6.4 Method (in Action)

After completion of the study during data analysis we realised how most of the measures contributed to a rich description of fidelity. Below is a discussion of the fidelity measures of delivery and engagement, coupled with our learnings gained with the benefit of hindsight.

The video

Video was approved by Ethics for observing participants in the group. We viewed the 14 group sessions after all had been completed. The camera captured all the participants however as they were sat around a table less than half participants faces were visible, so it was not possible to view whether everyone was engaged e.g. awake, facial expression or body language. As we began to search the literature to guide coding the video observations, we realised the "fly on the wall" approach we had taken with a group was not common. Generally, environments are set up for observations with the camera facing participants and whatever task they were undertaking. In hindsight the "fly on the wall" approach provided invaluable information about the delivery of the class however, we did not have ethics approval to use the video to observe the facilitators delivering the programme. In future studies we would invite the facilitators to also be study participants and gain ethics approval to use the video as a record of what the facilitators did.

Facilitator paperwork (attendance and session sheets)

The paperwork was collected after completion of the 14 sessions. One facility had complete paperwork for all CST and CogEx sessions. The other facility kept attendance sheets for 12/14 CogEx sessions, no CST sessions and no CogEx session sheets. This was also the facility that did not deliver CogEx after week 2 or 3 reverting to CST however without paperwork it is not possible to know exactly when the exercises stopped. The completed session sheets demonstrated that 1 minute of standing exercise occurred in the 10-minute exercise segment with almost all exercises done in sitting.

The attendance and session sheets worked well, when completed. Being able to quantify the dose of standing exercise in minutes is novel in falls prevention research. In hindsight we would have asked the facilitators to send paperwork to us at the end of each week (i.e. after every 2 sessions). While this is asking more of the facilitators that level of programme oversight would have enabled us to know what was being delivered and to intervene with support.

Facilitator interviews

The facilitators that delivered CogEx were honest with their feedback however they were not critical. The facilitators perceived no negativity for delivering the exercises predominantly in sitting and were encouraged to explain their choices. Both interviewees were very experienced in delivering activity groups in sitting and this was their strength, being able to engage participants. They were very well versed in erring on the side of safety and comfort as opposed to physiotherapists who are trained to encourage people to work to their limits knowing that challenging balance is important to stimulate physiological change and traditionally deliver falls prevention exercise (Sherrington & Tiedemann, 2015). In hindsight using a researcher not known by the facilitators to be involved with the programme would have created an opportunity for them to feel comfortable to be critical when interviewed however, they understood that this was a pilot study and that their feedback was vital to refining the programme; also the researcher remaining inquisitive/curious in the interview and not judging facilitator choices was crucial for them to express why they did what they did.

The Manager of the facility where the CogEx programme was stopped asked that her staff were not interviewed as the perception of the facilitators could be that they had failed. This was respected. In hindsight word choice was crucial, the facilitators had not failed they had made a choice and it had greatly informed the study. While interviewing the manager was not planned, they offered industry insight that the facilitators did not.

Participant focus groups

To accommodate for cognitive impairment focus groups were held immediately following the last group so that participants knew what the questions related to. Due to the inclusive ethos of the facilities non-research participants took part in the focus groups rather than being asked to leave. The focus groups were challenging as not everyone could hear and rather than being a group conversation, at one facility it was reduced to asking each participant what they thought. It had been envisaged that from the focus groups individuals could be selected and asked to give their views in an interview but with the level of cognitive impairment of participants this was not pursued. All comments made in the focus group were transcribed and used in analysis as it was not possible to identify and remove non-participants. In hindsight we are still unsure of a better way to elicit the thoughts of people with cognitive impairment. While attendance could be a proxy measure of satisfaction this may not be so when people live in an environment where staff may strongly encourage attendance at activities.

Section summary

- Apply to the Ethics committee for amendments to be able to use data in previously unconsidered ways
- Consider how data collection tools may have to be tailored to your study population i.e. children, people with cognitive impairment
- Unplanned observations can inform your thinking – be open to them and take time to reflect

Practical Lessons Learned

The feasibility study question was answered. It was not feasible to deliver CogEx (falls prevention exercises embedded in CST) in the way originally conceived with the workforce currently delivering CST in NZ. So why was the intervention not delivered how we thought it would be?

The trial design aimed to elicit acceptability of the programme to the participants and facilitators and whether fall prevention exercises fitted in the CST structure. It was triangulating the results that provided a rich description of fidelity but not only the “what” was delivered but a step further to trying to unpack the “why”. The analysis of “why” the intervention ran the way it did taught us the following:

We had previously worked in RAC so were comfortable in this environment and felt we knew and understood staff roles well. It was during the interview with the manager that they described there being an industry dynamic in RAC of the activities staff feeling sorry for a person who can't do something, staff like everyone to do the same so no-one misses out therefore a task is changed and nobody else can do it either. In a group exercise environment this is the complete opposite of how a physiotherapist would tailor an exercise to the individual so within the group everyone could be working at their own level of capability; this programme was set up so that each exercise had different levels of challenge in order to allow for individual variation. The facilitator interviews also revealed that they understood standing was important but were not comfortable encouraging people to stand. The culture of activities staff is to promote resident engagement, comfort and safety, they are also highly skilled in delivering group activity in sitting and this is what they reverted to.

<u>Teaching a new skill or changing practice?</u>

With the knowledge gained regarding the industry dynamic, in hindsight 1 hour of training was insufficient to change practice. We could have attend the first 2 classes to assist the facilitators in on the job training and build their confidence with standing exercises but would the facilitators have stepped back and let us take over if we were present rather than lead the exercises with our support? How much ongoing input is needed to change usual practice significantly? Would a video of the exercise programme have enabled the participants to follow along and facilitators to be available to assist people to try a little less hand support? The above options all have cost implications and the driver for this study was delivering fall prevention programmes in RAC without increasing costs.

<u>Maintain weekly contact with facilitators</u>

Collecting the paperwork weekly would have been light touch but have given us oversight of what exercises were being delivered. We could have then responded to the lack of standing exercises and determined how to intervene to encourage the facilitators to deliver the standing exercises. A regular weekly phone call or email from the trainer would have been another light touch way to check the delivery of the programme with the facilitator. Neither of these options would have greatly increased programme costs. A class visit to do a fidelity check after 4 sessions could also have been used to start a conversation with the facilitators about the level of exercises being delivered.

Section summary

- Use fidelity measures during your study so you have oversight of what is being delivered
- What level of oversight do you need of your study? Be aware that your presence could change the intervention

6.5 Conclusion

The triangulation of multiple fidelity measures provided a rich description of the study intervention which not only answered the question of feasibility but enabled us to look past the “what” was delivered to reflect on the “why” of delivery. Our learnings from conducting a feasibility study were greatly enhanced through developing objectives that required qualitative and quantitative methods. On reflection, in our pragmatism to run the trial as we envisaged it to be delivered, we lacked oversight of what was being delivered. A light touch measure of fidelity (research paperwork) would have brought to our attention that the intervention was being delivered predominantly in sitting. Measuring fidelity should not necessarily be left to the end of a trial.

For researchers conducting trials in a real-world environment an understanding of the “why” an intervention was successful or not is critical as the environment is complex and many factors are in play. Therefore, planning to measure fidelity will provide data which can demonstrate a rich description of “what” and prompt thinking as to the “why”. Otherwise, there is a possibility that an intervention could be completely disregarded when in fact only one factor needed changing or conversely one factor is changed when many needed addressing.

Section summary

- Measuring fidelity during a trial can be beneficial
- Multiple fidelity measures can be triangulated to give a rich description
- The “what’ and the “why” are equally important

End of published manuscript.

Chapter 7 Beyond the Randomised Controlled Trial

The CogEx feasibility study findings demonstrated that the uptake of a health intervention is crucially dependent on the health providers' perception of the intervention (Binns et al., 2020a, 2020b). These perceptions can extend beyond the intervention itself to include fit with staff's current workload, perceived need and benefit, and occur at multiple organisational levels from clinicians, to service providers, funders and the wider health care system (Linnerud et al., 2023; Markle-Reid et al., 2015; van Rhyn & Barwick, 2019). These perceptions can be referred to as views about the implementability of an intervention. Implementability has been defined as "the likelihood that an intervention will be adopted into routine practice across settings over time"(Klaic et al., 2022, p. 2). With the decision made not to refine CogEx further to address the identified feasibility issues, the learnings from the CogEx study were used to form the basis of a qualitative enquiry into another falls prevention exercise trial that was underway in ARC, the Staying UpRight (SUp) in Aged Residential Care randomised controlled trial (Taylor et al., 2020; L. M. Taylor et al., 2023). This work addressed the second objective of the thesis to understand the complexities around the delivery of a fall prevention exercise programme in the complex context of ARC.

7.1 Staying UpRight in Aged Residential Care

The Staying Upright (SUp) exercise programme was developed to address the modifiable fall risk factors of decreased lower limb strength and impaired balance in older adults living in ARC. It was one component in a mixed methods, randomised, multifactorial fall prevention intervention which was piloted to establish feasibility for a RCT (Kerse et al., 2009). The SUp exercise programme was informed by clinical practice, previous research, an understanding of the physiological systems of balance and the principals of rehabilitation (dose, intensity and progression) (Taylor et al., 2020). The exercise programme was a twice weekly, 1-hour group exercise class. Physiotherapists, working in the facility or contracted to deliver the intervention, were trained to deliver the programme. The programme was manualised, and support was available from the researchers as needed. A dose matched, control group did a seated exercise programme. A pilot study found that recruitment was feasible and the interventions were acceptable to residents in two ARC facilities (n = 70) (Kerse et al., 2009). As it was a pilot study, it was not powered to find a statistically significant result but a trend for improvement in physical performance measures was observed. No adverse events were reported.

The management, clinical staff, and residents randomised to the multifactorial intervention were also interviewed to explore their experiences of the interventions. There was a stark contrast with how the programme was received and implemented, with one facility completely embedding it into practice and the other struggling to deliver the components as designed. Management buy-in and the role of the falls champion were identified as being crucial to programme implementation. However, all interviewees were positive about the exercise component of the programme with all observing or experiencing benefit.

The trends to improvement on physical measures in the pilot, led to a proposal of an RCT to evaluate the efficacy and cost effectiveness of a fall prevention group exercise programme to reduce falls in older adults living in ARC (Taylor et al., 2020).

7.2 Complex intervention or an intervention in a complex system?

At face value, the SUp exercise intervention appears to be straightforward. However, it could be described as a complex intervention due to the behaviour change required by ARC staff to support the programme, the skill level of physiotherapists needed to individually tailor the exercises to participants in a group setting, and the investment required by organisations and management to support the programme (Craig et al., 2008). It could also be described as an intervention in a complex system (Hawe et al., 2009; Moore et al., 2019; Moore et al., 2017). This moves the concept of complexity from within the intervention to being within the setting or context that the intervention is introduced into and interacts with (Hawe et al., 2009). The context is an ecological system comprised of three dimensions: the setting; the relationships that link people and people to the setting; and time (Hawe et al., 2009). When an intervention is introduced, it is an event in the system and creates new structures and meaning. The intervention impacts on the interactions of the person-place-time network which changes relationships, displacing current activities and redistributing resources (Hawe et al., 2009). The healthcare context has been described as a complex adaptive system (Braithwaite et al., 2018; Plsek & Greenhalgh, 2001; Rouse, 2008). Characterised by uncertainty, emergence and unpredictability, the healthcare system responds to a triggering mechanism and the interdependent components of the system flex, adjust and adapt to a new way of working with resources redistributed to accommodate anything new that is introduced to the system (Braithwaite et al., 2018). The system self-organises in predictable and unpredictable ways, learns from experience and adapts to a new normal (Ratnapalan & Lang, 2020). Within the healthcare system there are a myriad of actors and multiple levels of influence from government, organisation, management, health professional, service provider, patients and their families, each with their own culture and relationships and networks, and each exerting an effect on the system (Rouse, 2008). Intervention complexity is a newer term designed to guide authors of Cochrane Systematic Reviews (Thomas et al., 2019). This term is used to describe the components of an intervention, the interactions between the intervention and its context, or both and the wider system within which the intervention is introduced. This reads as a combination of 'complex intervention' and 'an intervention in a complex system' however, it prompts systematic reviewers to consider how questions should be framed to consider complexity. The reverse is also compelling, however complexity is defined it needs to be identified and considered when interventions are being developed.

In the SUp RCT, each ARC facility was a complex micro-system within the complex macro-system of an organisation which in turn was within the NZ healthcare system (Reed et al., 2018). Whether the SUp intervention is considered complex or the ARC context is, the advantage of using a systems approach lens to analyse data, is it considers the relationships and context, not just the simple cause and effect of an intervention, suggests new possibilities for change and provides a more complete picture of the forces affecting the observed outcomes (The Evidence Centre, 2010). This approach also recognises that knowledge is generated from the implementers and recipients of SUp as much as it comes from the researchers (Hawe, 2015).

7.3 Implementation science

It is estimated that there is a lag of 17-20 years from clinical innovation to implementation (Bauer & Kirchner, 2020), due to the staged health research pipeline of establishing clinical efficacy, followed by clinical effectiveness and finally implementation (Curran et al., 2012). Despite the investment of millions of dollars and thousands of hours by researchers and participants to establish the effectiveness of an intervention, fewer than 14 - 50% of evidence-based practices are implemented into routine clinical care (Bauer & Kirchner, 2020; Kirchner et al., 2020; Meeks & Pruchno, 2017). The lack of uptake of effective clinical innovations is a longstanding problem (Bauer & Kirchner, 2020). To reduce research waste much more is needed to be understood about an intervention beyond whether it is effective or not using a RCT. To achieve this, researchers need to adopt a wider range and combination of research perspectives and methods (Skivington et al., 2021b).

The field of implementation science developed to enhance the uptake of evidence-based practices into routine healthcare practice, with the aim of ultimately improving health services and care; it also studies the influences on healthcare professional and organisational behaviour (Bauer & Kirchner, 2020; Eccles & Mittman, 2006; Handley et al., 2016). While still considered a relatively young area of scientific enquiry (Curran, 2020), the Implementation Science journal was launched in 2006 and published 29 papers (Eccles & Mittman, 2006), this climbed to 134 in 2011 and was 40% of submissions (Eccles et al., 2012), it continues to publish around 120 papers per year, 15% of the 800 submissions now received annually (Wensing et al., 2021). With the journal providing a dedicated platform to disseminate knowledge, a complex array of more than 61 theories, models and frameworks have been developed to facilitate the selection and application of relevant approaches (Curran, 2020) however, they can be categorised into five categories to aid identification, which are:

1. Process models

2. Determinant frameworks
3. Classic theories
4. Implementation theories
5. Evaluation frameworks (Nilsen, 2015)

These implementation theories, models and frameworks, fit within the three overarching aims of implementation science, which are:

- Describing and/or guiding the process of translating research into practice (process models)
- Understanding and/or explaining what influences outcomes (determinant frameworks, classic theories, implementation theories)
- Evaluating the implementation of intervention (evaluation frameworks) (Nilsen, 2015)

The SUp trial was planned as a classic RCT to evaluate the efficacy of a group exercise programme to prevent falls in residents living in ARC. The cost-effectiveness of the intervention was a secondary aim of the trial (Taylor et al., 2020). However, the research team were cognisant of the need to consider the implementability of SUp. Intervention implementability can be influenced by the interrelated concepts of acceptability, fidelity, feasibility, scalability and sustainability (Brown et al., 2017; Curran, 2020; Klaic et al., 2022). Acceptability, fidelity and feasibility should be explored during an evaluation of an intervention's effectiveness as they are context and population specific (Klaic et al., 2022). It is important for researchers to be cognisant that clinical innovation is implemented into routine practice because of clinical partners not in spite of them and so understanding their perceptions of an intervention is crucial in further development of the scalability of an intervention and its sustainability (Bauer & Kirchner, 2020; Klaic et al., 2022). The SUp team had already learnt from the pilot that context differs between ARCs and what works in one facility does not necessarily work in another (Kerse et al., 2009). To capture the experiences of those involved with the SUp intervention within different levels of ARCs and their organisation, a hybrid effectiveness-implementation research design was used.

7.4 Hybrid-effectiveness models

Hybrid effectiveness-implementation design models blend the design components of clinical effectiveness and implementation research (Curran et al., 2012). These designs enable examination of both effectiveness and implementation outcomes within a study. This disrupts the traditional staged health research pipeline, potentially decreasing the time lag for research findings to be adopted into routine health care (Landes et al., 2019). Hybrid effectiveness-implementation designs are recognised a useful extension to the standard designs of RCTs (Skivington et al., 2021b).

There are three types of hybrid designs, distinct by whether the primary focus is effectiveness, implementation or an equal focus on both (Curran et al., 2012; Landes et al., 2019). A type 1 hybrid design has a primary aim of establishing the effectiveness of the intervention, with a secondary aim of understanding the context for implementation. It is used when the clinical effectiveness of an intervention has yet to be established and therefore studying implementation alone is premature (Landes et al., 2019). A type 2 design has the co-aims of establishing the effectiveness of the intervention and determining the feasibility and impact of an implementation strategy. This design is used when there is an explicit implementation strategy to be tested as well as the effectiveness of an intervention (Landes et al., 2019). A type 3 design primarily aims to determine the impact of an implementation strategy and has the secondary aim of observing or gathering information on intervention outcomes This design is used to compare implementation strategies (Landes et al., 2019). A type 1 hybrid effectiveness-implementation design was chosen to explore the factors that influenced whether SUp would be continued as part of usual practice in the ARC facility at the conclusion of the funded trial period.

Chapter 8 Staying UpRight in Residential Aged Care qualitative study

This chapter comprises the following manuscript:

Binns, E., Bright, F., Parsons, J., Peri, K., Taylor, L., Kerse, N., & Taylor, D. (2023). "It's all about the money": An interpretive description of embedding physical therapy-led falls prevention group exercise in long-term care. *BMC Geriatrics, 23*(1), Article 14. https://doi.org/10.1186/s12877-022-03722-z

To maintain consistency of style throughout the thesis, the manuscript is presented here in a format that differs slightly to the accepted manuscript.

8.1 Prelude

The following published manuscript reports the qualitative arm of the type 1 hybrid effectiveness-implementation study. This explored the factors that influenced whether SUp would be continued as part of usual practice in the ARC facility at the conclusion of the funded trial period. In this publication we have used the term long-term care (LTC), rather than ARC, to be consistent with the terminology used by other manuscripts published in the journal.

8.1.1 Background to this study: Positioning the researcher

The upcoming manuscript reports the qualitative study, this section outlines the position of the researcher and provides the reader with information about the lens through which this research was conducted (Berger, 2015). My first physiotherapy job was on an assessment and rehabilitation ward for older adults in a public hospital. While the motivating factor for taking the job was the location, the local hospital, that was quickly replaced by a passion for working with older adults. I enjoyed hearing their stories and working with them to be discharged back to their own home, the ultimate goal. For many patients the functional tasks needed to achieve that goal were sit to stand and walking; and achieving those tasks needed lower limb strength and balance. Numerous patients were rehabilitating from fractured hips following a fall, so preventing another fall was also a goal. Not all my patients achieved their goal of returning home and were discharged to ARC; a setting that was part of my second job.

My next job was in a university neurological outpatient clinic. Two afternoons a week were contracted to provide onsite physiotherapy service to a rest home and private hospital facility (ARC). The goal of treatment here was different, the focus was on maintenance, keeping people on their feet and supporting the nursing staff to encourage people to be on their feet. The consequences of a fall in ARC were also different. Here a fall could result in admission to hospital for medical treatment, a move from rest home to private hospital level care or death. Falls seemed to be accepted as something that just happens. I didn't agree with this acceptance and so began a search to understand more about falls and what could be done. More specifically, I was interested to know how could falls be prevented for older adults living in ARC.

While working in this role I completed a Masters of Health Science. This study explored the change in lower limb strength and balance after community dwelling older women participated in the Otago Exercise Programme (a fall prevention exercise programme) (Binns & Taylor, 2011). Findings from this study were non-significant however, it was possible that clinical measures may not detect small changes in strength and balance that occur following exercise. The concept of task specificity, later described by Sherrington (2019) as functional exercise, also appeared to be important for this population.

As a result of my clinical and research experience, I believe in exercise for health. I have seen how doing a little exercise often can have a big impact on a person's life, for example practicing sit to stand daily and using that to become independent in toileting.

I also served two terms as the President of Physiotherapy New Zealand during my time as a doctoral candidate. This experience grew my knowledge of policy, provided an overview of the profession, and enabled me to see gaps in healthcare services where physiotherapy could be better utilised. Although no longer a clinician, I describe physiotherapy being in my DNA. I am motivated to explore how physiotherapy can be used to benefit older adults to age well.

8.1.2 Supporting documents

Supporting documents associated with this chapter can be found in Appendices N-X. They are:

Appendix N SUp HDEC ethical approval
Appendix O SUp Participant Information Sheet Executive Management
Appendix P SUp Participant Information Sheet facilitators
Appendix Q SUp Participant Information Sheet Care Home Manager
Appendix R SUp Permission Form Executive
Appendix S SUp Permission Form Care Home manager
Appendix T SUp Consent Form Executive
Appendix U SUp Consent Form Care Home Manager
Appendix V SUp Consent Form facilitators
Appendix W SUp transcriber confidentiality agreement
Appendix X SUp published manuscript

Supplementary information was included with this publication and can be found in Appendix Y SUp Additional file 1 (Interview guides).

8.2 Introduction

The fall rate for older adults living in long-term care (LTC) is higher than community dwelling older adults (Carryer et al., 2017; Wabe et al., 2022), which is a reflection of residents' high levels of physical frailty and disability; both high risk factors for falls (Deandrea et al., 2013). The LTC environment may compound physical impairment through staff limiting the physical activity of residents they consider to be fall-prone or considering 'walking' to be the domain of physical therapists, leading to increased sedentary behaviour and lower limb muscle weakness in residents (Brown et al., 2015; Gulka et al., 2020).

To be admitted into LTC, an older adult is assessed as no longer able to live independently at home (Jorgensen et al., 2009). The International Resident Assessment Instrument (interRAI) Home Care is a mandated component of this assessment and determines what level of care is needed (Goodhew, 2012). A national contract (Age-Related Residential Care Services Agreement (Ministry of Health, 2013a)) between the national health authority (NZ Ministry of Health) and LTC facilities defines the Government funded care services provided to a resident. Services covered by the agreement include an individualized care plan based on the interRAI LTC facilities assessment. The agreement specifies a facility must have a falls prevention policy and assess, prevent and manage falls however, it does not require that there is physical therapy input into falls prevention (Central Region Technical Advisory Services Limited, 2021a, 2021b).

The Staying UpRight (SUp) falls prevention exercise program was developed to address the fall risk factors of decreased lower limb strength and impaired balance in older adults living in LTC. The program was informed by clinical experience, previous falls prevention research, and an understanding of the physiological systems of balance and principles of rehabilitation (task specificity, progression and overload) (Binns & Taylor, 2011; Powers & Howley, 2007; Tresch & Jarc, 2009; Yiou et al., 2018). The SUp exercise program (intervention) was delivered by physical therapists and the dose matched chair exercise program, Flex and Stretch (control), was delivered by LTC activities staff. A pilot study found improvements in physical function, no adverse events, and that the program was acceptable to participants and staff (Kerse et al., 2009).

There is limited evidence regarding the sustainability of falls prevention programs in LTC. There is a lack of evidence from the experience of different levels of staff within the same LTC facility (senior management, onsite management, and frontline staff) examining the sustainability of falls prevention interventions. The field of implementation science currently focusses more on the initial uptake of evidence-based practice rather than whether it is sustained. This means we lack an understanding of what happens over time (Birken et al., 2020). The limited evidence from community falls prevention programs suggests that health practitioners experience personal and interpersonal influences, clinical barriers and limitations of research evidence as barriers to implementation (van Rhyn & Barwick, 2019). At an organizational level funding has been identified as a critical factor for sustainability (Smith et al., 2018).

This paper reports a qualitative study completed as part of an effectiveness-implementation hybrid type 1 study (Curran et al., 2012). This study ran alongside the Staying UpRight (SUp) randomized controlled trial (RCT) which assessed the effectiveness of a 12-month strength and balance group exercise program compared with a control program (Flex and Stretch) (Taylor et al., 2020). The RCT findings will be published separately. Qualitative studies are the most common design used to evaluate sustainability of evidence-based interventions (Flynn et al., 2022). Our qualitative study explored what factors influenced the maintenance of SUp as usual practice. In this paper, we report the perspectives of managerial and clinical LTC staff.

8.3 Methods

Study design

This study utilises an Interpretive Description (ID) (Thorne, 2016) methodology. This qualitative approach seeks to provide insight into practice-oriented issues and generate findings which could be applied in practice settings. The study is reported in accordance with the Standards for Reporting Qualitative Research (O'Brien et al., 2014). Ethical approval was given by the New Zealand Health and Disability Ethics Committee (HDEC) (18/NTB/151/AM04). This study is a sub-study of the RCT which was registered to the Australian New Zealand Clinical Trials Registry ACTRN12618001827224 on 09/11/2018. Universal trial number U1111-1217-7148.

Sampling and recruitment

Three NZ LTC organizations involved in the RCT were purposively sampled, seeking variation across business structure: one publicly listed ('for-profit') company, one private company ('for-profit') and one charitable organization (charity). Grouping facilities by organization enabled exploration of whether organizational influence impacted SUp being embedded in facilities. The sample were staff from the three organizations. Once organization consent was gained, researchers sampled for maximum diversity in participants by job role: senior management, onsite management and clinical staff. Eligible staff were emailed an invitation to participate by researchers. All participants gave written informed consent. All methods were carried out in accordance with relevant guidelines and regulations.

Data collection

Interviews and focus groups took place between April and August 2021 in person or via Zoom. Two experienced qualitative researchers (JP and KP) who were not involved in the trial conducted the interviews and focus groups. Interviews were conducted with senior management and onsite management staff. These allowed for detailed exploration of organizational contexts and discussion of commercially sensitive information. Focus groups were held with exercise group facilitators to allow exploration of a breadth of experiences and explore similarities and differences across practice settings. Separate focus groups were held specific to the exercise group (SUp and Flex and Stretch). One physical therapist had an individual interview as no other therapists attended the planned focus group. Three unplanned focus groups occurred when management and clinical staff at the same facility chose to be interviewed together. Questions followed an interview guide informed by Curran (Curran et al., 2012), supplemented with follow up questions and prompts to deeply explore participant experiences (Appendix Y SUp Additional file 1 (Interview guides)). In response to low facilitator participation and COVID lockdowns, an amendment was approved by HDEC on 23 September 2021 (ref 2021 AM 7851), to use facilitator emails sent during the RCT that discussed the classes, as data.

Data analysis

Interviews and focus groups were recorded and transcribed. Transcripts and high-level summaries were sent back to participants for confirmation of accuracy and meaning intent (Johnson et al., 2020). De-identified transcripts were organised and coded in NVivo, release 1.0 (QSR International, Melbourne, Australia) (QSR International Pty Ltd., 2020). We used conventional content analysis and followed the steps of listening to the recordings, reading, re-reading, coding individual transcripts, and refining codes as data analysis progressed. These were defined within a codebook. We worked across multiple transcripts and inductively formed categories (Hsieh & Shannon, 2005). Emails were also organised and coded in NVivo. Conventional content analysis was used and followed the steps of reading and re-reading, coding with codes generated from the interview and focus groups analysis and further code development. Once coded, initial themes were generated by category handling, specifically, writing themes on paper and manually arranging them (Richards, 2009). These were represented in a concept map for final discussion between research team members (Terry et al., 2017). Direct quotes were used to illustrate points made to ensure confirmability. Maximum variation sampling enabled data triangulation of interviews with multiple participants and constant comparison was used to ensure not privileging one account over another.

To aid rigour, a reflexive approach was taken throughout the analysis process to acknowledge the researcher's professional training, clinical experience, previous research, and role in developing the RCT exercise programs. The involvement of independent interviewers and co-authors with methodological expertise added rigour, as did processes such as negative case analysis, triangulation, journaling and constant reference to raw data.

8.4 Results

Fifteen people took part (Table 8.1). Five interviews were held, lasting between 15 and 34 minutes and five focus groups, lasting between 19 and 41 minutes. Twenty-four facilitators (n=19 SUp facilitators and n=5 Stretch and Flex facilitators) gave retrospective consent for their emails to be included in the data analysis. Quotes are reported with a participant identifier; SM (senior management), Mgmt (onsite management) and FAC (exercise group facilitator).

Table 8.1

Characteristics of the interview and focus group participants (n=15)

Characteristics	n (%)
Gender	
Male	1 (7)
Female	14 (93)
Role	
Senior Management	4 (27)
Onsite Management	5 (33)
Staying UpRight Facilitator (physical therapist)	4 (27)
Flex and Stretch Facilitator	2 (13)
Professional background	
Nurse	8 (53)
Physical Therapist	6 (40)
- facility Employee (NZ registered)	1
- facility Employee (overseas trained, not NZ registered)	2
- contractor (NZ registered)	3
Unknown	1 (7)
Years working in LTC	
<5	3 (20)
5-10	6 (40)
10+	5 (33)
Unknown	1 (1)

The decision-making of management staff was key in embedding falls prevention in organizations. The decisions made regarding use of resource and funding influenced what types of falls prevention approaches were used and who they were delivered by. Decision-making regarding how individual programs were delivered happened at clinician level – the activities co-ordinator or physical therapist. Decision-making appeared to be informed by several factors: business models and philosophies, requirements for evidence, and valuing the contribution of physical therapy. Table 8.2 illustrates the main factors and subtopics that emerged from the interview, focus group and email data.

Table 8.2

Summary of findings

Themes	Sub-themes
Business models and philosophies	Driven for profit versus being driven by care No specified model of care
Requirements for evidence	Knowledge of results required for financial investment Anecdotal evidence informed practice change
Valuing physical therapy	The invisible skillset Time equals money and money equals time

The influence of business models and philosophies on embedding SUp

An organization's ability and, perhaps more significantly, willingness to embed SUp as a sustained usual care program appeared to be informed by their business model and philosophy.

<u>Being driven by the need to generate a profit versus being driven to provide care</u>

For-profit organizations needed to make a profit for shareholders and required their facilities to be "fiscally responsible" (SM#2). Government funding was considered insufficient, with one senior management participant saying: "the amount we get per day doesn't look after the residents right now" (SM#1). Some facilities were not financially viable. Organizations used profits from the sale of independent units co-located in the retirement village (self-care apartments and villas) for facility operational costs however, doing so decreased organization profits. One senior management participant observed that "…unless the government recognises (the shortfall), there's gonna be a lot of providers go out of business. Particularly those that don't have villages. [to embed SUp in practice] We would have to actually think about how we funded it in the tight environment that we're in at the moment". In this financial context, physical therapist delivery of SUp was perceived as a cost. This brought tensions. Whilst valued for being "resident focused and quality of life focused" (SM#1), delivery of SUp was balanced against organizational finances, with participants saying "we have to be able to afford them [SUp classes] and not go down the gurgler" (SM#1) and "I would absolutely love to have something like this (SUp) in, but it's the matter of the money" (SM#2). Another senior management participant discussed weighing up the increase of a resident's wellbeing against their length of stay in a facility to determine the return on investment in SUp, "should it be an investment that we make to ensure that our rest home level care residents are more well? But then do we get them all well and they go home? (laughter) That's one side of the coin, but the other side of it is, get them all well and more mobile so that their quality of life is better and they live longer in a lovely environment with us" (SM#3). This comment was immediately followed by an expression of discomfort about basing a decision to improve a person's quality of life on financial gain, "[it] sounds pretty horrible" (SM#3).

In contrast to the for-profit organizations, the charity LTC organization received government and charitable funding. The charity required only that the organization provide care for those in need. This saw the organization foreground the well-being of residents alongside prudent financial management. Business decision-making was guided by principles of "promoting well-being" (Mgmt#5) and feedback gathered through surveys and resident focus groups. This created an environment where management did not feel financially constrained and could approach the Board for new initiative funding. The Board's view on the positive contribution made by physical therapy to resident's wellbeing was well known. The management participant reflected on the possibility of continuing SUp as designed if it was found to be effective, "is there a really good argument now to actually increase physio not just hold status quo" (Mgmt#5).

The for-profit organizations drive for profitability meant management had an acute awareness of cost. This led to tight budgeting which constrained the uptake of any new initiatives in the absence of specific funding. The charity organization's drive for resident well-being led to regular review of service delivery. Services were updated as part of business as usual to deliver better resident outcomes. The charity, in contrast to the for-profit organizations, had a mechanism for management to gain financial support for new initiatives if needed.

No model of care specified to determine the delivery of care

The NZ Government service specifications outline *what* is to be delivered in LTC but not *how* it should be delivered. Whilst a falls prevention policy was a requirement, the assessment and management of falls was determined by the LTC facility. This included to what extent physical therapy was involved.

Organizations were acutely aware of the NZ Government service specifications and what they were paid to provide. They also knew that the configuration and delivery of services were not dictated by the Government. A senior management participant quoted the service specification almost word for word, "there's a responsibility to ensure that older people remain active and have access to doing active things…there's not a specific model of care, if you like. And so the variation in the sector, not just for [organization name] but for everyone, is significant." (SM#1). Management participants knew that physical therapy was not in the service specifications. Most facilities had access to physical therapy however, this was variable within and across organizations, "physio is a bit of a challenge in the aged care sector and for us particularly it's quite variable. So it is something that I think has more, has value, but there isn't a really clear program of how physios would actually interface with aged care" (SM#1).

Usual therapy for residents was planned and supervised by physical therapists but often delivered by unregistered health professional staff: "[We] do a thorough physio assessment on them and then at facilities where we have assistants, we hand on to them mostly, for the ongoing care" (FAC#3). A management participant echoed "[physical therapist name] is more of like overseeing what's happening in the care home. So that's why she has a physio assistant. So the physio assistant can continue the plan. She's like the brain and the physio assistant is the skills" (Mgmt#3). Several participants expressed the personal conflict experienced by knowing what residents needed wasn't necessarily provided, "it comes back to my core values and belief that we don't have a reablement pathway in aged residential care at the moment. And it's not even everybody that needs it, is it? But for those that do, I think it's unfair that they don't really get that" (SM#3). Similarly, another said: "they [residents] often come in very deconditioned and we build them up. So being able to actually do some really good physio intervention as part of that gets them into a much better health state. So it should be part of what we do, frankly" (SM#2).

Senior and management participants' desire to care for people revealed the ethos of their clinical background. They understood how the service specifications impacted on service delivery through what was and wasn't specifically funded and how this effected outcomes for residents in their care.

Requirements for evidence

All participants considered SUp was valuable, but they wanted evidence that falls were prevented in order to support a case for SUp being integrated into everyday practice. This was needed for organizational resourcing, and to support individual therapists to change their practice.

Knowledge of results required for financial investment

For organizations to support routine SUp provision, participants in management roles needed to "see what the results are first" (SM#2). They stated that having data would strengthen a business case for ongoing funding. A manager said, "it would be tremendous to see the results of the overall research because it always just reinforces that you're on the right track with something. And it should drive business decisions," (Mgmt#5) and knowing that "(SUp) would be evidence based and proven" (SM#4) would be crucial to being able to fund the delivery of SUp after the program of research finished. There was also an awareness of the economics of being able to deliver the program in a group setting: "I think group exercise session is probably a much better bang for your buck, because you're covering off a large group" (SM#2).

This perhaps reflects the dominant discourse of evidence-based practice entrenched in health care services.

Anecdotal evidence informed practice change

Clinicians, predominantly, considered the practice-based evidence they observed through participating in the RCT was sufficient to support using SUp in usual care. In particular, they drew on observations of individual residents, referring to changes in (1) residents' capabilities: "one of the ladies walked all the way up from the downstairs wing and walked back - previously she was using a wheelchair to get to and from the class" (FAC#4); (2) increased fitness and balance: "I was very pleasantly surprised how rapidly I could get them up to 60 minutes of exercise and how far I could get in the difficulty of exercises challenging their balance" (FAC#8); and (3) resident engagement: "residents had asked for more exercises" (FAC#6). Some physical therapy participants built on this, adding classes to usual care where previously none were available or increasing the number of classes offered and applying concepts from SUp within these: "It's hard to teach an old dog new tricks, but we have learnt some… it has made us realise that we can push them" (FAC#2). The engagement of the physical therapists themselves was seen as positive and convinced some management participants to support practice change, with one reflecting: "physios don't change stuff without good evidence" (Mgmt#5), while another requested the physical therapist run more classes. While physical therapy SUp facilitators could see changes in individual residents' functional abilities, management participants needed to measure the change across all those who took part in the SUp program and were specifically focused on the falls prevention outcome. Observing changes in participants and perceiving the program produced better outcomes for residents resulted in clinicians being more open to change. However, this resulted in clinicians incorporating concepts of SUp into usual care rather than management looking for additional funding to continue the SUp program.

Valuing the contributions of physical therapy in falls prevention

Physical therapists were part of the multidisciplinary team in all facilities, but their skillset was utilised differently between the for-profit and charity organizations. In the for-profit organizations their input in falls prevention was minimal.

The invisible skillset of physical therapy in LTC

Physical therapy input was viewed positively at the charity, reflected by the manager observing “it’s such a drawcard for lots of families, having such a proactive physio team” (Mgmt#5). However, in the for-profit organizations physical therapists were predominantly “limited to assessment and advice” (FAC#4), contributing to multidisciplinary resident assessments and care plans. A senior management participant observed that “the physios do more paperwork than they do time with the residents doing walking programs” (SM#4). This perhaps meant managers and other staff did not experience and understand what falls prevention skills physical therapists had. Instead, falls prevention practices were a set of discrete tasks completed by a nurse or caregiver, mainly focused on the physical environment. If residents were having recurrent falls, physical therapists were sought for advice on how to manage the environment rather than for therapeutic intervention, as one manager illustrated: “when the resident had a fall, usually the clinical team will send an email to [physio name], “Can you please review this transfer plan? Is there something else that we can do?”” (Mgmt#3). This then contributed to senior management participants’ expectations not being met and they questioned the value of physical therapy. One commented: “Whenever I … do any clinical reviews of [residents], their physio assessments and the physio input into their plan is nothing like what I think it could be or should be. So it comes down to telling them, ‘Yes, carry on with the walker’. Well the nurse could’ve figured that out. So I don’t see a great depth of investment. Or individual planning.” (SM#3). The clinical reasoning of physical therapists appeared to be invisible to managers but was evident when physical therapists described how demanding it was to challenge a participant “to their level”. Observations and ongoing clinical decisions needed to be made during each

SUp class, “you need to make a quick assessment of who is safe to stand up and try standing on one leg” (FAC#4). This demonstrated how assessment and clinical reasoning skills are central to individualising SUp and supporting individual progress. However, if this skillset is not usually recognised within an organization, this may not be ‘seen’ by those who make the financial decisions.

Time equals money and money equals time

All physical therapists in the for-profit organizations were contracted on an hourly basis. Any increase in physical therapist time had budgetary impact. The SUp research funded the physical therapists’ time and enabled physical therapists to prioritise SUp classes in their workload. In everyday practice, often group classes were cancelled or given to an assistant to take: “an exercise class is often the first thing to go off my list if I have lots of new referrals or someone very acute” (FAC#4). One physical therapist reflected on the possibility of continuing to provide SUp, saying “there’s no way they would be likely to allow me an hour out of my contracted hours… I couldn’t afford that much time. I would just get way too far behind on all my other stuff” (FAC#3). However, in the charity, physical therapy was available to all with the onsite physical therapy gym open to treat residents in the morning. In the afternoon physical therapists visited residents who “needed to be seen individually” (FAC#2). There appeared to be no cost sensitivity in the charity. The value the Board placed on physical therapy was reflected in physical therapists being employed on staff and well resourced. As such, the cost of physical therapy was already incurred “…we just know we fund physio…our team have just absorbed it” (Mgmt#5); this perhaps made it easier to make changes to physical therapist programs and for SUp to be maintained after the research program finished.

To deliver SUp without additional funding in the for-profit organizations, management participants looked for workarounds that would mean the program was not delivered by physical therapists as designed and tested in the RCT. Even when value was seen, the cost was considered: “…I think there’s absolute value in it, it’s just about how we do it, what the workforce’s availability is and what the cost is to the sector” (SM#1). To this end, the management preference was to deliver SUp using diversional therapists or activity coordinators already employed so they wouldn't have to pay for a physical therapist. When a physical therapist SUp facilitator asked a manager about SUp continuing: "…he [the manager] said yes to carrying on [SUp] but he thought that his activity coordinators were able to take over both sessions a week so he wouldn't have to pay for a physio" (FAC#7). Another appeared resigned, saying "It is a bit of a pity but what I expected as they don't like spending money on physio" (FAC#5). This led to not wanting to deliver the program with FAC#5 saying, "I don't imagine [name] will pay for me to continue sadly as the classes literally double the hours I get there!". Contracted physical therapists were acutely aware of their time costs and the impacts of funding. The contrast of contracting versus employing physical therapists to work in facilities demonstrated spending as little as possible to meet the requirements of the service agreement and create a profit versus not being profit driven. This highlights how business models and philosophies shaped care decision-making.

8.5 Discussion

The study results revealed that organizational budgets, and underpinning contractual and financial requirements, influenced whether managers and/or physical therapists considered it was possible to embed a falls prevention exercise program as standard practice in LTC after the cessation of the research program. Identifying these factors highlights to designers of future falls prevention initiatives that on-going funding, as an aspect of delivery and maintenance, must be considered. This evidence also illustrates to policy makers that service specifications are used as drivers of care delivery and that identifying and addressing key health issues such as falls prevention should be considered in the wording of contractual documents.

Healthcare can be considered a complex adaptive system, as it comprises different components that are dynamically inter-related, changing in response to events (Braithwaite et al., 2018; Hawe et al., 2009; Rouse, 2008). In this study facilities, organizations and the Government are system components however, each is also its own system. With this in mind, a complex adaptive systems view was taken and SUp considered as an event occurring in the complex adaptive system of the NZ health system (Braithwaite et al., 2018). While the study findings are contextual to NZ due to the funding model, the findings may be translatable to other countries when considering service delivery of falls prevention programs in LTC.

In NZ, means testing is used to determine the amount of government subsidy paid to a LTC facility for a person's residency. Most residents receive a form of subsidy (Ministry of Health, 2020). Government funding varies for residents assessed as requiring low dependency, high dependency and dementia level care, but is not based on the individual care needs of the resident as assessed by the interRAI. All study participants with budget responsibility described not only the cost of physical therapy as a barrier but also the larger issue of insufficient government funding for the increasing level of care residents needed. Their experiences echo an industry report that sought to update the funding model for LTC from the current three broad levels of low dependency, high dependency and dementia level care (Parsons et al., 2018). This report proposed a case-mix funding model and validated the use of interRAI Resource Utilisation Group (RUG-III) data to better reflect the need and funding required to care for each resident (Parsons et al., 2018). Following publication of the report, a NZ Government commissioned review of the LTC funding model recommended the use of interRAI RUG-III as a more sensitive model for allocating funding (Ernst & Young, 2019). With each resident assessed with the interRAI 6 monthly, adopting a case-mix funding model would match the resident's current care needs on an ongoing basis (Central Region Technical Advisory Services Limited, 2022). The review recommendations have not yet been adopted. The rationalisation of health resources in the face of an ageing population will be an ongoing pressure as LTC is increasingly used for end of/late life care, with residents living in LTC for an average of 18 months but the mortality rate within one month of admission reported as high as 36.5% in NZ (Connolly et al., 2014; Ernst & Young, 2019). Providing the level of care needed at this stage of life is resource intensive. The senior management participants' call for more funding to embed SUp rather than redistributing resources to falls prevention is understandable.

Considering the financial environment, growing care demands from increasingly frail residents and the drive for fiscal responsibility, if physical therapy is not understood and valued, it is likely that management either will seek cheaper methods of delivering SUp or not continue it at all. Delivering SUp without increasing costs saw participants adapting the intervention for their context (Moore et al., 2019). Physical therapist participants adapted SUp content by selecting elements of the program and integrating concepts in their current workload, while management participants' adapted SUp delivery by using unregistered (cheaper) healthcare professionals. Using unregistered healthcare professionals to deliver falls prevention exercise is not uncommon in the community and can be effective (Robertson et al., 2001; Sherrington et al., 2020). However, in previous LTC research, unregistered healthcare professionals were trained to deliver a manualised falls prevention exercise program and exercised participants in sitting "for safety", removing the element of standing balance, a critical component of falls prevention exercise (Binns et al., 2020a; Sherrington et al., 2017). This suggests that more physical therapist input may be required to train and maintain program delivery by unregistered healthcare professionals, negating cost savings by not using physical therapists to deliver programs. The lack of parameters for physical therapy service in LTC creates the potential for providers to deliver to the minimal contractual obligation. A NZ survey of 373 facilities reported only 16 physical therapists were employed but 55 assistant physical therapists and 895 activities co-ordinators (New Zealand Aged Care Association, 2020). However, the annual NZ physical therapy workforce survey reported 111 physical therapists working in LTC (Physiotherapy Board of New Zealand., 2020). Rather than employ physical therapists like the charity in this study, it appears that most facilities contract physical therapists and employ activities co-ordinators to carry out physical therapy plans and provide "activity" to meet government service specifications. This may also reflect the shift from socially oriented and charitable providers to large corporations now providing the majority of LTC beds and needing to generate investor profit (Kilian, 2018). A lack of parameters to guide delivery of physical therapy services in LTC is not unique to NZ and has been found to vary widely between countries (Brett et al., 2019). The Netherlands utilised physical therapy the most; with a focus on rehabilitation and the goal of discharging people back to their own homes from LTC. In Canada, UK, Denmark, Italy and Japan some LTC facilities had no physical therapy services. Government funding appears to be the common denominator for determining physical therapy utilisation with the Netherlands Government fully funding physical therapy and the UK, Canadian and NZ governments only partially funding physical therapy in LTC (Benjamin et al., 2009; Brett et al., 2019).

The research funding allowed the delivery of SUp to be prioritised; that the program ceased when funding ended was not surprising. When an intervention (SUp) is introduced to a complex system (LTC), the system realigns to accommodate the new event, often at the expense of another component within the system. In the LTC facilities that ran exercise programs prior to SUp, they were typically only 30 minutes long. For the SUp classes to be accommodated, these class times were gradually increased. In facilities that had not run classes prior, the SUp classes were additional as the extra staff time was paid for and the physical therapist's usual case load was not affected. When funding was stopped status quo returned to the system (LTC), with physical therapists applying some elements of SUp to their work but not delivering SUp as designed. The sustainability of falls prevention programs beyond external funding is an ongoing problem (Lovarini et al., 2013). Partnerships and collaborations, supported by policy have been identified as critical elements for sustainability (Smith et al., 2017). What is not clear in the literature is why there appears to be an expectation that falls prevention can be delivered without appropriate ongoing financial resourcing. With the large cost of falls to the health system being known, surely it is cheaper to prevent a fall than pay to deal with the consequences.

8.5.1 Strengths and limitations

A strength of this study was the sample of staff through the levels of LTC organizations from senior managers in corporate offices to clinicians providing care for residents in facilities. This diversity of roles represented in the sample enabled experiences of SUp to be explored from different perspectives and triangulated to gain a fuller understanding of what might help or hinder embedding SUp in everyday practice in LTC. These findings will contribute to program implementation decision making should SUp prove to be an effective falls prevention exercise program. While it was planned to include residents and their families, the sample did not include residents as the NZ COVID-19 restrictions impacted this study. During this time visitors were not being permitted to LTC facilities and therefore researchers were not able to run resident focus groups or gain resident permission to contact their family. Lockdown protocols also increased staff workload and some participants chose to be interviewed together, saving time, and resulting in unplanned focus groups. Power relationships from the staff hierarchy (nurse manager, nurse) may have played out with participants not speaking as freely as they may otherwise have in an interview.

8.6 Conclusions

The results of this study suggest that if SUp is effective in preventing falls in LTC it may not become embedded within everyday practice, as designed, without additional funding support. This study identifies that policies that underpin funding decisions need to support physical therapy-led falls prevention exercise programs to be embedded in LTC. To be funded and resourced appropriately, the LTC facility service specifications need to be updated to recognise the health issue of falls in this population and current best practice evidence in LTC falls prevention. However, if status quo remains and funding is not attainable, the essential components of SUp need to be identified and a complexity informed approach taken to work with individual facilities to adapt SUp to suit.

End of published manuscript.

Chapter 9 Discussion

The overall objectives and aims of the thesis were:

1. **To develop and evaluate a combined cognitive and physical exercise programme in ARC.**

   Specific aims:

   1.1. To develop a combined cognitive and physical fall prevention exercise programme.

   1.2. To test the feasibility for a randomised controlled trial (RCT) evaluating the combined programme.

2. **To understand the complexities around the delivery of a fall prevention exercise programme in the complex context of ARC.**

   Specific aims:

   2.1. To explore the factors that impact ARC providers' decisions to implement fall prevention exercise programmes.

To achieve Aim 1.1 a literature-based investigation was undertaken to support the decision to use CST and the prescription of the physical fall prevention exercises (Chapters 2 and 3). This was followed by combining physical exercise with the CST programme to develop the CogEx programme (Chapter 4). To achieve Aim 1.2 a mixed-methods feasibility RCT was undertaken to establish the feasibility of a fully powered RCT using CogEx to prevent falls in ARC (Chapter 5). A more nuanced interpretation of the fidelity data was undertaken to better understand *what* contributed to the observed fidelity and inform what refinements were needed to CogEx (Chapter 6). Due to the feasibility issues identified a decision was made not to further refine the CogEx intervention.

The second objective of the thesis was established as a result of the findings from the earlier thesis work and represented a change in direction to expand our understanding of the complexities around the delivery of a fall prevention exercise programme in the context of ARC (Chapter 7). To meet Aim 2.1 a type 1 hybrid effectiveness-implementation design was used and interviews with staff in different roles across ARC organisations explored the factors that influenced whether a fall prevention exercise programme (SUp) would be continued as part of usual practice in ARC facilities at the conclusion of the funded trial period (Chapter 8).

In this chapter, the study findings are drawn together, discussing the contributions made and demonstrating how these support or challenge current falls prevention initiatives for older adults living in ARC. Limitations of this thesis are acknowledged while implications for further research discussed.

9.1 Summary of findings

There are four key findings arising from the thesis and are presented in this section.

9.1.1 Physical exercise can be incorporated into CST but was it?

Aim 1.1 of this thesis was to combine physical exercise with CST to develop a fall prevention intervention for ARC residents that had both cognitive and physical exercise components. The results from the first study demonstrated that this was possible (Binns et al., 2020a). CST was flexible enough to allow physical exercise to be combined. It is important to note that the facilitators successfully kept the CogEx session to an hour by removing the news reading activity. This timeframe was the same as CST and therefore did not increase staff resource utilisation or burden on the ARC residents. The adaptability of the component parts of CST to the ARC context demonstrates that the CST programme can be used as a vehicle to deliver other elements which may be beneficial to ARC residents. The programme was developed however, study Aim 1.2 found that facilitators trained to deliver CogEx, when left to run the programme without researcher support did not deliver the CogEx programme as designed. An important finding was that the facilitators delivered the programme predominantly in sitting, which removed the balance component from the physical exercises (Binns et al., 2020a).

Supported by the above thesis work it became obvious that the provision of fall prevention exercise programmes in ARC is complex and requires more than simply packaging components together and training deliverers. Whilst it was possible to combine components and train people to deliver, it was infrequently delivered as planned under routine conditions in ARC. The following section discusses the complex context of ARC and how this can impact the delivery of fall prevention exercise programmes in ARC.

9.1.2 Falls prevention requires investment

Falls are a major health problem for residents and care providers in ARC however, falls prevention is under resourced. The SUp study (Chapter 8) showed that in the tight financial environment, Managers perceived the introduction of anything new through a lens of budgetary impact. The resource to provide care for residents is so tight that the introduction of a new intervention to the package of care is at the expense of removing something else. Falls will not decrease without adequate investment to support ARC to provide falls prevention programmes, an observation also made in other ARC fall prevention studies (Hewitt et al., 2018; Logan et al., 2021). In the social welfare system of NZ, the Government funding for ARC needs to be increased so that if and when effective fall prevention interventions for ARC are established facilities can afford to implement them.

9.1.3 Physiotherapists have minimal input into falls prevention in ARC

Related to the above finding is the underutilisation of physiotherapy and concomitant undervaluing and lack of understanding of what physiotherapy can offer ARC residents. The service specifications that shape the care delivered in ARC do not include direction for how physiotherapists should be used (Te Whatu Ora – Health New Zealand, 2022a). Although physiotherapists are the health professionals trained to deliver physical fall prevention (which includes sensory and environmental risks as well strength and balance) (Sherrington & Tiedemann, 2015), the SUp study found their role had been reduced to one of assessment with delivery of any intervention typically handed over to unregistered (cheaper) healthcare professionals (Binns et al., 2023). Residents' and family expectations of a physiotherapy service in ARC may well differ.

9.1.4 The impact of the ARCs ethos on research

The qualitative data of the CogEx and SUp studies (refer to Chapters 5, 6 and 8) captured the unanticipated impact of the ARC ethos on the delivery of the fall prevention exercise programme. For example, the ARC culture of inclusivity respects that the ARC facility is a resident's home and that if they want to join an activity they can join. This resulted in both studies seeing non-research participants join classes. It also saw some facilitators err towards delivering exercises to the lowest level of physical ability so that everyone was then doing the same. Knowledge of this ethos could have been included in the content of the training. However, when training a person to deliver an intervention, unlike trialling a pharmaceutical for physiological effects, you are asking a community of individuals with their own world view to do something your way. You are asking them to displace what they have always done and trust that an outsider knows better. The hierarchical research process needs to be replaced by a methodology that privileges the voice of the people within the context where the research is being undertaken so that ethos and culture become visible (Nicolaidis et al., 2011; Pandya-Wood et al., 2017; Pollock et al., 2019; Zullig et al., 2023).

9.2 Reviewing and reiterating the research approach to falls prevention in ARC

These four key findings led to the following analysis that considers a change in the approach to research implementation of programmes in ARC.

9.2.1 Re-thinking research in complex adaptive systems

Commonly, health researchers identify a clinical problem, develop and then test a solution using traditional approaches such as a controlled clinical trial sometimes using models such as the Medical Research Council framework for developing and evaluating complex interventions to guide the structure of the research (Brown et al., 2017; Craig et al., 2008; Landes et al., 2019; Skivington et al., 2021b; Zullig et al., 2023). However, in a complex adaptive system such as ARC (see Chapter 7) this approach may not account for the context minutiae that can influence the success of the intervention (Braithwaite et al., 2018; Logan et al., 2022). A common finding across Chapters 5, 6 and 8 was the impact of ARC stakeholders *not* being involved in the development of the research and intervention. This led to unforeseen adaptations to the interventions over time. Importantly, whilst the researchers were familiar with the ARC environment, all were health professionals now working as university academic staff, they did not have intimate knowledge of the current work environment in ARC.

Over the last twenty years the NZ ARC population has become more frail with 57% of residents now receiving the highest level of care (private hospital, dementia or psychogeriatric level care) compared to 41% in 2008 (Grant Thornton New Zealand, 2010; New Zealand Aged Care Association, 2022). Staff ratios are lower than those in Australia, with one staff member on duty for 10 or fewer residents, for up to 30 residents an additional staff member must be on call, while two staff members must be on duty for more than 30 residents, rising to 3 if more than 60 residents (Te Whatu Ora – Health New Zealand, 2022a). In Australia, the ratio is higher and changes to accommodate the times when residents need more staff input, with one staff member to 6 residents during the day shift, increasing to one to nine in the afternoon shift and one to 20 during the night (Brett et al., 2021). In rest home level care, a registered nurse must be employed and predominantly develops care plans, provides primary medical treatment, supervises and delegates care tasks to the non-registered healthcare workers who provide the majority of the care for this frail population (Burrow et al., 2017; Te Whatu Ora – Health New Zealand, 2022a). At private hospital level care one registered nurse and one other staff member must be on duty (Te Whatu Ora – Health New Zealand, 2022b). This staff mix is driven by the minimum standard set out in the funding agreement. Healthcare assistants are paid less than registered nurses and so are employed when resident numbers increase. As the role of healthcare assistants expands to deliver care to increasingly frail residents, the workload of supervision and delegation of the registered nurses also increases (Burrow et al., 2017; Parsons et al., 2018). Not fully understanding the extent of the work pressures on ARC staff resulted in an intervention developed *for* ARC rather than *with* ARC. Had we talked to stakeholders before we developed the research and interventions, the programme we designed may have looked quite different.

The influential Medical Research Council framework originally recommended the sequential phases for developing an RCT to test complex interventions (Campbell et al., 2000). The 5 phases guided the fundamental research processes from development to implementation, they are:

- Preclinical phase to identify evidence to support the proposed intervention
- Phase 1 to define the components of the intervention through modelling or qualitative testing
- Phase 2 to assess the feasibility of the intervention and evaluation design
- Phase 3 to evaluate the intervention with a definitive trial
- Phase 4 to promote effective implementation (Campbell et al., 2000; Skivington et al., 2021b)

Revision and updates have been made as experience in evaluating complex interventions has grown and limitations in the framework have been identified, acknowledging that the research process may not be linear and recommended considering alternative research designs to RCTs when biomedical methods may not apply (Campbell et al., 2000; Campbell et al., 2007; Craig et al., 2008; Skivington et al., 2021b). One key change is the addition of six core elements that should be considered throughout the research phases above to answer the following questions:

- How does the intervention interact with its context?
- What is the programme theory underpinning the intervention?
- How are stakeholders' engaged so that their perspectives are included in the research?
- What are the key uncertainties?
- How can the intervention be improved?
- What are the economic considerations for resource and outcome consequences? (Skivington et al., 2021a, 2021b).

The answers to these questions assist researchers to look beyond solely whether an intervention works.

The field of implementation science has seen the development of many models and frameworks to guide researchers to understand the implementation of research into practice (Damschroder, 2020; Nilsen, 2015). Those frameworks categorised as determinant, specify the barriers and enablers that influence implementation outcomes and consider the influence of relationships and interactions in complex environments (Nilsen & Bernhardsson, 2019). There are at least 17 identifiable determinant frameworks and can be grouped by the outcome to be achieved such as adherence to clinical guidelines, implementing innovation in organisations, practice change, behaviour change, policy implementation, or the adoption, implementation and sustainability of health care interventions (Huybrechts et al., 2021; Nilsen & Bernhardsson, 2019). However, context is inconsistently defined across these frameworks with some of them identifying specific contextual aspects such as organisational support, financial resources, social relations and support, leadership, and organisational culture and climate, positioning context as a multidimensional concept (Nilsen & Bernhardsson, 2019). Selecting which framework to use is challenging as there is considerable overlap as development has seen framework elements selected and used to form a new framework. What is not obvious in these frameworks is the input of the end users or recipients of the intervention.

Health research co-design is a term that can be used to describe any creative process that engages the end users in the research process and includes more than 60 research approaches (Masterson et al., 2022; Robert et al., 2021; Slattery et al., 2020). Some of these approaches are:

- co-design (Masterson et al., 2022; Slattery et al., 2020)
- co-production (Hickey, 2018; Masterson et al., 2022)
- collaboration (Nierse et al., 2012)
- co-ownership (Nierse et al., 2012)
- co-creation (Goodyear-Smith et al., 2015)

The term ‘cobiquity’ was coined to encompass the plethora of ‘co-‘ words that have emerged to describe approaches that include the end user in research

(Williams et al., 2020). A concomitant rise has been seen in the range of definitions given to each approach, reflecting that these concepts are evolving (Masterson et al., 2022). For this thesis the term co-design will be used as an umbrella term to encompass any of these approaches that have the users voice as an integral component.

Co-design approaches have been used in the development of some fall prevention initiatives. These three studies are examples of the diversity of co-design in health research. For example, a multifactorial fall prevention programme The Guide to Action for Care Homes used a co-design approach to develop their programme (Logan et al., 2021; Robertson et al., 2012). In this instance, co-design was described as including clinicians on the research team to develop the initial programme and then seeking input from ARC residents and staff after taking part in the programme to provide information on which to modify the programme. A collaborative approach was used to implement a community fall prevention training programme, A Matter of Balance training programme, in which partnerships were developed with a government agency, community organisations and emergency services to share information to improve the implementation (Severance et al., 2022). Only a third of the targeted areas implemented the programme and the researchers reflected that the at-risk communities (end user) should have also been involved in the implementation planning. Co-design was used in the development of a home based monitor of balance to understand the needs and values of older adults and health professionals in order to establish the usability of the device (Lan Hing Ting et al., 2020). The researchers describe using a participatory design involving the end user in the design of the device and the features that were ultimately changed during this process. Given the lack of concrete definitions of co-design, the best way forward may be to state the guiding principles, identify who should be involved and describe the co-design methods that will be used to answer the research question (Hickey, 2018; Wolcott & McLaughlin, 2023).

The voice of the end user is becoming privileged. For example, the National Institute for Health and Care Excellence has a patient and public involvement policy to ensure that their interests are represented and there are opportunities to contribute to guidance developed by the organisation (National Insitute for Health and Care Excellence, 2013). The hybrid effectiveness methodology includes the stakeholder voice to assess implementation outcomes (Landes et al., 2019). Stakeholders are all those who will be involved in the real-world implementation of an intervention such as the residents, programme facilitators, ARC staff and the managers in the CogEx and SUp studies, or those who have a vested interest in the outcomes following implementation such as the executive managers and ARC organisations. However, these voices should be key in intervention planning (Harrison et al., 2019) as it is the end users who experience the intervention (the programme facilitators and the ARC residents) in the real world setting and ultimately will adopt and adapt interventions to suit their needs and context (Evans et al., 2019; Evans et al., 2021; Movsisyan et al., 2019). The impact of end users was starkly demonstrated in the CogEx study when the intervention was adapted to be delivered in sitting (Chapter 5) and in the SUp study when the physiotherapists adapted components of SUp for real world use once the trial funding ceased to pay the delivery costs (Chapter 8).

There is no one perfect model or framework to guide researchers undertaking research in complex systems. Knowing the desired research outcome can assist in determining which frameworks would be appropriate to use (Nilsen, 2015). However, the best guides are the people within the complex system that know the system and the competing drivers that operate within that system and create the complex context. The research methodology for testing interventions in complex systems needs to move away from the RCT which factors out the system context with randomisation and control (Rutter et al., 2017). Attempting to evaluate a complex intervention such as a falls prevention exercise programme in ARC but removing the contextual elements that will ultimately influence the intervention outcome, does not make sense. Changing our research approach to move towards authentic partnerships and a research agenda driven by the end user and includes them from concept development may result in research that is meaningful, appropriate and sustainable (Franck et al., 2020; Greenhalgh et al., 2016; Skovlund et al., 2020; Zibrowski et al., 2021).

The level of engagement required of all interested parties in partnership is high and the investment maybe perceived as prohibitive however, the research waste created from repeatedly using RCTs in complex environments and expecting usable real world outcomes needs to be addressed (Ivers & Grimshaw, 2016; Showell et al., 2023).

9.2.2 Changing behaviour to prevent falls in ARC

A key finding of Chapters 5, 6 and 8 showed that the introduction of a fall prevention exercise programme in ARC required more than providing education and training of a new skillset, and this was seen in the impact of ARC ethos on programme delivery in both studies. Although an aim of ARC is to keep people safe (New Zealand Government, 2024), it appears that this may be achieved through limiting physical activity and long periods of time spent sedentary, which results in muscle weakness and increasing fall risk (Barber et al., 2015; Benjamin et al., 2016; Gulka et al., 2020; Kazoglu & Yuruk, 2020; McArthur & Iaboni, 2021; Toulotte et al., 2003).

In our CogEx study, CST facilitators had been trained to deliver and progress the physical exercises in the CogEx programme, it should be remembered that the CST facilitators were non-registered staff (activities co-ordinators) and not registered health professionals. They defaulted to their usual practice of delivering group activity in sitting for resident comfort, engagement and safety and did not encourage standing and balancing (Chapter 5). This suggests that the training was insufficient and raises the question of what would be required to change the routine behaviour of the activities staff who delivered the programme (Chapter 6).

In the SUp study, SUp classes were affected by the physiotherapists' role in ARC typically being one of assessing residents, giving advice and then a healthcare assistant delivering the ongoing care (Chapter 8). Physiotherapists did not want the exercises to be too hard for the residents even though they had the skills to safely challenge balance and the knowledge of exercise prescription from their physiotherapy training. At the end of the study, they selected elements of SUp to continue with rather than continue delivering the 1-hour programme as designed (Chapter 8).

The difference between the two studies was CogEx exercise sheets were returned at the end of the study, while the SUp exercise sheets were returned to the research team monthly and the physiotherapists were asked to progress the class content and length of time, providing an external driver for practice change. It is likely that this change was transient given that most physiotherapists doubted that once the research funding ceased, they would have the time to deliver a 1-hour exercise class as well as their usual work. The research did not change behaviour, rather the research imposed a task to perform.

Changing routine practice is challenging as it is driven by personal, professional, and organisational influences (Fixsen et al., 2011; Linnerud et al., 2023; van Rhyn & Barwick, 2019; Vandervelde et al., 2023). This was demonstrated by physiotherapists selecting SUp components that they considered useful, fit within their current practice and the limited time to take classes. Provision of education through meetings and printed materials are commonly used methods to promote behaviour change in health care professionals (Forsetlund et al., 2021; Giguère et al., 2020), as are local opinion leaders, marketing and reminders (Johnson & May, 2015). Action based methods such as monitoring and auditing or reminders, like those used in SUp, are more likely to change behaviour (Johnson & May, 2015). However, collective action rather than an individual changing, is more likely to support a new behaviour becoming the new normal (Johnson & May, 2015). With this in mind, Managers have been identified as a key to successful implementation of falls prevention in ARC when they maintain fall prevention as a key task for staff thereby encouraging collective action (Linnerud et al., 2023). Involving stakeholders in the implementation process identified that a multicomponent approach was needed that also included establishing implementation teams, tailoring improving competence and implementation support (Linnerud et al., 2023).

Behaviour change approaches have been used in the implementation of fall prevention initiatives. An examination of fall prevention initiatives across a region in Ireland identified 21 behavioural change techniques that were used

(McHugh et al., 2018). Specific techniques varied depending on the context and the target population. Action planning and problem-solving techniques were used to prepare organisations for programme implementation. Coaching was used to train, educate and persuade the health professionals to refer to or deliver the programme. Patients received written information to encourage programme attendance. Of these three groups, it appears the patients received the least input to support behaviour change which is surprising as if they do not engage with the programme, the aim to decrease falls will not be achieved. A study to increase primary care providers screening of falls in America used the technique of falls champion to deliver the health professional education and lead the implementation (Stevens et al., 2020). To embed the screening in everyday practice prompts were developed and added to clinical records, while audit and feedback provided the professionals with knowledge of results to maintain motivation to continue to screen. Common elements of behavioural change used in these studies were tailoring, consciousness raising and peer education however, both demonstrated that for implementation to be successful investment into supporting implementation is required (Liddle et al., 2018; Vandervelde et al., 2023).

9.2.3 Matching falls prevention approaches to the changing ARC sector

In the 10 years between piloting the Staying UpRight multifactorial intervention in 2008 and the SUp RCT in 2018, ARC became less delineated between rest home and private hospital meaning residents required increasing levels of care (New Zealand Aged Care Association, 2020; Parsons et al., 2018). Triggered by the NZ Government policy directive for people to age in place, people are entering ARC older, frailer, and closer to the end of their life (Boyd et al., 2011; Braithwaite et al., 2018; Ernst & Young, 2019; Ministry of Social Development, 2001). ARC in NZ now increasingly provides end late life care, with residents living in ARC for an average of 18 months but the mortality rate within 1 month of admission is reported as high as 36.5% (Connolly et al., 2014; Ernst & Young, 2019). European countries have similar statistics with a median length of ARC stay ranging from 2.1 years in Germany to 2.3 years in Northern Ireland (Achterberg et al., 2019). During the last decade in NZ, the business of aged care has emerged from privatisation of the sector that has seen private and publicly listed companies become the dominant providers where previously not-for-profit organisations had been (New Zealand Aged Care Association, 2020).

A key finding of Chapter 8 was the tight financial environment in the NZ ARC sector which did not support funding of physiotherapist led fall prevention exercise programmes. Faced with the fiscal responsibility to meet growing care costs with limited Government funding and the drive to return a profit to shareholders, the decision not to invest in fall prevention can be understood. When viewed from a business perspective and return on investment, is investing in group exercise to prevent a potential fall in a person's last years of life appropriate?

The heterogeneity of ARC residents necessitates an individual assessment to identify a person's fall risk factors, followed by an appropriate intervention. All residents are assessed on admission into ARC with a variety of assessment tools (Courtney et al., 2003; O'Connell et al., 2011; Robertson et al., 2012) and in NZ ARC residents are assessed 6 monthly with the international Resident Assessment Instrument (interRAI), which contains a clinical assessment protocol for falls (Norman & Hirdes, 2020). So, the opportunity to identify fall risks for an individual already exists within ARC at no additional cost. Individual resident assessment supported by a decision tool to guide management and trigger the appropriate intervention to address the identified fall risks was shown to reduce falls in ARC (Logan et al., 2021). Staff education and ongoing support was a part of the programme to encourage a culture change that included fall prevention being a priority for all staff, and all staff being empowered to take action through access to resources (Logan et al., 2021; Robertson et al., 2012). Despite the extra resource that was invested the programme was found to be cost effective.

There is now moderate certainty evidence that exercise can prevent falls in ARC residents however, residents need a minimum level of cognitive ability and mobility to participate (Dyer et al., 2023). Considering the interrelatedness of cognition with motor function in the fall risk factor of cognitive dysfunction, there may be a point at which physical intervention is not suited to an individual and a different approach is needed. The investment of interpreting individual routine assessment and then targeting identified fall risk factors with an appropriate intervention may be a much lower cost to ARC than the increased level of care needed by a resident following a fall.

9.3 Limitations of the thesis

Limitations of specific studies have been discussed in the chapters that comprise the published manuscripts. However, the limitations of the thesis in its entirety deserve further consideration.

Firstly, the initial research plan for the thesis was not followed. Originally, an objective of the feasibility study was to observe if the CogEx programme was better suited or more beneficial to older adults living with dementia in the community or in ARC (Chapter 5). It was planned to refine the CogEx programme using the feasibility findings and complete a fully powered RCT. The feasibility study identified significant other issues including intervention fidelity that needed to be addressed so a change in direction was instigated.

Secondly, the CogEx findings (Chapters 5 and 6) were not available to inform the development of the SUp RCT as the SUp study had received funding before the CogEx findings were completed (Taylor et al., 2020). The learnings from the feasibility study would have provided a strong rationale for stakeholders to be members of the SUp research team from the developmental stage of the study. However, the SUp study then became a vehicle by which we could explore the complex reasons underpinning the feasibility issues in CogEx. The candidate was an original member of the SUp programme development and research team (2008). Given that SUp, like CogEx, was a fall prevention exercise programme for ARC residents, it offered an opportunity to use the CogEx learnings to inform the interpretation of the data. Also, as the SUp RCT was already underway the timeframe fitted within the doctoral enrolment.

In the CogEx study, the candidate was part of the development team of the CogEx programme and the interviewer for the qualitive data collection (class facilitator interviews and CogEx group participants). This introduced potential bias that using a researcher external to the development team would not have. However, there were advantages to the candidate doing the interviews as she knew CogEx intimately, understood ARC and was a health professional. This enabled a more natural line of questioning to be followed, especially to prompt for further explanations when the facilitators described delivering most of the exercises in sitting. On reflection, using an external researcher would have provided more rigour to the study however, details about programme delivery may have been explored on differently.

The SUp trial was impacted by COVID-19 restrictions in NZ. Due to external visitors to ARC being restricted to only those categorised as *essential*, researchers were unable to complete interviews or focus groups face to face. A pragmatic approach was taken, and interviews were conducted by video conferencing. This worked for executive and management staff who had quickly adapted to conducting meetings this way during COVID, but it did not work for the group facilitators or residents. Group facilitators either did not have access to video conferencing at work or were unable to attend during work hours. While residents could not be gathered for a focus group due to the culture change in ARC and residents not mixing widely as they had prior to COVID. Taking a pragmatic approach and switching the interview mode allowed the research to continue, however it also revealed the demands on the time of the ARC staff caring for residents and that researchers need to be flexible and consider research participants workplace demands.

9.4 Implications for practice

Fall prevention education needs ongoing support in ARC

An important consideration in delivering falls prevention in ARC is to determine who will deliver the fall prevention exercise programme, limited resources in ARC means that fall prevention exercise programmes may be delivered by non-registered staff. These staff are commonly trained by physiotherapists. In the fall prevention literature a common training format is the provision of a 1-hour training supported by a manual to teach the fall prevention programme to staff deliverers in studies (Hewitt et al., 2018; Logan et al., 2022). This is consistent with how we trained staff to deliver the CogEx and SUp interventions. One difference between the CogEx and SUp studies was that CogEx used non-registered staff (activities co-ordinators) to deliver the programme and SUp used physiotherapists. Physiotherapists are typically the deliverers of exercise interventions in falls prevention research, reflecting their traditional clinical role (Hewitt et al., 2018; Kovács et al., 2013; Sherrington & Tiedemann, 2015; Toots et al., 2019). However, exercise is not the exclusive domain of physiotherapists, for example, nurse deliverers of the Otago Exercise Programme falls prevention exercise programme were as effective as when the programme was delivered by physiotherapists (Gardner et al., 2002).

When planning fall prevention exercise programmes in ARC it is important to consider the type, level and amount of ongoing support that will be provided to those delivering the programme. In this research, for physiotherapists, the SUp programme did not contain new knowledge but did ask for a higher level of exercise prescription than was normally delivered in NZ ARC. Prompting was needed to support a behaviour change to facilitate physiotherapists to do this. For activities co-ordinators, the CogEx programme contained new knowledge and asked for activities co-ordinators to stand up residents and challenge their balance, which was different to their usual practice. Support was needed to develop this new skill. Other fall prevention studies have shown that ongoing support of programme deliverers was needed in order to deliver the programme as designed (Hewitt et al., 2018; Logan et al., 2022). The need for ongoing support of these programmes may demonstrate the complexity of introducing a new programme into the complex context of ARC. Or it may be a result of the utility of the programme for individual ARC facilities. When providing ongoing support, consideration needs to be given to not only teaching the manual skills of exercise delivery but also supporting behaviour change that may then support the sustainability of the programme within the individual ARC setting. What this ongoing support may look like is dependent on the ARC facility and the individuals involved.

Advocating for physiotherapy in ARC

When non-registered staff deliver fall prevention exercise programmes the exercise content and balance challenge can be negatively impacted. A greater involvement of physiotherapists within the ARC environment may prevent this by providing the necessary support to non-registered staff or by delivering the programme themselves. In the financially constrained ARC environment, the value of physiotherapy needs to be demonstrated to managers, funders and ARC staff. Opportunities to do so may differ among ARC facilities but documentation could be one of the easiest and least time-consuming ways for the benefit of physiotherapy to be visible. One implication for physiotherapy practice in ARC would be to ensure that adequate documentation of assessments and treatments is captured in the residents' notes. This will help to ensure a more unified approach by the entire staff. A manager in the SUp study bemoaned inadequate physiotherapy assessments and treatment planning documentation indicating the lack of transfer of information across the ARC team. A clear use of objective measures by physiotherapists in resident notes to monitor and inform care plans can demonstrate the knowledge and skillset that is particular to the profession and helps to maintain team communication.

Research using exercise interventions in ARC usually uses physiotherapy input (I. D. Cameron et al., 2018; Hewitt et al., 2018; Toots et al., 2019) however once the research concludes our findings suggest that the nature of the intervention changes (Binns et al., 2023; Binns et al., 2020a). This is likely due to once the research funding is no longer available the physiotherapy intervention is a task delegated to activity co-ordinators (non-registered staff) for whom delivering standing exercise to residents is outside their scope of practice (Ministry of Health, 2013a). There are challenges around scope of practice and effective supervision of falls prevention exercises, with a lack of clarity around the role of non-registered staff. Considering the guidance from Dyer et al. (2023) for exercise to be ongoing in ARC, perhaps there is an argument to be made that physiotherapists should continue to be involved to ensure that the evidence-based findings are delivered into individual ARC facilities.

Attending resident review meetings to actively engage with the ARC medical team is a more time intensive opportunity to showcase and promote the use of physiotherapy in ARC. This utilises the behavioural change element of consciousness raising, as other health professions do not inherently know what contribution physiotherapy can make in the ARC environment. Given the hierarchical staffing in ARC, the doctor and registered nurse can enable collective action by maintaining fall prevention as a focus for staff activity (Johnson & May, 2015)

9.5 Implications for future research

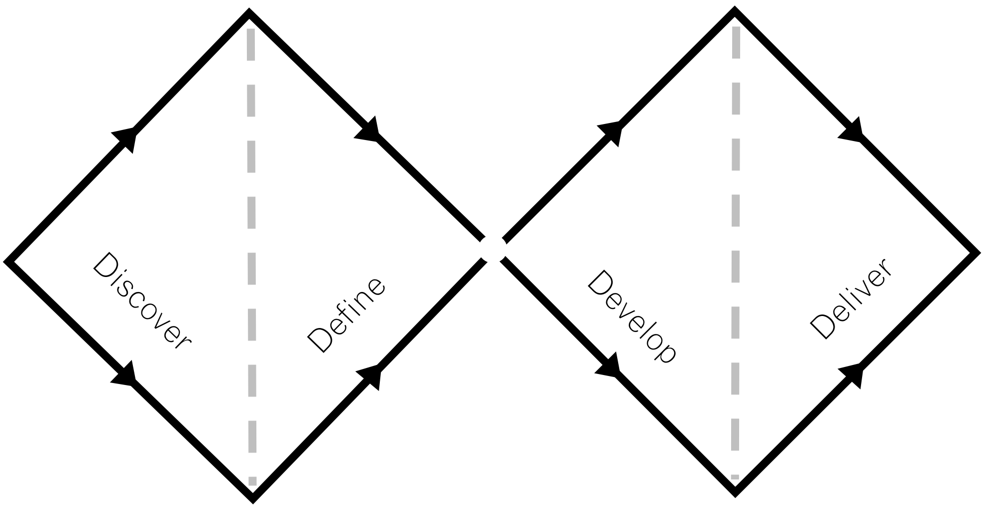
A focus of this doctoral work was to understand the complexities around delivering fall prevention exercise programmes in ARC. These studies have shown that it is only possible to fully understand the ARC context from the inside. Future research work in complex adaptive systems like ARC needs to include a strong stakeholder voice (Meyer et al., 2020; Skivington et al., 2021b). A paradigm shift in research methodology is recommended to prevent further wasted resource and accomplish meaningful outcomes for end users, funders, researchers and ultimately better health care (Canadian Institutes of Health Research, 2011). More resource should be given to the development phase. A co-design approach should be used to design a fall prevention programme with *each* ARC facility to include essential components that can be adapted to their ARC context (Evans et al., 2021; Harrison et al., 2019; Harvey & Kitson, 2016; Hawe et al., 2004; Movsisyan et al., 2019). This approach would privilege and acknowledge the individuality of that facility, its residents and staff (Reed et al., 2018) and warrants further investigation.

Taking the lessons learned from the CogEx and SUp studies, I would recommend undertaking research in a complex environment differently. I would use the latest MRC framework to guide the process (Skivington et al., 2021b) with the addition of engaging with stakeholders prior to design the trial rather than once the process has begun. Using a user-centred design approach such as The Double Diamond (Design Council, 2024) supports consideration of the complexities in culture by privileging the users voices. Co-design, as a fundamental component of user-centred design, ensures that every step of the research process involves privileging the end users voice so that the end result will meet the needs of the people the intervention was designed with and for (Banbury et al., 2021).

To undertake research *with* people in ARC rather than *in* ARC, the first step would be to form relationships with people across an ARC facility (residents, staff, managers and executives). Relationship building would enable working with people in ARC to identify the 'problem' and understand from their perspectives how the problem came to be and what they think the solution may be. One possible methodology that could be used to ensure user participation in the research process is the Double Diamond design methodology (Design Council, 2024). Using the four phases of the Double Diamond framework of discover, design, develop and deliver, enables different research methods to be chosen depending on the desired outcome (Figure 9.1).

Figure 9.1

The Double Diamond design methodology



Note. Modified from the Design Council, 2024

The start of the design project begins with an initial idea, for example preventing falls, and the forming of a project team of researchers and stakeholders (users). The first diamond is used to understand what the problem is. In the discovery phase, researchers and users work together to identify what the user needs. To gather information, user research methods that focus on user needs and experiences are employed such as focus groups, in-depth interviews, or observation of daily routines. Next the definition phase analyses the discovery stage findings to refine and define the problem in a different way from how it had been previously. The project team develops solutions, prototypes them and then the fit with business objectives is considered, such as how the solutions would be resourced. At this point a go/no-go decision is made. The solution is either thrown out and the process starts again from the discovery phase or sign off is gained from a management level to progress with solutions. The second diamond seeks to use co-design to develop different answers to the problem. In the development phase, solutions are developed further, tested and refined. Using iterations, the solutions can be trialled and be refined with user testing and feedback. Finally, in the delivery phase, the solution that works is chosen and implemented. If this process had been used in the development of the SUp fall prevention exercise programme, it is likely that the programme would not have been given management sign off in the definition phase due to the cost of physiotherapists' time (Chapter 8). The user voice may have resulted in a very different looking solution to the problem of falls prevention in ARC.

Elements of behaviour change should accompany the implementation of a fall prevention exercise intervention. It is likely that a co-design project will not include all stakeholders no matter how widely invitations to participate are sent. Taking a systems approach that views introducing a new event such as a fall prevention exercise programme recognises that a redistribution of resources needs to occur across the facility. Identifying a behavioural change approach that results in collective action to support the new fall prevention exercise programme may create the best opportunity for the programme to be sustained and become part of routine care. The elements of behaviour change may differ between facilities and stakeholders and future research should consider development of criteria to assist in selecting elements that are best suited for the context they will be used in (McKenzie-Mohr & Schultz, 2014; Michie et al., 2021).

9.6 Thesis conclusion

Cognitive and physical impairments contribute to the high fall risk of older adults living in ARC. A fall prevention exercise programme to address these risk factors in ARC residents was developed by combining physical exercise with CST (CogEx). However, feasibility testing of CogEx identified significant issues. The most striking fidelity issue was the delivery of the fall prevention exercise programme which was completed predominantly in sitting. This demonstrated that delivery of standing exercise was outside of non-registered ARC staff scope of practice, and while skilled in delivering group activity programmes, non-registered ARC staff prioritised resident engagement and comfort over completing the exercises in standing. Although the staff had received training in how to deliver the CogEx programme they did not deliver the programme in standing and consequently did not challenge the ARC residents' balance. This finding raised questions of the suitability of the training programme and about the use of non-registered ARC staff to deliver fall prevention exercises. A decision was made to explore further the factors that impact delivery of falls prevention exercise programmes, rather than to continue to refine the CogEx intervention.

In most ARC facilities fall prevention exercise programmes are not routinely delivered by physiotherapists due to the lack of resource in the sector. Exploring the complexities that impacted the decision for an ARC facility to continue to deliver a fall prevention exercise programme after the funded trial revealed that the decision making of ARC management was key. The business model of for-profit ARC organisations required profitability and a financial return to investors. This saw managers describe being unable to embed SUp into ARC facilities without additional funding from the Government. In contrast the business model of not-for profit organisations was guided by principles of well-being and direct feedback from their residents about services. Managers were able to gain financial support from the organisation's board to provide new initiatives they considered beneficial for residents. With for-profit organisations becoming the dominant providers of care in ARC, greater Government funding of ARC is required for physiotherapists to deliver fall prevention exercise within this context. Robust evidence is needed about the positive impact of a fall prevention programme to reduce incidences, and the costs associated from a fall to demonstrate to for-profit providers financial benefit from funding fall prevention programmes.

Currently physiotherapy services in ARC are either a) limited to assessing residents, with prescribed physiotherapy interventions delegated to non-registered care staff with physiotherapy supervision, or b) privately funded by the residents/whānau themselves. This is driven not only by the lack of resource but also by managers being acutely aware of what is required to be provided to residents under the terms of the Government contract. The resultant lack of visibility of physiotherapy in the ARC context, contributes to physiotherapy being undervalued and limits what services can be offered in the ARC context. To break this cycle, contractual change is needed. This requires not only evidence of the effectiveness of physiotherapy for ARC residents but advocacy at the level of government to campaign for the prioritisation of falls prevention in ARC.

Any future research should consider using co-design with a broad range of sector stakeholders. This may result in the *problem* of falls being redefined and new solutions developed. Core components of fall prevention exercise could be identified that may then be adapted to suit individual ARC facilities. This may see fall prevention interventions developed that are sustainable beyond the availability of research funding and become part of routine practice in ARC.

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Appendices

Appendix A CogEx facilitator manual

CogEx manual

The principles of CogEx

SAFETY

Each exercise has options from seated, to supported, to no support/independent.

If in doubt err on the side of caution and offer the option with more support.

FUN

People should be enjoying themselves.

CLASS ACTIVITIES

Where possible encourage standing and movement: when discussing items at a table ask people to stand and reach for the items (the table can be used for support); can the person write on a white board or walk over and blue tack a picture on the board themselves?

CHALLENGE

To improve balance the exercise needs to be challenging. This can be done by the person: standing with their feet closer together (decreasing the base of support); decreasing hand support; moving.

When progressing an exercise only progress one aspect at a time.

EFFORT

Encourage people to keep going for all 30seconds and do as much as they can.

30 SECOND BOUTS

All exercise are in bouts of 30 seconds (instead of a number of times).

SAFETY

Each exercise has options from seated, to supported, to no support/independent.

If in doubt err on the side of caution.

The manual is set up so that all the exercises can be viewed on 1 page while you take the class (Exercises for start/end song and for 10minute exercise session).

The photos are for your prompts while you get familiar with the programme.

To increase exercise on the group session:

- ✓ movements have been added to the start & end song of the class
- ✓ movement and weightbearing is encouraged during the CST group activity
- ✓ a 10-minute exercise session is included after the CST activity

Start/End of class song (3 minutes long)

Repeat the exercise routine for both songs.

The exercises in the song stay the same for all sessions so it becomes familiar.

Each exercise is done continuously for 30 seconds (as many repetitions as possible).

Everyone standing – chair close by for hand support if required.

If someone wants to sit and rest there are seated versions of each exercise.

These exercises challenge balance as well as encouraging movement of head/shoulders on hips.

These exercises should also increase heart rate as they are continuous.

10-minute exercise session

These exercises aim to:

- ✓ Improve strength
- ✓ Improve balance
- ✓ Challenge the vestibular system

To improve balance, it needs to be challenged however err on the side of caution and select the level of exercise (2 hand support, 1 hand support, no hand support) that is right for each person.

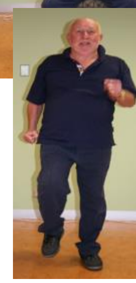
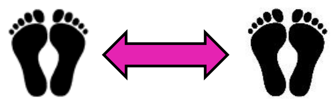
The chair can be used as support to help someone get into position then hand support decreased if able.

Timer

The interval timer will beep every 30seconds.

On the beep move on to the next exercise.

Start/End of class song (3 minutes long)

Big breath in circling arms up over head Breathing out circling arms down x3		
Walking on the spot	Sitting on chair 2 hands on chair for support 1 hand on chair for support Arms swinging (forward and back)	
Step to the left, feet together, to the right, feet together	Sitting on chair 2 hands on chair for support 1 hand on chair for support Arms swinging (side to side)	
Washing machine (hands on hips, feet apart, turn head and shoulders to the left and then to the right)	Sitting on chair 1 hand on chair for support Hands on hips	
Turn head and shoulder and try to tap your neighbour on the shoulder to your right then to your left	Sitting on chair 1 hand on chair for support No hand support	
High knee marching on the spot	Sitting on chair 2 hands on chair for support 1 hand on chair for support Arms swinging (forward and back)	
Washing machine (as above)	Sitting on chair 1 hand on chair for support Hands on hips	
Big breath in circling arms up over head and breathing out circling arms down x3		

The 10-minute exercise session

Sit to stand: Use both hands to push up

Push up with one hand

No hand support

Sideways walking: Support

No support

Calf raises: Support

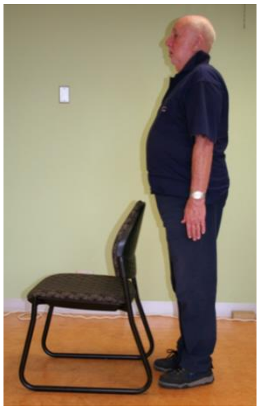
No support

Standing with feet together: Support

No support

Standing lift heel to bottom: Support

No support



Position of chair to provide support

Head

Nod up/down

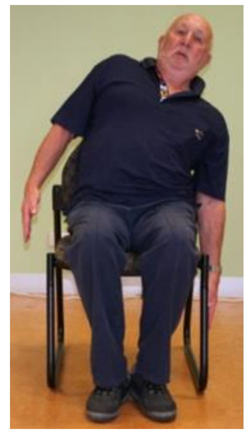
Turn side/side

Elbow to opposite knee

Focus eyes on own fingertip

Move head from side to side

Move head up/down



Bend to touch the ground

(all in sitting)

To your toes

To the one side then the other

To the opposite foot

Look  at own finger, pointing to corner of the room then diagonally down to point at the floor

Backwards chair bends

Pass object to neighbour

Clockwise

anticlockwise

Write name on ground with toe

Recording sheets of level of exercise completed in class (circle or tick)

Session 1 Date:___________________________

30s of each exercise	Sit to stand	Use both hands to push up Push up with one hand No hand support
	Sideways walking	Support No support
	Calf raises	Support No support
	Standing with feet together	Support No support
	Standing heel to bottom	Support No support
Head Nod up/down Turn side/side	Sitting Standing – support no support	10x each in time to the music. Rotate thru movements for 30s
Focus eyes on own fingertip Move head from side to side Move head up/down	Sitting Standing– support no support	As above
Look at own finger pointing to corner of the room then diagonally to point at the floor	Sitting Standing – support no support	Big slow movements for 30s
Elbow to opposite knee	Sitting Standing – support No support	30s
Bend to touch the ground (all in sitting)	To your toes To the one side then the other To the opposite foot	10x each movement rotate thru movements for 30s
Backwards chair bends	Sitting arms crossed over chest Standing arms crossed over chest	Sit up tall as you lift your arms, when arms can go no higher gently lean back
Pass object to neighbour Clockwise anticlockwise	Sitting Standing – support no support	15s one way 15s the other way
Write name on ground with toe	Sitting Standing – support no support	30s
30s of each exercise	Sit to stand	Use both hands to push up Push up with one hand No hand support
	Sideways walking	Support No support
	Calf raises	Support No support
	Standing with feet together	Support No support
	Standing heel to bottom	Support No support

Session 2 Date:____________________________

30s of each exercise	Sit to stand	Use both hands to push up Push up with one hand No hand support
	Sideways walking	Support No support
	Calf raises	Support No support
	Standing with feet together	Support No support
	Standing heel to bottom	Support No support
Head Nod up/down Turn side/side	Sitting Standing – support - no support	10x each in time to the music. Rotate thru movements for 30s
Focus eyes on own fingertip Move head from side to side Move head up/down	Sitting Standing– support - no support	As above
Look at own finger pointing to corner of the room then diagonally to point at the floor	Sitting Standing – support - no support	Big slow movements for 30s
Elbow to opposite knee	Sitting Standing – support - No support	30s
Bend to touch the ground (all in sitting)	To your toes To the one side then the other To the opposite foot	10x each movement rotate thru movements for 30s
Backwards chair bends	Sitting arms crossed over chest Standing arms crossed over chest	Sit up tall as you lift your arms, when arms can go no higher gently lean back
Pass object to neighbour Clockwise anticlockwise	Sitting Standing – support - no support	15s one way 15s the other way
Write name on ground with toe	Sitting Standing – support - no support	30s
30s of each exercise	Sit to stand	Use both hands to push up Push up with one hand No hand support
	Sideways walking	Support No support
	Calf raises	Support No support
	Standing with feet together	Support No support
	Standing heel to bottom	Support No support

Session 3 Date:________________________

30s of each exercise	Sit to stand	Use both hands to push up Push up with one hand No hand support
	Sideways walking	Support No support
	Calf raises	Support No support
	Standing with feet together	Support No support
	Standing heel to bottom	Support No support
Head Nod up/down Turn side/side	Sitting Standing – support no support	10x each in time to the music. Rotate thru movements for 30s
Focus eyes on own fingertip Move head from side to side Move head up/down	Sitting Standing– support no support	As above
Look at own finger pointing to corner of the room then diagonally to point at the floor	Sitting Standing – support no support	Big slow movements for 30s
Elbow to opposite knee	Sitting Standing – support No support	30s
Bend to touch the ground (all in sitting)	To your toes To the one side then the other To the opposite foot	10x each movement rotate thru movements for 30s
Backwards chair bends	Sitting arms crossed over chest Standing arms crossed over chest	Sit up tall as you lift your arms, when arms can go no higher gently lean back
Pass object to neighbour Clockwise anticlockwise	Sitting Standing – support no support	15s one way 15s the other way
Write name on ground with toe	Sitting Standing – support no support	30s
30s of each exercise	Sit to stand	Use both hands to push up Push up with one hand No hand support
	Sideways walking	Support No support
	Calf raises	Support No support
	Standing with feet together	Support No support
	Standing heel to bottom	Support No support

Session 4 Date:_______________________________

30s of each exercise	Sit to stand	Use both hands to push up Push up with one hand No hand support
	Sideways walking	Support No support
	Calf raises	Support No support
	Standing with feet together	Support No support
	Standing heel to bottom	Support No support
Head Nod up/down Turn side/side	Sitting Standing – support no support	10x each in time to the music. Rotate thru movements for 30s
Focus eyes on own fingertip Move head from side to side Move head up/down	Sitting Standing– support no support	As above
Look at own finger pointing to corner of the room then diagonally to point at the floor	Sitting Standing – support no support	Big slow movements for 30s
Elbow to opposite knee	Sitting Standing – support No support	30s
Bend to touch the ground (all in sitting)	To your toes To the one side then the other To the opposite foot	10x each movement rotate thru movements for 30s
Backwards chair bends	Sitting arms crossed over chest Standing arms crossed over chest	Sit up tall as you lift your arms, when arms can go no higher gently lean back
Pass object to neighbour Clockwise anticlockwise	Sitting Standing – support no support	15s one way 15s the other way
Write name on ground with toe	Sitting Standing – support no support	30s
30s of each exercise	Sit to stand	Use both hands to push up Push up with one hand No hand support
	Sideways walking	Support No support
	Calf raises	Support No support
	Standing with feet together	Support No support
	Standing heel to bottom	Support No support

Session 5 Date:________________________

30s of each exercise	Sit to stand	Use both hands to push up Push up with one hand No hand support
	Sideways walking	Support No support
	Calf raises	Support No support
	Standing with feet together	Support No support
	Standing heel to bottom	Support No support
Head Nod up/down Turn side/side	Sitting Standing – support no support	10x each in time to the music. Rotate thru movements for 30s
Focus eyes on own fingertip Move head from side to side Move head up/down	Sitting Standing– support no support	As above
Look at own finger pointing to corner of the room then diagonally to point at the floor	Sitting Standing – support no support	Big slow movements for 30s
Elbow to opposite knee	Sitting Standing – support No support	30s
Bend to touch the ground (all in sitting)	To your toes To the one side then the other To the opposite foot	10x each movement rotate thru movements for 30s
Backwards chair bends	Sitting arms crossed over chest Standing arms crossed over chest	Sit up tall as you lift your arms, when arms can go no higher gently lean back
Pass object to neighbour Clockwise anticlockwise	Sitting Standing – support no support	15s one way 15s the other way
Write name on ground with toe	Sitting Standing – support no support	30s
30s of each exercise	Sit to stand	Use both hands to push up Push up with one hand No hand support
	Sideways walking	Support No support
	Calf raises	Support No support
	Standing with feet together	Support No support
	Standing heel to bottom	Support No support

Session 6 Date:___________________________

30s of each exercise	Sit to stand	Use both hands to push up Push up with one hand No hand support
	Sideways walking	Support No support
	Calf raises	Support No support
	Standing with feet together	Support No support
	Standing heel to bottom	Support No support
Head Nod up/down Turn side/side	Sitting Standing – support no support	10x each in time to the music. Rotate thru movements for 30s
Focus eyes on own fingertip Move head from side to side Move head up/down	Sitting Standing– support no support	As above
Look at own finger pointing to corner of the room then diagonally to point at the floor	Sitting Standing – support no support	Big slow movements for 30s
Elbow to opposite knee	Sitting Standing – support No support	30s
Bend to touch the ground (all in sitting)	To your toes To the one side then the other To the opposite foot	10x each movement rotate thru movements for 30s
Backwards chair bends	Sitting arms crossed over chest Standing arms crossed over chest	Sit up tall as you lift your arms, when arms can go no higher gently lean back
Pass object to neighbour Clockwise anticlockwise	Sitting Standing – support no support	15s one way 15s the other way
Write name on ground with toe	Sitting Standing – support no support	30s
30s of each exercise	Sit to stand	Use both hands to push up Push up with one hand No hand support
	Sideways walking	Support No support
	Calf raises	Support No support
	Standing with feet together	Support No support
	Standing heel to bottom	Support No support

Session 7 Date:___________________________

30s of each exercise	Sit to stand	Use both hands to push up Push up with one hand No hand support
	Sideways walking	Support No support
	Calf raises	Support No support
	Standing with feet together	Support No support
	Standing heel to bottom	Support No support
Head Nod up/down Turn side/side	Sitting Standing – support no support	10x each in time to the music. Rotate thru movements for 30s
Focus eyes on own fingertip Move head from side to side Move head up/down	Sitting Standing– support no support	As above
Look at own finger pointing to corner of the room then diagonally to point at the floor	Sitting Standing – support no support	Big slow movements for 30s
Elbow to opposite knee	Sitting Standing – support No support	30s
Bend to touch the ground (all in sitting)	To your toes To the one side then the other To the opposite foot	10x each movement rotate thru movements for 30s
Backwards chair bends	Sitting arms crossed over chest Standing arms crossed over chest	Sit up tall as you lift your arms, when arms can go no higher gently lean back
Pass object to neighbour Clockwise anticlockwise	Sitting Standing – support no support	15s one way 15s the other way
Write name on ground with toe	Sitting Standing – support no support	30s
30s of each exercise	Sit to stand	Use both hands to push up Push up with one hand No hand support
	Sideways walking	Support No support
	Calf raises	Support No support
	Standing with feet together	Support No support
	Standing heel to bottom	Support No support

Session 8 Date:___________________________

30s of each exercise	Sit to stand	Use both hands to push up Push up with one hand No hand support
	Sideways walking	Support No support
	Calf raises	Support No support
	Standing with feet together	Support No support
	Standing heel to bottom	Support No support
Head Nod up/down Turn side/side	Sitting Standing – support no support	10x each in time to the music. Rotate thru movements for 30s
Focus eyes on own fingertip Move head from side to side Move head up/down	Sitting Standing– support no support	As above
Look at own finger pointing to corner of the room then diagonally to point at the floor	Sitting Standing – support no support	Big slow movements for 30s
Elbow to opposite knee	Sitting Standing – support No support	30s
Bend to touch the ground (all in sitting)	To your toes To the one side then the other To the opposite foot	10x each movement rotate thru movements for 30s
Backwards chair bends	Sitting arms crossed over chest Standing arms crossed over chest	Sit up tall as you lift your arms, when arms can go no higher gently lean back
Pass object to neighbour Clockwise anticlockwise	Sitting Standing – support no support	15s one way 15s the other way
Write name on ground with toe	Sitting Standing – support no support	30s
30s of each exercise	Sit to stand	Use both hands to push up Push up with one hand No hand support
	Sideways walking	Support No support
	Calf raises	Support No support
	Standing with feet together	Support No support
	Standing heel to bottom	Support No support

Session 9 Date:___________________________

30s of each exercise	Sit to stand	Use both hands to push up Push up with one hand No hand support
	Sideways walking	Support No support
	Calf raises	Support No support
	Standing with feet together	Support No support
	Standing heel to bottom	Support No support
Head Nod up/down Turn side/side	Sitting Standing – support no support	10x each in time to the music. Rotate thru movements for 30s
Focus eyes on own fingertip Move head from side to side Move head up/down	Sitting Standing– support no support	As above
Look at own finger pointing to corner of the room then diagonally to point at the floor	Sitting Standing – support no support	Big slow movements for 30s
Elbow to opposite knee	Sitting Standing – support No support	30s
Bend to touch the ground (all in sitting)	To your toes To the one side then the other To the opposite foot	10x each movement rotate thru movements for 30s
Backwards chair bends	Sitting arms crossed over chest Standing arms crossed over chest	Sit up tall as you lift your arms, when arms can go no higher gently lean back
Pass object to neighbour Clockwise anticlockwise	Sitting Standing – support no support	15s one way 15s the other way
Write name on ground with toe	Sitting Standing – support no support	30s
30s of each exercise	Sit to stand	Use both hands to push up Push up with one hand No hand support
	Sideways walking	Support No support
	Calf raises	Support No support
	Standing with feet together	Support No support
	Standing heel to bottom	Support No support

Session 10 Date:___________________________

30s of each exercise	Sit to stand	Use both hands to push up Push up with one hand No hand support
	Sideways walking	Support No support
	Calf raises	Support No support
	Standing with feet together	Support No support
	Standing heel to bottom	Support No support
Head Nod up/down Turn side/side	Sitting Standing – support no support	10x each in time to the music. Rotate thru movements for 30s
Focus eyes on own fingertip Move head from side to side Move head up/down	Sitting Standing– support no support	As above
Look at own finger pointing to corner of the room then diagonally to point at the floor	Sitting Standing – support no support	Big slow movements for 30s
Elbow to opposite knee	Sitting Standing – support No support	30s
Bend to touch the ground (all in sitting)	To your toes To the one side then the other To the opposite foot	10x each movement rotate thru movements for 30s
Backwards chair bends	Sitting arms crossed over chest Standing arms crossed over chest	Sit up tall as you lift your arms, when arms can go no higher gently lean back
Pass object to neighbour Clockwise anticlockwise	Sitting Standing – support no support	15s one way 15s the other way
Write name on ground with toe	Sitting Standing – support no support	30s
30s of each exercise	Sit to stand	Use both hands to push up Push up with one hand No hand support
	Sideways walking	Support No support
	Calf raises	Support No support
	Standing with feet together	Support No support
	Standing heel to bottom	Support No support

Session 11 Date:______________________________

30s of each exercise	Sit to stand	Use both hands to push up Push up with one hand No hand support
	Sideways walking	Support No support
	Calf raises	Support No support
	Standing with feet together	Support No support
	Standing heel to bottom	Support No support
Head Nod up/down Turn side/side	Sitting Standing – support no support	10x each in time to the music. Rotate thru movements for 30s
Focus eyes on own fingertip Move head from side to side Move head up/down	Sitting Standing– support no support	As above
Look at own finger pointing to corner of the room then diagonally to point at the floor	Sitting Standing – support no support	Big slow movements for 30s
Elbow to opposite knee	Sitting Standing – support No support	30s
Bend to touch the ground (all in sitting)	To your toes To the one side then the other To the opposite foot	10x each movement rotate thru movements for 30s
Backwards chair bends	Sitting arms crossed over chest Standing arms crossed over chest	Sit up tall as you lift your arms, when arms can go no higher gently lean back
Pass object to neighbour Clockwise anticlockwise	Sitting Standing – support no support	15s one way 15s the other way
Write name on ground with toe	Sitting Standing – support no support	30s
30s of each exercise	Sit to stand	Use both hands to push up Push up with one hand No hand support
	Sideways walking	Support No support
	Calf raises	Support No support
	Standing with feet together	Support No support
	Standing heel to bottom	Support No support

Session 12 Date:__________________________

30s of each exercise	Sit to stand	Use both hands to push up Push up with one hand No hand support
	Sideways walking	Support No support
	Calf raises	Support No support
	Standing with feet together	Support No support
	Standing heel to bottom	Support No support
Head Nod up/down Turn side/side	Sitting Standing – support no support	10x each in time to the music. Rotate thru movements for 30s
Focus eyes on own fingertip Move head from side to side Move head up/down	Sitting Standing– support no support	As above
Look at own finger pointing to corner of the room then diagonally to point at the floor	Sitting Standing – support no support	Big slow movements for 30s
Elbow to opposite knee	Sitting Standing – support No support	30s
Bend to touch the ground (all in sitting)	To your toes To the one side then the other To the opposite foot	10x each movement rotate thru movements for 30s
Backwards chair bends	Sitting arms crossed over chest Standing arms crossed over chest	Sit up tall as you lift your arms, when arms can go no higher gently lean back
Pass object to neighbour Clockwise anticlockwise	Sitting Standing – support no support	15s one way 15s the other way
Write name on ground with toe	Sitting Standing – support no support	30s
30s of each exercise	Sit to stand	Use both hands to push up Push up with one hand No hand support
	Sideways walking	Support No support
	Calf raises	Support No support
	Standing with feet together	Support No support
	Standing heel to bottom	Support No support

Session 13 Date:____________________________

30s of each exercise	Sit to stand	Use both hands to push up Push up with one hand No hand support
	Sideways walking	Support No support
	Calf raises	Support No support
	Standing with feet together	Support No support
	Standing heel to bottom	Support No support
Head Nod up/down Turn side/side	Sitting Standing – support no support	10x each in time to the music. Rotate thru movements for 30s
Focus eyes on own fingertip Move head from side to side Move head up/down	Sitting Standing– support no support	As above
Look at own finger pointing to corner of the room then diagonally to point at the floor	Sitting Standing – support no support	Big slow movements for 30s
Elbow to opposite knee	Sitting Standing – support No support	30s
Bend to touch the ground (all in sitting)	To your toes To the one side then the other To the opposite foot	10x each movement rotate thru movements for 30s
Backwards chair bends	Sitting arms crossed over chest Standing arms crossed over chest	Sit up tall as you lift your arms, when arms can go no higher gently lean back
Pass object to neighbour Clockwise anticlockwise	Sitting Standing – support no support	15s one way 15s the other way
Write name on ground with toe	Sitting Standing – support no support	30s
30s of each exercise	Sit to stand	Use both hands to push up Push up with one hand No hand support
	Sideways walking	Support No support
	Calf raises	Support No support
	Standing with feet together	Support No support
	Standing heel to bottom	Support No support

Session 14 Date:____________________________

30s of each exercise	Sit to stand	Use both hands to push up Push up with one hand No hand support
	Sideways walking	Support No support
	Calf raises	Support No support
	Standing with feet together	Support No support
	Standing heel to bottom	Support No support
Head Nod up/down Turn side/side	Sitting Standing – support no support	10x each in time to the music. Rotate thru movements for 30s
Focus eyes on own fingertip Move head from side to side Move head up/down	Sitting Standing– support no support	As above
Look at own finger pointing to corner of the room then diagonally to point at the floor	Sitting Standing – support no support	Big slow movements for 30s
Elbow to opposite knee	Sitting Standing – support No support	30s
Bend to touch the ground (all in sitting)	To your toes To the one side then the other To the opposite foot	10x each movement rotate thru movements for 30s
Backwards chair bends	Sitting arms crossed over chest Standing arms crossed over chest	Sit up tall as you lift your arms, when arms can go no higher gently lean back
Pass object to neighbour Clockwise anticlockwise	Sitting Standing – support no support	15s one way 15s the other way
Write name on ground with toe	Sitting Standing – support no support	30s
30s of each exercise	Sit to stand	Use both hands to push up Push up with one hand No hand support
	Sideways walking	Support No support
	Calf raises	Support No support
	Standing with feet together	Support No support
	Standing heel to bottom	Support No support

Appendix B CogEx HDEC ethical approval

Health and Disability Ethics Committees
Ministry of Health
Freyberg Building
20 Aitken Street
PO Box 5013
Wellington
6011

04 816 3985
hdecs@moh.govt.nz

23 August 2016

Miss Elizabeth Binns
A-11, Private Bag 92006
Auckland 1142

Dear Miss Binns

Re:	**Ethics ref:**	**16/NTB/121**
	Study title:	Brain and body stimulation (CogEx) for older people with mild to moderate dementia: feasibility study

I am pleased to advise that this application has been *approved* by the Northern B Health and Disability Ethics Committee. This decision was made through the HDEC-Full Review pathway.

Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Northern B Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.
2. Before the study commences at *any* locality in New Zealand, it must be registered in a clinical trials registry. This should be a WHO-approved (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au). However https://clinicaltrials.gov/ is acceptable provided registration occurs prior to the study commencing at *any* locality in New Zealand.
3. Before the study commences at *a given* locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

Non-standard conditions (if applicable):

- Please add page numbers, date, and version number to all participant facing documents and the clinician enrolment form.
- Please add a section for the enrolling clinician's signature and date to the clinician enrolment form.
- Please include information in all relevant participant information sheets about travel costs being covered for community dwelling participants.

Appendix C CogEx Participant Information Sheet

Participant Information Sheet

Brain and body stimulation (CogEx) for older adults with mild to moderate dementia: A feasibility study

Investigators:

Prof Ngaire Kerse	923 4467
Dr Gary Cheung	923 9491
Dr Denise Taylor	921 9680
Dr Kathy Peri	923 1112 ext. 81112
Liz Binns	921 9785

You are invited to take part in a Cognitive Stimulation Therapy and Exercise Research Project

You are invited to take part in a research project. We are doing research to understand if Cognitive Stimulation Therapy combined with an exercise programme might improve your quality of life, general fitness and your memory. This study is being organised by the University of Auckland and AUT University.

What the research is about?

- We want to compare **two groups of activities that might** help with memory loss and preventing falls.

- You will be **randomly put in one of the two groups**. One group will do Cognitive Stimulation Therapy, and one group will do Cognitive Stimulation Therapy combined with an exercise programme.

- We want to invite people **like yourself** who are living in their own home or in a rest home and **who have some memory problems**.

You can choose if you want to take part in the research. **It is your choice**. If you decide not to take part, it will not affect your care from XX.

If you do take part, you can **change your mind** at any time, that is ok and you don't have to give a reason.

You **do not have to decide now** about taking part in the study. **Please talk with your family or whanau** first if you wish.

What does it involve?

- We would like to talk to you before you start and after you finish the activity program about your general health and wellbeing and whether you have fallen or not.

- We would like to do some tests before you start and after you finish the activity program. They are "pen and paper" and balance and walking tests. These tests measure your memory and thinking abilities, how strong your legs are and how good your balance is.

- We will also like to ask you some questions about what you liked and what you didn't like about attending the group activity.

One of our three research assistants will visit you to ask these questions and do the tests.

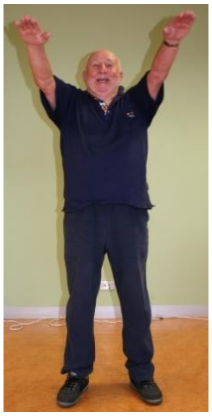
BJ Wilson **Nitika Kumari** **Shikha Chaudhary**

Attending the activity program

This will **involve you attending classes of interesting activities twice a week for 7 weeks, everyone will have these activities.**

- These activities will include stimulating activities such as **newspaper reading, creative activities such as drawing or word games**

- Some of you will also participate in **some gentle physical exercise,** like the ones in the pictures. The choice of who gets the stimulation group combined with exercise is made by chance, like tossing a coin.



The activity programme will **be held at XX**.

All classes will be videoed but only the researchers will watch the video.

How does this research benefit me?

- You may find that attending the classes offers you stimulation and companionship.
- You may feel an increased sense of wellness and your balance and strength in your legs and arms get better.
- You will be helping us learn more about how doing stimulating activities and exercises might help others in the future.

Are there any risks?

- You might find that you get a bit tired when you start doing the exercises.
- You can stop at any time if this happens and rest.

Who pays for the study? 

- This study will not cost you any money.

How do the researchers keep information private?

We will keep your information private and confidential. This means:

- Your information will be stored in locked and password protected files.
- We will not use your name or any information that might identify you when presenting the findings
- Only the researchers will have access to your information
- Information will be all stored at the University of Auckland.

What happens after the study?

All information that you provided will be kept securely at University of Auckland for 10 years.

After 10 years this material will be destroyed.

Will I find out the results?

Yes

- If you want to have a summary of the findings we can provide this to you or your family.
- We can do this face to face or we can send you a copy of the findings. You can decide how you want us to tell you about what happened.

Who do I contact for more information?

If you want more information, please contact

Kathy Peri.

Phone 923 1112 ext 82111

Email K.peri@auckland.ac.nz

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email:
advocacy@hdc.org.nz

You can also contact the Health and Disability Ethics Committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS

Email: hdecs@moh.govt.nz

Approved by the Health and Disability Ethics Committee (HDEC) on **23 August 2016**, HDEC Reference number **16/NTB/121.**

Appendix D CogEx Consent Form

THE UNIVERSITY OF AUCKLAND
FACULTY OF MEDICAL AND HEALTH SCIENCES

AUT UNIVERSITY
TE WĀNANGA ARONUI O TAMAKI MAKAU RAU

Brain Research NEW ZEALAND
Rangahau Roro Aotearoa

Brain and body stimulation (CogEx) for older adults with mild to moderate dementia: A feasibility study

Lead investigators: Prof Ngaire Kerse

Dr Gary Cheung

Dr Denise Taylor

Dr Kathy Peri

Liz Binns

I have had time

- To think about **whether I want to participate**
- To **talk with my family and whanau** about taking part

I understand

- I **do not have to take part.** It is my choice
- I **can change my mind**
- I can **ask questions at any time**
- I can **stop the exercises and memory project** at any time.

I understand what is involved

- I will be **interviewed about my health before and after** I attend the classes
- I will attend a **class twice a week for 7** weeks where I will **do some exercises and participate in some stimulating activities**
- The classess will be videoed
- My information will be kept confidential and no one will know what I have said and only the researchers will see the video.

I agree that the researcher can

Talk to my doctor about me taking part if they need to, to find out what happened to me if I am not available to contact and to inform them I am in the trial

Yes No

If I want to ask any questions about the study I need to contact

Kathy Peri

Phone 923 1112 ext82111 email: k.peri@auckland.ac.nz

I understand what this research is about Yes No

I agree to take part in this research Yes No

I would like to receive a summary of the results Yes No

Declaration by participant:

I hereby consent to take part in this study:

Participant's name:

Signature: Date:

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate:

Researcher's name:

Signature: Date:

Approved by the Health and Disability Ethics Committee (HDEC) on 23 August 2016, HDEC Reference number 16/NTB/121.

THE UNIVERSITY OF AUCKLAND
FACULTY OF MEDICAL AND HEALTH SCIENCES

Brain Research
NEW ZEALAND
Rangahau Roro Aotearoa

AUT
UNIVERSITY
TE WĀNANGA ARONUI O TAMAKI MAKAU RAU

Brain and body stimulation (CogEx) for older adults

Baseline Information

Assessor name ______________________________ Date of assessment _____/______/ 2018

Participant Name ___________________________ Female / Male

Address _____________________________________ Home / Rest Home / Hospital

____

Phone number ________________________________ Mobile ___________________________________

Email _____________________________________

Date of birth ________________________________ Ethnicity _________________________________

If at home living with whom? Alone / spouse / family / other *(please state)* ________________________

NoK _______________________________________

Address _____________________________________ Email ___________________________________

____

Phone number ________________________________ Mobile ___________________________________

Do you use a walking aid? Yes / No used indoors / outdoors/ both?

Is it a Stick / Quadstick / Crutch 1 or 2 / Walking frame / other _________________________________

(Please circle or if other please state)

How old were you when you left school? _____ (Number of years ___ of education)

(use level as a prompt Primary / Intermediate / Secondary school / University)

Do you have any medical conditions? *(if no)* Have you see the Dr in the last 3 months? (*if yes)* what for?

____

____

____

____

Are you taking any medications?

____

____

____

____

Do you have pain in any part of your body? Yes / No (*please circle)*

____

____

____

____

Any other comments/observations

The Montreal Cognitive Assessment (MOCA)

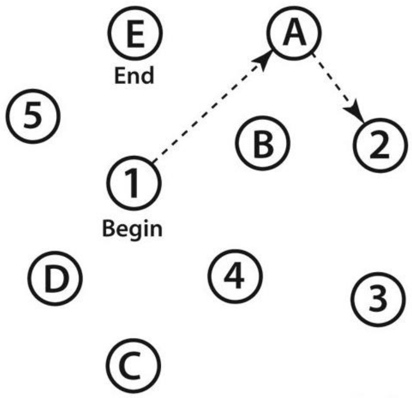
See instruction manual for administration and scoring instructions

If the participant scores less than 10, **stop** after this test and thank them for their time (a score less than 10 means they are excluded from the study – they can still take part in the

NAME :
Education : Date of birth :
Sex : DATE :

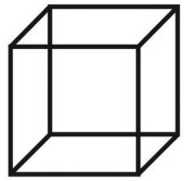
MONTREAL COGNITIVE ASSESSMENT (MOCA)
Version 7.1 Original Version

VISUOSPATIAL / EXECUTIVE



[ ]

Copy cube



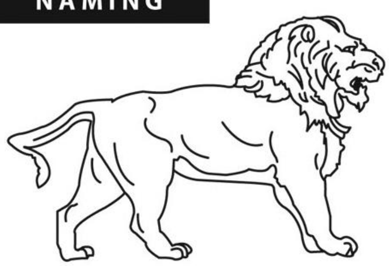
[ ]

Draw CLOCK (Ten past eleven)
(3 points)

[ ] Contour [ ] Numbers [ ] Hands

POINTS: ___/5

NAMING



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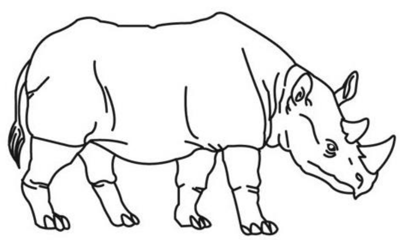

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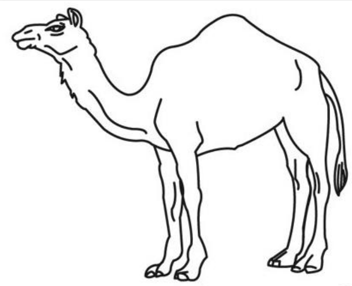


[ ]

___/3

MEMORY

Read list of words, subject must repeat them. Do 2 trials, even if 1st trial is successful. Do a recall after 5 minutes.

	FACE	VELVET	CHURCH	DAISY	RED
1st trial					
2nd trial					

No points

ATTENTION

Read list of digits (1 digit/ sec.). Subject has to repeat them in the forward order [ ] 2 1 8 5 4
Subject has to repeat them in the backward order [ ] 7 4 2
___/2

Read list of letters. The subject must tap with his hand at each letter A. No points if ≥ 2 errors
[ ] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B
___/1

Serial 7 subtraction starting at 100 [ ] 93 [ ] 86 [ ] 79 [ ] 72 [ ] 65
4 or 5 correct subtractions: **3 pts**, 2 or 3 correct: **2 pts**, 1 correct: **1 pt**, 0 correct: **0 pt**
___/3

LANGUAGE

Repeat : I only know that John is the one to help today. [ ]
The cat always hid under the couch when dogs were in the room. [ ]
___/2

Fluency / Name maximum number of words in one minute that begin with the letter F [ ] _____ (N ≥ 11 words)
___/1

ABSTRACTION

Similarity between e.g. banana - orange = fruit [ ] train – bicycle [ ] watch - ruler
___/2

DELAYED RECALL

	FACE	VELVET	CHURCH	DAISY	RED	
Has to recall words **WITH NO CUE**	[ ]	[ ]	[ ]	[ ]	[ ]	Points for UNCUED recall only
Optional Category cue						
Multiple choice cue						

___/5

ORIENTATION

[ ] Date [ ] Month [ ] Year [ ] Day [ ] Place [ ] City
___/6

 www.mocatest.org Normal ≥ 26 / 30

TOTAL ___/30
Add 1 point if ≤ 12 yr edu

Administered by: ______________________________

Geriatric Depression Scale

Please ask the participant the questions below and circle their response

"Choose the best answer for how you have felt over the past week":

1. Are you basically satisfied with your life?	YES / **NO**
2. Have you dropped many of your activities and interests?	**YES** / NO
3. Do you feel that your life is empty?	**YES** / NO
4. Do you often get bored?	**YES** / NO
5. Are you in good spirits most of the time?	YES / **NO**
6. Are you afraid that something bad is going to happen to you?	**YES** / NO
7. Do you feel happy most of the time?	YES / **NO**
8. Do you often feel helpless?	**YES** / NO
9. Do you prefer to stay at home, rather than going out and doing new things?	**YES** / NO
10. Do you feel you have more problems with memory than most?	**YES** / NO
11. Do you think it is wonderful to be alive now?	YES / **NO**
12. Do you feel pretty worthless the way you are now?	**YES** / NO
13. Do you feel full of energy?	YES / **NO**
14. Do you feel that your situation is hopeless?	**YES** / NO
15. Do you think that most people are better off than you are?	**YES** / NO
	TOTAL ______

Score each answer in **bold 1 point**, non-bold answers score 0.

Quality of Life-AD
Instructions for Interviewers

The QOL-AD is administered in interview format to individuals with dementia, following the instructions below. Hand the form to the participant, so that he or she may look at it as you give the following instructions (instructions should closely follow the wording given in **bold type**):

See manual for more detailed administration instructions

Quality of Life: AD

(Interview Version for the person with dementia)

Interviewer administer according to standard instructions (see manual). Circle responses.

	1	2	3	4
1. Physical health.	Poor	Fair	Good	Excellent
2. Energy.	Poor	Fair	Good	Excellent
3. Mood.	Poor	Fair	Good	Excellent
4. Living situation.	Poor	Fair	Good	Excellent
5. Memory.	Poor	Fair	Good	Excellent
6. Family.	Poor	Fair	Good	Excellent
7. Marriage.	Poor	Fair	Good	Excellent
8. Friends.	Poor	Fair	Good	Excellent
9. Self as a whole.	Poor	Fair	Good	Excellent
10. Ability to do chores around the house.	Poor	Fair	Good	Excellent
11. Ability to do things for fun.	Poor	Fair	Good	Excellent
12. Money.	Poor	Fair	Good	Excellent
13. Life as a whole.	Poor	Fair	Good	Excellent

SCORING INSTRUCTIONS FOR THE QOL:
Points are assigned to each item as follows: poor=1, fair=2, good=3, excellent=4.
The total score is the sum of all 13 items.

SCORE = ________

Comments:

____

____

Family member or **Caregiver** completes the measure as a questionnaire about the person with dementia's QOL

Quality of Life: AD (Questionnaire Version for the Family Member or Caregiver)				
The following questions are about your relative's quality of life. When you think about your relative's life, there are different aspects, some of which are listed below. Please think about each item, and rate your relative's current quality of life in each area using one of four words: **poor, fair, good, or excellent**. Please rate these items based on your relative's life **at the present time** (e.g. within the past few weeks). If you have questions about any item, please ask the person who gave you this form for assistance. *Circle your responses.*				
	1	2	3	4
1. Physical health.	Poor	Fair	Good	Excellent
2. Energy.	Poor	Fair	Good	Excellent
3. Mood.	Poor	Fair	Good	Excellent
4. Living situation.	Poor	Fair	Good	Excellent
5. Memory.	Poor	Fair	Good	Excellent
6. Family.	Poor	Fair	Good	Excellent
7. Marriage.	Poor	Fair	Good	Excellent
8. Friends.	Poor	Fair	Good	Excellent
9. Self as a whole.	Poor	Fair	Good	Excellent
10. Ability to do chores around the house.	Poor	Fair	Good	Excellent
11. Ability to do things for fun.	Poor	Fair	Good	Excellent
12. Money.	Poor	Fair	Good	Excellent
13. Life as a whole.	Poor	Fair	Good	Excellent

SCORING INSTRUCTIONS FOR THE QOL:
Points are assigned to each item as follows: poor=1, fair=2, good=3, excellent=4.
The total score is the sum of all 13 items.

SCORE = ________

ADAS – Cognitive Behaviour

1. WORD RECALL TASK: Indicate the total number of **correct** responses for each trial

Trial 1	Trial 2	Trial 3

Record

2. NAMING OBJECTS AND FINGERS: Check each object/finger named **correctly** or check "NONE."

NONE

- ☐ Flower ☐ Rattle ☐ Wallet
- ☐ Bed ☐ Mask ☐ Harmonica
- ☐ Whistle ☐ Scissors ☐ Stethoscope
- ☐ Pencil ☐ Comb ☐ Tongs
- ☐ Thumb ☐ Index ☐ Ring
- ☐ Pinky/ little ☐ Middle

Score /5

3. COMMANDS: Check each command performed **Incorrectly** or check "NONE." ☐ NONE

- ☐ Make a fist.
- ☐ Point to the ceiling, then to the floor.
- ☐ Put the pencil on top of the card, then put it back.
- ☐ Put the watch on the other side of the pencil and turn over the card.
- ☐ Tap each shoulder twice with two fingers keeping your eyes shut.

Score /5

4. CONSTRUCTIONAL PRAXIS: Check each figure drawn **Incorrectly**.

- ☐ None: attempted but drew no forms correctly. Patient
- ☐ drew no forms; scribbled; wrote words. Circle
- ☐ Two overlapping rectangles
- ☐ Rhombus
- ☐ Cube

(see scoring instructions)

Score /5

5. Ideational PRAXIS: Check each step completed **Incorrectly** or check "NONE" Fold a ☐ NONE

- ☐ letter.
- ☐ Put letter in envelope.
- ☐ Seal envelope.
- ☐ Address envelope.
- ☐ Indicate where stamp goes.

Score /5

6. ORIENTATION: Check each item answered **Incorrectly** or check "NONE." NONE ☐

- ☐ Full name ☐ Day
- ☐ Month ☐ Season
- ☐ Date ☐ Place
- Year Time of day

Score /8

7. WORD RECOGNITION TASK:

Trial 1

Record

8. LANGUAGE: Check level of impairment.

- **0** ☐ **None**: patient speaks clearly and/or is understandable.
- **1** ☐ **Very Mild**: one instance of lack of understandability.
- **2** ☐ **Mild**: patient has difficulty < 25% of the time.
- **3** ☐ **Moderate**: patient has difficulty 25–50% of the time.
- **4** ☐ **Moderately Severe**: patient has difficulty more than 50% of the time.
- **5** ☐ **Severe**: one- or two-word utterances; fluent, but empty speech; mute.

Score /5

9. COMPREHENSION OF SPOKEN LANGUAGE: Check level of impairment

- **0** ☐ **None**: patient understands.
- **1** ☐ **Very Mild**: one instance of misunderstanding.
- **2** ☐ **Mild**: 3–5 instances of misunderstanding.
- **3** ☐ **Moderate**: requires several repetitions and rephrasing.
- **4** ☐ **Moderately Severe**: patient only occasionally responds correctly; i.e., yes – no questions.
- **5** ☐ **Severe**: patient rarely responds to questions appropriately; not due to poverty of speech.

Score /5

10. WORD FINDING DIFFICULTY: Check one response.

- **0** ☐ **None.**
- **1** ☐ **Very Mild**: 1 or 2 instances, not clinically significant.
- **2** ☐ **Mild**: noticeable circumlocution or synonym substitution.
- **3** ☐ **Moderate**: loss of words without compensation on occasion.
- **4** ☐ **Moderately Severe**: frequent loss of words without compensation.
- **5** ☐ **Severe**: nearly total loss of content words; speech sounds empty; 1– to 2-word utterances.

Score /5

11. REMEMBERING TEST INSTRUCTIONS: Check level of impairment.

- **0** ☐ **None**.
- **1** ☐ **Very Mild**: forgets once.
- **2** ☐ **Mild**: must be reminded 2 times.
- **3** ☐ **Moderate**: must be reminded 3–4 times.
- **4** ☐ **Moderately Severe**: must be reminded 5–6 times
- **5** ☐ **Severe**: must be reminded 7 or more times.

Score /5

ADAS - Cog –Word Recall

Question 1:

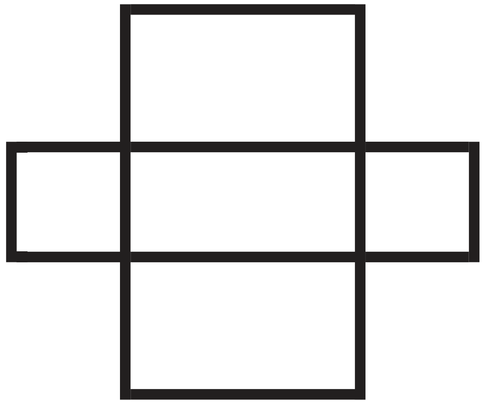
Check EACH word Not recalled.

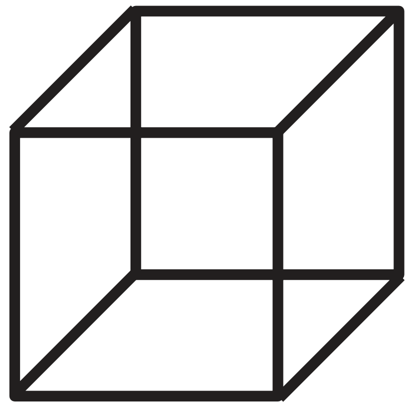
TRIAL 1	TRIAL 2	TRIAL 3
☐ BOTTLE	☐ FOREST	☐ GIRL
☐ POTATO	☐ TEMPLE	☐ TEMPLE
☐ GIRL	☐ BOTTLE	☐ POTATO
☐ TEMPLE	☐ STAR	☐ ANIMAL
☐ STAR	☐ POTATO	☐ FOREST
☐ ANIMAL	☐ GIRL	☐ LAKE
FOREST	☐ CLOCK	☐ OFFICE
☐ LAKE	☐ ANIMAL	☐ CLOCK
☐ CLOCK	☐ LAKE	☐ BOTTLE
☐ OFFICE	☐ OFFICE	☐ STAR
☐ **TOTAL**	☐ **TOTAL**	☐ **TOTAL**

Indicate total number of words not recalled for EACH trial.

If any item(s) 1-11 are incomplete or not done (test page 1), please specify reason:

- ☐ Subject too cognitively impaired to complete
- ☐ Subject was unable to complete for physical reasons
- ☐ Subject refused
- ☐ Not Done, for reason other than above (please explain in free text)





ADAS –Word Recognition

Question 7:

Check subject's response for each word. Subject should respond "yes" to original words which are bolded. INCORRECT responses are shaded. One trial of reading and recognition are given.

	Yes	No
COST		
NATION		
CHIMNEY		
SPARROW		
DAMAGES		
TRAFFIC		
SANDWICH		
SERVICE		
SHELL		
SOLUTION		
YARD		
TUBE		
BODY		
GROUND		
STICK		
ENGINE		
RICHES		
GRAVITY		
SUMMER		
WISDOM		
MAN		
MEAL		
PASSENGER		
ACID		

Total incorrect

Total incorrect

Total incorrect

(Shaded boxes)

Score = Total incorrect/2= __________

Place final totals on Page 7 Question 7

Brief Balance Evaluation Systems Test Tested with flat soled shoes OR shoes and socks off *(please circle)*

Section I. Biomechanical Constraints		
Item 1: Hip/Trunk Lateral Strength ***"Rest fingertips in my hands while you lift your leg to the side and hold, keep trunk vertical. You will hold for 10s."*** Time 10s, watch for straight knee; if they use moderate force on your hands, score as "without keeping trunk vertical."	(3) Normal (10s with trunk vertical) (2) Mild (10s without trunk vertical) (1) Moderate (1 hip abducts with trunk vertical) (0) Severe (neither hip, 10s and vertical or not vertical)	Score:
Section II. Stability Limits		
Item 2: Functional Reach Forward ***"Stand normally; lift both arms straight in front of you; reach as far forward as you can with arms parallel to the ruler without lifting your heels."*** 2 attempts. Observe that person does not lift heels, rotate trunk, or protract scapula. Watch for vertical initial alignment. Record best reach.	(3) >32 cm (2) 16.5–32 cm (1) <16.5 cm (0) No measurable lean (or must be caught)	Trial 1 (cm) Trial 2 (cm) (Circle best reach)
Section III. Transitions–Anticipatory Postural Adjustment		

Items 3 and 4: Stand on One Leg–Left and Right *"Look ahead; hands must stay on your hips; bend one leg behind you; stand on 1 leg as long as you can for up to 30s. Do not let your lifted leg touch the other leg."* Allow 2 attempts, record best attempt; record time up to 30s (stop time if hands off hips or leg on floor or leg touches supporting leg).	(3) Normal (stable >20s) (2) Trunk motion OR 10-20s (1) Stand 2–10s (0) Unable	Left (s) Right (s)
Section IV. Reactive Postural Response		
Items 5 and 6: Compensatory Stepping–Lateral, Left and Right *"Stand with feet nearly together; lean into my hands; I will remove my hands; do whatever necessary to keep balance, trying to take 1 step."* Stand next to and behind person. Place hand on greater trochanter and brace yourself to hold the person's weight shifted to supported leg.	(3) Recovers with 1 side/crossover step (2) Several steps to recover independently (1) Steps but needs assist to prevent fall (0) No step OR falls	Left = Right =
Section V. Sensory Orientation		
Item 7: Stance With Eyes Closed, on Foam Surface *"Stand on foam with your eyes closed, hands on your hips, and your feet close but not*	3 30 stable (2) 30s unstable	Trial 1 (s)

touching. Start by looking straight ahead, I will start timing when you close your eyes. Stay as stable as possible and keep your eyes closed. The goal is 30s." Two trials, if necessary. Patient must step off foam between trials.	**(1) <30s** (0) Unable	Trial 2 (s)
Section VI. Stability in Gait		
Item 8: Timed "Up & Go" Test (3m) ***"When I say 'go,' stand up and walk quickly but safely to the tape, turn, and walk back and sit in chair."*** Start sitting on chair, stop timing when buttocks hit the chair; chair should have arms to push from, if necessary. Imbalance might include trips or lateral/backward stumbles or crossovers.	**(3) Fast, <11s, good balance** **(2) Slow, >11s, good balance** **(1) Fast, <11s, imbalance** (0) Slow, >11s, imbalance	Time taken (s)

Short Physical Performance Battery Protocol and Score Sheet

1. BALANCE TESTS

SCORING:

A. Side-by-Side stand

Held for 10 sec ❐1 point

Not held for 10 sec ❐0 points

Not attempted ❐0 points

If 0 points, end Balance Tests

Number of seconds held if less than 10 sec:

_____.___Sec

If participant did not attempt test or failed, circle why:

Tried but unable	1
Participant could not hold position unassisted	2
Not attempted, you felt unsafe	3
Not attempted, participant felt unsafe	4
Participant unable to understand instructions	5

B. Semi-Tandem Stand

Held for 10 sec ❐1 point

Not held for 10 sec ❐0 points

Not attempted ❐0 points

(circle reason to the right)

If 0 points, end Balance Tests

Number of seconds held if less than 10 sec:

_____.___Sec

If participant did not attempt test or failed, circle why:

Tried but unable	1
Participant could not hold position unassisted	2
Not attempted, you felt unsafe	3
Not attempted, participant felt unsafe	4
Participant unable to understand instructions	5
Other (specify)	6

C. Tandem Stand

Held for 10 sec ❐2 point

Held for 3 to 9.99 sec ❐1 points

Held for < than 3 sec ❐0 points

Not attempted ❐0 points

(circle reason above)

Number of seconds held if less than 10 sec:

_____.___Sec

If participant did not attempt test or failed, circle why:

Tried but unable	1
Participant could not hold position unassisted	2
Not attempted, you felt unsafe	3
Not attempted, participant felt unsafe	4
Participant unable to understand instructions	5
Other (specify)	6
Participant refused	7

Total Balance Tests score ___ (sum points)

Comments:

2. GAIT SPEED TEST SCORING: Length of walk test course: Four meters ❒ Three meters ❒

A. Time for First Gait Speed Test (sec)

1. Time for 3 or 4 meters____.____sec
2. If participant did not attempt test or failed, circle why: Tried but unable 1

   Participant could not walk unassisted 2

   Not attempted, you felt unsafe 3

   Not attempted, participant felt unsafe 4

   Participant unable to understand instructions 5

   Other (Specify)______________________________6

   Participant refused 7

   Complete score sheet and go to chair stand test
3. Aids for first walk............... None ❒ Stick ❒ Other ❒

B. Time for Second Gait Speed Test (sec)

1. Time for 3 or 4 meters____.____sec
2. If participant did not attempt test or failed, circle why:

   Tried but unable 1

   Participant could not walk unassisted 2

   Not attempted, you felt unsafe 3

   Not attempted, participant felt unsafe 4

   Participant unable to understand instructions 5

   Other (Specify) 6

   Participant refused 7
3. Aids for second walk............ None ❒ Stick ❒ Other ❒

What is the time for the faster of the two walks?

Record the shorter of the two times_____.____sec

[If only 1 walk done, record that time]_____.____sec

If the participant was unable to do the walk: ❒0 points

For 4-Meter Walk:		For 3-Meter Walk:	
If time is more than 8.70 sec:	❒1 point	If time is more than 6.52 sec:	❒1 point
If time is 6.21 to 8.70 sec:	❒2 points	If time is 4.66 to 6.52 sec:	❒2 points
If time is 4.82 to 6.20 sec:	❒3 points	If time is 3.62 to 4.65 sec:	❒3 points
If time is less than 4.82 sec:	❒4 points	If time is less than 3.62 sec:	❒4 points

3. CHAIR STAND TEST

Single Chair Stand Test

	Yes	No
A. Safe to stand without help	❒	❒

B. Results:

Participant stood without using arms Test	❒	→ Go to Repeated Chair Stand
Participant used arms to stand	❒	→ End test; score as 0 points
Test not completed	❒	→ End test; score as 0 points

C. If participant did not attempt test or failed, circle why:

Tried but unable	1
Participant could not stand unassisted	2
Not attempted, you felt unsafe	3
Not attempted, participant felt unsafe	4
Participant unable to understand instructions	5
Other (Specify)	6
Participant refused	7

Repeated Chair Stand Test

	Yes	**No**
A. Safe to stand five times	❒	❒

B. If five stands done successfully, record time in seconds. Time to complete five stands _.____________________sec

C. If participant did not attempt test or failed, circle why:

Tried but unable	1
Participant could not stand unassisted	2
Not attempted, you felt unsafe	3
Not attempted, participant felt unsafe	4
Participant unable to understand instructions	5
Other (Specify)	6
Participant refused	7

Scoring the Repeated Chair Test

Participant unable to complete 5 chair stands or completes stands in >60 sec:	❒0 points
If chair stand time is 16.70 sec or more:	❒1 points
If chair stand time is 13.70 to 16.69 sec or more:	❒2 points
If chair stand time is 11.20 to 13.69 sec:	❒3 points
If chair stand time is 11.19 sec or less:	❒4 points

Scoring for Complete Short Physical Performance Battery

Test Scores

Total Balance Test score___________points

Gait Speed Test score_____________points

Chair Stand Test score_____________points

Total Score___________points (sum of points above)

Appendix F CogEx Guiding questions

Guiding questions for participants

1. Tell me about your experience of the group?
2. What prompted you to join the group?
3. Did you have goals you hoped would be achieved in attending the group? What were they? Were your goals achieved?
4. What part of the group did you enjoy?
5. What parts of the group were less satisfying and why?
6. What benefit did you feel the group provided to you?
7. What benefit do you feel the group provided for your family?
8. Were there aspects of the group which were missing, or you consider could have been done differently?
9. Was seven weeks enough? Would there be value in a further 16 week – 24 week group? And what would be gained by a longer group?
10. What assistance if any did the group play in helping you adjust to the diagnosis of dementia and your future?

Guiding questions for staff delivering CST

1. Describe the benefits people with dementia gained as a result of being part of the group?
2. Describe the benefits their families received as a result of being part of the group?
3. What observable changes did you see for participants during the group?
4. What observable changes did you see for families during the group?
5. Were there aspects of the group which were missing, or you consider could have been done differently?
6. Daytime activity, company and psychological distress* are identified as the most important unmet 'needs' for people with memory problems, (identified by health professionals): Do you think that the group helped the participants address any of these needs?
*Psychological distress refers to negative feelings such as anger, sadness, loneliness, confusion, and worrying.
7. What could have improved the ability of the group to achieve these?
8. Was the training you received before running the group adequate?
9. What was good and what was unsatisfactory about the training?
10. What skills do you believe that you have that enabled the group process?
11. What skills do you think need improvement to enable the group?
12. What barriers were there to carrying out the group e.g. access, structure, timing?

Appendix G CogEx feasibility study published manuscript

Binns et al. Pilot and Feasibility Studies (2020) 6:108
https://doi.org/10.1186/s40814-020-00646-6

Pilot and Feasibility Studies

RESEARCH Open Access

Combining cognitive stimulation therapy and fall prevention exercise (CogEx) in older adults with mild to moderate dementia: a feasibility randomised controlled trial

Elizabeth Binns[1,2*], Ngaire Kerse[3], Kathy Peri[4], Gary Cheung[5] and Denise Taylor[2]

Abstract

Background: People living with dementia (PLwD) have a high fall risk as cognitive impairment compromises control of gait and balance. Fall prevention exercises that are effective in healthy older adults may not work for PLwD. Cognitive stimulation therapy (CST) has been shown to improve global cognition in PLwD. A programme which combines cognitive (CST) with physical exercises may reduce falls in PLwD. The aim of this study was to assess the feasibility of undertaking a full scale randomised controlled trial to test the effectiveness of CogEx in decreasing falls in PLwD. Specific objectives included recruitment strategy, data collection, outcome measures, intervention fidelity and facilitator/participant experience.

Methods: A mixed methods feasibility randomised controlled trial recruited people from residential aged care. Inclusion criteria were ≥ 65 years old, Montreal Cognitive Assessment (MoCA) score of 10 to 26 and able to participate in a group. Participants were randomised to CST or CST combined with strength and balance exercises (CogEx). Both CST and CogEx groups were for an hour twice a week for 7 weeks. Descriptive statistics were used to report pre- and post-intervention outcome measures (MoCA, Geriatric Depression Scale–15, Quality of Life-Alzheimer's Disease, Alzheimer's Disease Assessment Scale—Cognitive 11, Brief Balance Evaluation Systems Test and Short Form Physical Performance Battery) and attendance. Qualitative analysis of participant focus groups and facilitator interviews used a conventional approach. Sessions were video recorded and exercise completion documented.

Results: Thirty-six residents were screened with 23 participants randomised to intervention (CogEx, n = 10) or control (CST, n = 13). The assessments took 45 min to 1.5 h, and there was repetition between two cognitive measures. Ten facilitators completed training with the manualised programme. Exercises were combined into the hour-long CST session; however, limited balance training occurred with participants exercising predominantly in sitting. The facilitators felt the participants engaged more and were safer in sitting.

(Continued on next page)

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Full list of author information is available at the end of the article

(Continued from previous page)

Conclusions: The results demonstrated that while fall prevention exercises could be scheduled into the CST structure, the fidelity of the combined programme was poor. Other components of the study design need further consideration before evaluation using a randomised controlled trial is feasible.

Trial registration: anzctr.org.au (ACTRN12616000751471) 8 Jun 2016, Australian New Zealand Clinical Trials Registry.

Keywords: Dementia, Cognitive stimulation therapy, Exercise

Introduction

Dementia is a neurodegenerative disorder in which there is deterioration in memory, thinking, behaviour and the ability to perform everyday activities [1]. It mainly affects older adults, although it is not considered a normal part of ageing [1]. Globally, it is estimated there are 47.5 million people living with dementia (PLwD) and 7.7 million new cases diagnosed every year. It is predicted that the worldwide number of PLwD is likely to rise to over 75.6 million by 2030, and almost triple to 135.5 million by 2050 [2].

Cognitive stimulation therapy (CST) is a treatment developed for people with mild to moderate dementia. CST aims to enhance cognitive and social functioning using group therapy incorporating reality orientation, reminiscing, socialising and actively stimulating PLwD, while providing an optimal learning environment and the social benefits of a group. The therapy is standardised into a published manual [3] and guides the CST facilitator through set topics of engagement while allowing the group participants to choose the specific content. The 7-week programme is comprised of a 1-h group activity session twice a week. CST is the only evidence-based treatment recommended for people with mild to moderate dementia in the NICE dementia guidelines [4] based on the evidence that it can improve cognition in people with mild to moderate dementia over and above any medication effects [5, 6]. The Dementia Care Framework [7] in Aotearoa New Zealand recommends CST as one of only two specific treatments considered as *good practice* for PLwD. To support this recommendation, 1-day CST programme training of group facilitators occurred nationally [8], and CST is now available through community-based (CB) programmes and in residential aged care (RAC) facilities.

The incident rate for falls in community-dwelling older adults is 0.65 falls per person-year and for older adults living in RAC this increases to 1.7 falls per person-year [9]. Dementia is an independent risk factor for falls, and PLwD are twice as likely to fall and sustain an injury than those without dementia [10]. With the rise in the prevalence of dementia, falls in older adults with dementia are an area of serious concern in health care.

Falls in PLwD are multi-factorial [11], as they are in older adults [12]. Superimposed on the risk factors for falls in older adults are specific clinical features in PLwD that contribute to falls, the two most commonly recognised being cognitive impairments and gait abnormalities [13]. Cognitive impairments and gait abnormalities have been found to be interrelated [14] reflecting that gait is no longer considered a purely motor task but an activity that requires interaction with the environment, attention and executive function [13, 15, 16]. In PLwD, these abnormalities can be observed as impaired judgement, decreased walking ability, lack of visual-spatial perception and a loss of ability to recognise and avoid hazards [17].

Strengthening and balance exercises are the critical components in fall prevention interventions for community-dwelling older adults [18] and are highly associated with falls [19]. However, fall prevention interventions that work in healthy older adults may not work in PLwD. A meta-analysis identified only three randomised controlled trials assessing the effectiveness of exercise programmes to reduce falls in community-dwelling older adults with dementia. While all three studies included strength and balance exercises and the results looked promising, more research is required to ascertain these are important components to include in fall prevention interventions for PLwD [17].

This leads us to ask whether effective fall prevention for PLwD can be developed that incorporates physical and cognitive exercise? Is it possible to reduce falls risk by improving cognition with cognitive exercise as well as strengthening lower limbs and retraining balance in PLwD using a top-down (cognitive) and a bottom-up (physical) approach? CST is a programme that can improve global cognition in PLwD over and above the effect of medication and is available through a widespread, trained workforce in Aotearoa New Zealand. The highly structured CST programme lends itself to easily incorporating physical exercise without becoming complex, thereby using the existing workforce and not increasing the use of health resource to deliver fall prevention to this at-risk population. We hypothesise that combing fall prevention exercises with CST (CogEx) can deliver fall prevention to PLwD through already established dementia care providers nationally. Prior to embarking on a full-scale clinical trial, there are several feasibility issues to address.

Aim

The aim of this study was to assess the feasibility of undertaking a full-scale randomised controlled trial to test the effectiveness of CogEx in decreasing falls in PLwD. For the full-scale RCT, the primary outcome is falls. This study will explore which secondary outcome measures are appropriate to measure the other potential benefits of CogEx and add important information for statistical modelling in the future RCT.

The specific objectives were as follows:

1. To test the recruitment strategy of facilities and individuals, percentage recruited and the resultant characteristics of PLwD who participated
2. To test the appropriateness of data collection procedures and select secondary outcome measures
3. To test combining fall prevention exercise into CST
4. To test training of CST facilitators to deliver CogEx
5. To test intervention fidelity of CogEx delivered by facilitators
6. To explore the facilitators' perceptions of delivering CogEx
7. To explore the participants' experience of CogEx

Establishing the feasibility of collecting fall data was not a study objective. The research team has a feasible and accurate method of recording falls which involves blinded assessors auditing the incident reports at an RAC facility for falls over a specified date range. We are currently using this method in another fall prevention study being conducted in RAC facilities [20].

Methods

Design

A mixed methods study design was used to evaluate the feasibility issues in two settings (Residential Aged Care and Community Based) [21]. This included quantitative outcome measures in a randomised controlled study comparing CST (control group) with CogEx (intervention group) and qualitative evaluation of the experience of study participants, group facilitators and blinded assessors. Ethical approval was given from the New Zealand Health and Disability Ethics Committee (16/NTB/121).

Setting

The Residential Aged Care (RAC) facility had a mixture of residents living in the rest home and private hospital-level care. For the community-based (CB) setting, a regional non-government organisation (NGO) supporting PLwD and their family delivering CST in the community had agreed to take part.

Recruitment of individual participants

The initial inclusion and exclusion criteria for participants are listed in Table 1.

The RAC clinical manager used their knowledge of the residents and applied the inclusion and exclusion criteria to screen all residents and identify those who may be eligible to participate in the study. The clinical manager then explained the research to individual residents and invited them to participate as well as contacting the Next of Kin (NoK) to explain the research and their relative's potential involvement. If agreeable to participating in the study, the participant and their NoK's names and contact details were forwarded to the primary researcher who then gave resident contact details to a research assistant (RA).

Potential CB participants and their NoK were informed about the study by an NGO keyworker and given the study information. The keyworker followed-up by phone a week later. If agreeable to participating in the study, the participant and their NoK's names and contact details were forwarded to the primary researcher who then gave the potential participant's contact details to a research assistant (RA).

Participants were asked to give verbal and written consent by the RA before completing the baseline assessments, and the NoK were asked to give verbal or written assent by the clinical manager or the primary researcher.

Procedures

The participants were enrolled by the RA prior to baseline assessment. At baseline assessment demographic information, medical conditions including a history of falls, current medication and use of walking devices were recorded for each participant as well as asking if they had experienced pain or fatigue over the past few days [22]. Outcome measures were also completed. The RA assessors were blinded and remained blinded throughout the study. It was not possible to blind the staff facilitating the groups or participants to group allocation.

Randomisation and allocation

The primary researcher created a computer-generated sequence and used this to randomise participants. The primary researcher allocated participants to a group within the setting where they lived and then sent the group lists to the staff who were facilitating the groups.

As this was a feasibility study, no sample size was statistically calculated. The intended sample size of 32 participants was based pragmatically on the usual size of a CST group being 8–10 participants and the feasibility study using two CogEx groups and two CST groups.

Table 1 Eligibility criteria

Inclusion criteria	1. Aged 65 years or older
	2. Living in their own home or in residential aged care
	3. A diagnosis of mild to moderate dementia
	4. Mobile with or without an assistive device
	5. A MoCA score between 15–26 out of 30
	6. Able to have a meaningful conversation
	7. Able to hear well enough to take part in small group discussion
	8. Able to see well enough to see pictures
	9. Likely to remain in a group for 1-h
Exclusion criteria	1. A recent significant medical illness
	2. Unable to participate due to severe visual or hearing impairment
	3. Wheelchair/bed bound or unable to walk
	4. Receiving terminal or palliative care.

MoCA Montreal Cognitive Assessment (0–30, a higher score = better cognition)

Interventions

The group facilitators were staff who already ran group exercises and activities, had completed the 1-day CST training and were asked by their manager to facilitate the groups for the study. None of the facilitators had run CST prior to the study. The facilitators completed CogEx training in small groups. The training sessions were an hour long and included working through the CogEx manual (available on request), discussing the principles of the programme (safety, fun, session activities, challenge, effort, 30 s bouts of exercise, safety), practicing the 3-min exercises to a song, practicing the strength and balance exercises and the progressions, discussing the attendance and exercise record sheet and practicing with the 30 s interval timer. The facilitators were asked to check with participants at the start of each session if they had any pain. The TIDiER Checklist is an additional file (see Additional file 1).

Cognitive stimulation therapy (control group)

CST was delivered as per the CST manual for group leaders [3] which was a group session for 1 h twice a week for 7 weeks, with each of the 14 sessions having a different theme.

CogEx (intervention group)

CogEx was CST (as above) with aerobic and progressive strength and balance exercises embedded. As socialisation and engagement are key elements of CST, it was important to keep both groups the same length of time; otherwise, if CogEx was longer, those participants would receive longer contact time and therefore more socialisation and engagement. To keep the CogEx sessions the same length of time as CST, 3 min of aerobic exercise was included during the welcome and the farewell song (6 min in total) and 10 min of strengthening and balance exercises occurred in the body of the session.

The aerobic exercises were continuous for 3 min and included 30 s bouts of exercises in standing (walking on the spot, stepping side to side, washing machines, turning to tap your neighbour, washing machines repeated). The strength and balance exercises were informed by clinical experience, previous fall prevention research [20, 23] and an understanding of the physiological systems of balance and rehabilitation principles. This included the following:

- *Motor control*—muscles are turned on according to the task [24, 25] and underpins specificity of exercises; therefore, exercises were functional, i.e., in weight-bearing and incorporated everyday movement.
- *Overload*—the body responds to a stimulus over and above what it normally experiences [26] so to improve balance it must be challenged.
- *Balance is multisystem* exercises—included muscle strengthening, vestibular adaptation and balance strategy retraining.

The exercises targeted major muscle groups, range of motion, physiological systems and were designed to be in weight-bearing (see Additional file 2). The exception was the vestibular ocular reflex exercises which were in sitting. Strengthening exercises were chosen that incorporated balance for example standing and flexing the knee to bring the heel toward the bottom strengthens hamstrings but also decreases the base of support with standing on one leg. Each exercise was completed for a period of 30 s.

The exercises were the same at each session so that the repetition might result in participants becoming familiar with the exercises and their balance self-efficacy increasing. Exercises were progressed individually according to the participant's ability by decreasing hand support and encouraging more repetitions within the 30 s.

CogEx was manualised and included the programme principles, session structure, photographs of exercises with instructions and progressions and a one-page exercise sheet for each session that could be used to plan and record the exercises (see Additional file 3).

All sessions (CST and CogEx) were run by two facilitators as per the usual CST practice [27]. The 1 h sessions were on days and times decided by the RAC and NGO.

Data collection

Quantitative and qualitative methods were used to answer the study objectives.

Outcome measures

Outcome measures were chosen that were widely used with older adults or PLwD; however, it was necessary to assess the appropriateness of the measures for this particular population of older adults as well as how long it took to complete all the outcome measures (study objectives 1 and 2). The MoCA score (to assess cognition) was completed first to screen participants for study eligibility [28]. Then, depression assessed with the 15-item Geriatric Depression Scale (GDS) [29], quality of life with the Quality of Life-Alzheimer's Disease (QOL-AD)—Version for the person with dementia [30], cognition with Alzheimer's Disease Assessment Scale—Cognitive (ADAS-Cog11) [31], balance with the Brief Balance Evaluation Systems Test (Brief BESTest) [32] and functional mobility with the Short Physical Performance Battery (SPPB) [33].

An attendance sheet documented participants' attendance at each session, and a record sheet of each CogEx session was kept documenting the level of the strength and balance exercises completed (study objectives 3 and 4) (see Additional file 3).

Adverse events were monitored by the facilitator asking each resident at the start of each session how they were. All outcome measures were reassessed the week following completion of the 7-week programme.

Qualitative evaluation

Focus groups were used to generate information about participants' experiences of CogEx sessions; they were facilitated by the primary researcher immediately after the final CogEx session (study objective 7). The participants were asked what they liked or did not like about the sessions, what they thought about the exercises and any changes they would like to see. The focus groups were audio-recorded and transcribed verbatim.

Semi-structured interviews were used to generate information about the facilitator's experience of running the groups (study objective 6). The primary researcher interviewed each facilitator after completion of the last group session. The interview was at a time that suited the facilitator and sought to ascertain their thoughts about the programme, the structure, the length of the session and the exercises. The interviews were audio-recorded and transcribed verbatim.

Semi-structured interviews were used to generate information about the assessor's experience of assessing the participants (study objective 2). The primary researcher interviewed each assessor after completion of the post-intervention assessments. The interview was at a time that suited each assessor and sought to ascertain their thoughts about using the outcome measures with the participants and how long each assessment took. The interviews were audio-recorded and transcribed verbatim.

A video camera was set up by a facilitator for each session. The camera was on a tripod in the corner of the room and recorded participant interactions and engagement (CST and CogEx) as well as how participants transitioned from one task to the other.

Data analysis

Descriptive statistics were used to describe the number of residents recruited (percentage), the group demographics at baseline, pre- and post-intervention outcome measures (means, standard deviations), change in outcome measures (difference, 95% confidence intervals) (objectives 1 and 2), session attendance (percentage) (objective 5) and exercise session content (minutes in sitting and standing) (objectives 3–5).

Qualitative analysis of the focus groups and semi-structured interviews (facilitators and assessors) used a conventional approach to content analysis informed by Hsieh and Shannon [34]. Common ideas were identified within and across the transcripts, then grouped into themes. The qualitative data were used to examine and the assessor's perception of the data collection (objective 2), identify acceptability of the session to the participants and examine facilitator perception of session delivery (objectives 6 and 7). The video of sessions was viewed to observe how the participants engaged with the exercises and transitioned from one task to another.

Results

There were changes to the original protocol after the commencement of the study.

Setting

The research groups first ran at the RAC. When the NGO went to identify CST groups for the trial, they discovered they were unable to provide any groups in the required timeframe. They found that three CST groups per geographical area per year met their current demand. No groups were scheduled to start until after the study funding had expired. Therefore, a second RAC facility (RAC2) was recruited to participate in the study. RAC2 was a facility providing a mix of assisted living, rest home and private hospital-level care.

Recruitment of individual participants

Changes in the study settings resulted in alterations to some of the initial eligibility criteria (Table 1):

> Inclusion criteria 2: Due to the NGO no longer taking part in the study, this was modified to "living in residential aged care".
>
> Inclusion criteria 3: Staff at RAC1 explained that if cognitive decline developed after admission to RAC, a resident may not be formally diagnosed with dementia. On this information, inclusion criteria were expanded to include "staff identified cognitive problems". In RAC2, staff only knew an assisted living (apartment with nursing services provided) residents' diagnosis if the person chose to share their medical history with care staff. Therefore, the study was advertised as seeking people to participate who felt they may have memory problems as well as inviting people with mild to moderate dementia or staff identified cognitive problems. Inclusion criteria and information sheets for participants and families were modified to include "self-identified memory problems".
>
> Inclusion criteria 5: The eligibility cut off score of > 15/30 on the MoCA had been used previously by the research team members in community-based CST research. However, of the first four residents assessed in RAC1, only one had a MoCA > 15/30. In a discussion with the research team, the cutoff MoCA score was lowered to > 10/30 to screen residents as eligible to participate in the study.

Recruitment at RAC2 involved the clinical manager inviting residents, as well as the research being advertised in the village flyer and a talk and information sheets given to interested residents.

The trial concluded as planned with all groups completing their 7-week programme and post group assessments. No adverse events were reported throughout the trial.

The flow of participants through the study can be seen in Fig. 1. At RAC1 recruitment from 94 residents occurred from January to March 2018. Of the 20 residents identified by the clinical manager as appropriate to participate in the study, 19 volunteered to participate and of those 12 were eligible. The recruitment for RAC1 was 13% (12/94); of those who were invited and eligible, all took part (100%). At RAC2 recruitment from 52 residents occurred from May to July 2018. Of the 29 residents self-identified or identified by the clinical manager as appropriate to participate in the study, 17 volunteered to participate and of those 11 were eligible. The recruitment rate for RAC1 was 21% (11/52). Of those who were invited and eligible, all took part (100%).

Of the nine residents who did not meet the inclusion criteria, three had a MoCA score > 26/30, four had a MoCA score < 10/30, one was awaiting a lower limb prosthetic and unable to stand, one was visually impaired and unable to do the pen and paper tests; the other reasons were one resident became distressed during the assessment, so it was stopped and one resident could not stay on topic long enough to complete any of the tests.

No participants were lost to follow-up at RAC1, and three were lost to follow-up RAC2 (one was in hospital, one had stopped going to sessions and declined reassessment, one was emotionally unwell, could not complete the MoCA and the assessment was stopped). Of those lost to follow-up, one was in the CST group and two were in the CogEx group.

Randomisation and allocation

At RAC1, CST ran first followed by the CogEx group. This was a pragmatic decision by management due to staff availability and allowed the facilitators to experience running a CST group before running CogEx. The research team was concerned that if all participants completed baseline assessments in the same week that those waiting 7 weeks for their group to start might deteriorate. For this reason, once residents and their NoK agreed to participate in the study, they were randomised and then assessed in the week prior to their group starting.

At RAC2, CST and CogEx groups were run in parallel; therefore, participants were randomised following baseline assessment.

Quantitative evaluation

Participants

The baseline group demographics in Table 2 demonstrate that the groups were similar except for the MoCA, ADAS-Cog 11 and mobility. On the MoCA, the CogEx group lower mean of 16.0 (SD 4.2) was in the moderate cognitive impairment band of 10–17 while the CST mean of 18.0 (SD 5.6) was in the mild cognitive impairment band [35]; however, the 2-point difference is smaller than

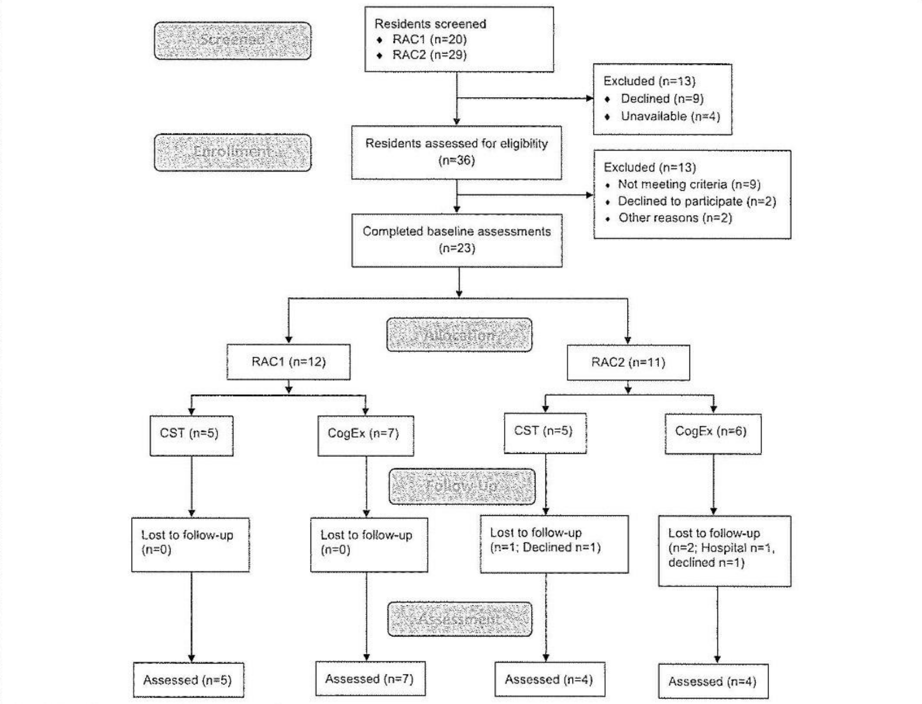

Fig. 1 Flow of participants through the trial

the 4-point minimum detectable change to be sure the difference is not due to measurement error [36]. Similarly, on the ADAS-Cog 11, the CogEx group had a lower mean ADAS-Cog 11 score of 17.4 (SD 5.9) compared to the CST mean of 15.0 (SD 10.4); however, a definitive cutoff score for dementia has not been established. If a score of ≥ 17 for dementia [37] is used then the CogEx group is classed as having dementia but if > 18 [38] is used, then both groups have a worse score than 5 being normal [39] but not classified as dementia. More participants in CogEx used an assistive device when walking.

All participants were reassessed in the week following the last session (Table 2). For RAC1, CST post group assessments occurred 14–18 May 2018 and CogEx 3–7 July 2018; and for RAC2, both group post group assessments occurred 29—30 August 2018.

The difference in group baseline and reassessments measures in Table 3 illustrate that no clinically meaningful change was observed in any outcome measure for either group.

Additional files show the individual participant change scores by group (see Additional files 4 and 5).

Interventions

Ten facilitators trained to deliver CogEx (RAC1 n = 5, RAC2 n = 5). RAC1 CST was delivered 26 March–9 May 2018 and CogEx 14 May–29 June 2018; RAC2 CST and CogEx were delivered 16 July–29 August 2018. Three of the four group sessions were held in lounges or activity rooms with participants sat at tables except for RAC2 CST where the group sat in a semi-circle in lounge chairs.

Attendance

RAC1 kept attendance sheets for all CST and CogEx sessions. RAC2 kept attendance sheets for 12/14 CogEx sessions and no CST sessions. The percentage of attendance was calculated as the number of participants attending the total number of available group sessions; participant attendance rate per session was also

Table 2 Baseline group characteristics and outcome measures at baseline and reassessment

	Baseline		Reassessment	
	CST	CogEx	CST	CogEx
Number of residents randomised	10	13	9	11
Mean age in years, (range)	83.6 (71-95)	87.5 (81-95)	-	-
Female, *n* (%)	8 (80)	9 (69)	-	-
Uses a walking device, *n* (%)	4 (40)	9 (69)	-	-
Medication, mean (SD)	5.2 (2.5)	6.8 (3.6)	-	-
MoCA, mean (SD)	18.0 (5.6)	16.0 (4.2)	18.3 (6.9)	14.6 (3.3)
GDS-15, mean (SD)	3.8 (3.4)	2.9 (2.8)	4.3 (5.1)	2.6 (2.0)
QoL: AD, mean (SD)	37.7 (5.8)	37.2 (6.4)	37.2 (5.7)	37.6 (4.8)
ADAS-Cog 11, mean (SD)	15.0 (10.4)	17.4 (5.9)	14.9 (9.5)	18.4 (5.5)
Brief BESTest, mean (SD)	8.5 (5.5)	9.0 (6.0)	10.3 (5.2)	8.2 (5.1)
SPPB				
Balance score, mean (SD)	2.4 (1.4)	2.4 (1.6)	3.0 (1.0)	2.3 (1.3)
Gait score, mean (SD)	2.3 (1.4)	2.6 (1.2)	2.0 (1.0)	2.2 (1.3)
Chair stand score, mean (SD)	0.8 (0.4)	1.3 (1.3)	1.2 (1.1)	0.9 (0.9)
Total score, mean (SD)	5.5 (2.1)	6.3 (3.8)	6.2 (2.2)	5.4 (2.9)

MoCA Montreal Cognitive Assessment (0–30, a higher score = better cognition); *GDS-15* Geriatric Depression Scale—15 (0–15, A score of > 5 = likely to have depression); *QoL* AD quality of life: Alzheimer's disease (13–52, a higher the score = better the quality of life); *ADAS-Cog 11* Alzheimer's Disease Assessment Scale—Cognitive 11 (0–70, a lower score = better cognition); *Brief BESTest* Brief Balance Evaluation Systems Test (0–30, a higher score = better balance performance); *SPPB* Short Form Physical Performance Battery (item score 0–4, total score 0–12, a higher score indicates better performance)

calculated. CST (n = 5) average session attendance was 92% (80–100%) and CogEx (n = 13) attendance rate was 55% (17–100%).

Class record sheets

The CogEx facilitators recorded the level of strength and balance exercises performed in the 10 min block; the 3 min of aerobic exercise (continuous movement) during the welcome and the farewell song was not recorded as these exercises were set and did not change over the 7 weeks of the programme. The RAC1 facilitators kept and returned the record sheets, the RAC2 facilitators did not. Exercises were performed in bouts of 30 s. Table 4 illustrates the time spent and number of exercises completed in standing at each session. Not all participants performed calf raises in standing. Sit to stand and calf raises were two of the five exercises performed at the start and end of the 10 min block; therefore, each bout of an exercise was counted individually.

Table 3 Change in group outcome measures after the intervention (with 95% confidence intervals)

	CST n = 9	CogEx n = 11
MoCA	1.2 (− 1.0, 3.5)	− 0.6 (− 2.2, 0.9)
GDS-15	0.1 (− 2.2, 2.5)	− 0.3 (− 1.8, 1.3)
QoL: AD	0 (− 2.4, 2.4)	0.5 (− 2.1, 3.0)
ADAS-Cog 11	− 1.1 (− 6.7, 4.6)	− 0.3 (− 2.7, 2.2)
Brief BESTest	1.3 (− 1.5, 4.2)	1.0 (− 1.1, 3.1)
SPPB		
Balance score	0.4 (− 1.0, 1.8)	0.1 (− 0.5, 0.7)
Gait score	− 0.3 (− 1.4, 0.7)	− 0.2 (− 0.6, 0.2)
Chair stand score	0.4 (− 0.2, 1.1)	− 0.1 (− 0.6, 0.4)
Total score	0.6 (− 0.9, 2.0)	− 0.2 (− 1.0, 0.6)

MoCA Montreal Cognitive Assessment (positive difference = improvement); *GDS-15* Geriatric Depression Scale–15 (a negative difference = improvement); *QoL* AD quality of life: Alzheimer's disease (a positive difference = improvement); *ADAS-Cog 11* Alzheimer's Disease Assessment Scale—Cognitive 11 (a negative difference = improvement); *Brief BESTest* Brief Balance Evaluation Systems Test (a positive difference = improvement); *SPPB* Short Form Physical Performance Battery (a positive difference = improvement)

Qualitative evaluation

Only the CogEx qualitative results are presented here to answer study objectives 6 and 7.

Participant focus groups

Both facilities had a culture of resident inclusiveness which meant a resident could take part in any activity that was on offer if they wanted to. Therefore, residents who were not research participants attended the sessions. This inclusiveness resulted in everyone at the last CogEx sessions being invited to participate in the focus group; they were shown the recorder and it was explained that what they said would be recorded, transcribed but not with names and this would be used for research purposes only. They were given the opportunity to leave however, everyone stayed and this resulted in a

Table 4 RAC1 CogEx standing exercises completed at each session

Week	Session	Standing exercises (n/16)	Total time in standing (minutes)
1	1	2	1
	2	2	1
2	3	Not recorded on a sheet	-
	4	Not recorded on a sheet	-
3	5	2	1
	6	2	1
4	7	Public holiday No session	-
	8	2	1
5	9	2	1
	10	2	1
6	11	4	2
	12	2	1
7	13	2	1
	14	2	1

mix of participants and non-research participant residents take part in the RAC1 and RAC2 focus groups. It was not possible to remove non-research participant comments from the analysis as transcriptions were anonymised. The ethics committee who had approved the study were notified of the protocol violation and gave further approval.

Seven residents took part in the RAC1 focus group (participants n = 4 and non-research participant residents n = 3) and six residents in the RAC2 focus group. At RAC2, the mix of RAC2 participants and non-research participants was unknown as there was no attendance sheet for the final CogEx session. The answers given by RAC1 participants tended to be briefer than those given by RAC2 participants.

The two main topics discussed at the focus groups were the group and the exercises.

Overall, the participants enjoyed being a part of the group, what they did in the sessions and wanted the sessions to continue. They enjoyed doing the sessions together and took pleasure in that. They experienced a feeling of being known and knowing as a result of the discussion topics that were used in the CST structure:

> Just the fact that somebody knows that you are (name)...all of us in a way have got to know each other better (female, RAC2)

> ...we have the questions, we play the games whatever and it means you can beat (others)...that it's not just sitting here nattering to another bunch of old people (female, RAC2)

The participant's comments on the exercises were mixed. There was also discussion at RAC2 of using music to make exercise more enjoyable:

> Oh, that was quite good, gets the whole body moving (male, RAC2)

> I've been doing them in my chair and quite happy (female, RAC2)

> I would have liked to have been able to do them better (male, RAC1)

> I remember not being able to do some of them, balancing and things. Some of them were very hard (female, RAC2)

One participant declined reassessment as she had stopped attending after session 2 or 3. She was not part of the focus group but wanted her thoughts known as she found the sessions did not make sense, did not help and did not find the topics enjoyable.

Semi-structured interviews

The RAC1 CogEx facilitators were invited to be interviewed and two accepted (n = 2/5). They were interviewed individually at the facility at a time that suited them following completion of CogEx. The RAC2 Manager offered to talk about CogEx and asked for the facilitators not to be interviewed as the exercise component of CogEx had been discontinued from the sessions in week 2 or 3.

Facilitators

The main topics of the facilitators' comments were time, engagement, improvement and exercises.

Time

Facilitators combined exercises into the welcome and farewell group song and used the 30 s interval timer for each exercise as planned. To keep the sessions to an hour long and the same length as CST, the facilitators removed the newspaper reading component of CST. They felt that not everyone could see the newspaper to read it, not everyone had an opinion on the news and the group was split when only a few participants gave their opinion whereas the exercises were all inclusive.

Engagement

The facilitators described participants engaging more as the weeks progressed, with participants enjoying singing along with the songs and doing the movements:

They start (singing) "It's a long way to Tipperary" so you know they are really enjoying it, I think it's great, even the heads are going from left to right, nobody's complaining this is sore (Facilitator 1)

One lady in the wheelchair was unable to try but her feet were moving so she was aware that something should be happening...engaging her feet (Facilitator 2)

The facilitators also felt that when participants physically touched each other during a trunk rotation exercise (when they reached their arm across their body to tap their neighbour on the shoulder), this increased their engagement with others in the group:

...they touch and they said o that is nice you gave me your hand (Facilitator 2)

I noticed one or two of them who weren't quite sure what they were doing, the other residents actually engaged with them (Facilitator 2)

There was also a sense of teamwork with participants copying each other and helping each other out during the group activities and exercises:

Other residents helping those who were slightly hesitant to stand up (Facilitator 2)

Improvement

The facilitators described that as the weeks progressed, the participants became more familiar with the exercises, required less prompting and remembered that the session started with a song and movement. The facilitators could see the participants getting better at the exercises:

...they are getting even lower you know bending... they have been here twice a week touching the ground, they are really touching the ground (Facilitator 1)

...some of them now are standing up (Facilitator 1)

One lady in particular made full use of her 30 seconds whereas another couple of people would just be able to do one or two (Facilitator 2)

Most of the sitting ones are very good (Facilitator 1)

Exercises

The facilitators described doing almost all the exercises in sitting. The two standing exercises that were performed were sit to stand and calf raises. A variety of reasons were given including the setup of the room, safety and it does not matter as long as participants moved:

I am scared that they will fall because they are standing up now...that's fine and then they want to sit back so yeah go and sit back so the most sitting ones are very good (Facilitator 1)

Not many of them stood...most of them preferred to remain seated most of the time (Facilitator 2)

I am happy with the exercises, only the standing ones we didn't really do that, maybe if we had another time only the standing ones, practice a lot on that you know, like sideways walking. Now we have seven but sometimes you have 11 and that's too many then to look after especially because everybody is a bit frail (Facilitator 1)

...standing up and tip toes was fine... everything we do it in the chair...it doesn't matter as long as they move (Facilitator 1)

The facilitator interviews description of performing almost all exercises in sitting was supported by video and the time spent standing in each session taken from the class record sheets (Table 4).

Manager

The RAC2 manager recalled asking the facilitators how the groups were going and finding out that the exercises had been discontinued from CogEx in week 2 or 3. The manager described an aged care industry dynamic of staff not wanting someone to feel left out of an activity and so if one person could not do something, then whatever it was would be discontinued:

...she said well we have got a couple of people who can't do them (the exercises) so didn't think it was very fair on the others that they couldn't do them... people do this all the time in aged care they feel sorry for the person who can't do it so therefore nobody else can take part and that's an interesting dynamic of this industry

The manager felt if there had been overall supervision of the groups by management that this may have kept the groups on track; however, it was not their role and maybe if they had a diversional therapist then, they would have overseen and been in charge of the project. Another suggestion was a visit by the researcher to check on the groups and if this had occurred the exercises could have been restarted:

...I think it would have been good to have someone with the research or someone just come back 2 or 3 weeks into it and just remind us how it's going and just having a review just a couple of weeks into it...I think that would have been good (and) got them back on track very quickly

The manager described the difference in ages, personalities and experience of the staff who trained to be facilitators. Some staff were new to diversional or recreational therapy, so CST had been viewed as a structured way to train staff:

...I wanted them to do CST so that they don't get into the traditional method of activities or social interaction but start to think about residents and their needs and to get the most out of them and that's what the spin off for us has been that the other staff are very much more engaged

Other factors that the Manager felt affected the CogEx group was morning being a challenging time of day to run a group due to the staff being busy and if someone called in sick it was hard to find cover; that the small room CogEx was run in was harder for participants to move in and participants having to walk through a part of the facility where residents were in hospital-level care may have been off-putting for participants attending the CogEx group.

Assessor semi-structured interviews

All assessors ($n = 3$) were interviewed individually at a time that suited them at the university. As this was a small number of people, repetitive comments around topics are presented rather than themes. The assessor's main comments related to time, repetition and not feeling comfortable.

Time

The six outcome measures took between 45 and 90 min to complete. The assessors recalled the assessments took longer at RAC1 as the participants were cognitively slower, needed to be redirected to answer questions and motivated to continue. Assessments were often interrupted at RAC1 by staff giving medication or a cup of tea. The assessors recalled a few of RAC1 participants commenting on the number of questions they had to answer with some becoming bored, agitated or emotional when answering questions about marriage and family. The assessors felt that RAC2 participants were more independent and appeared to enjoy the challenge of the tests.

Repetition

The assessors identified repetition of items of the MoCA and ADAS-Cog 11 and described participants also being aware of this:

...they are familiar with the question and they might do better just like for example the drawing of the cube...several of them mentioned that "I have done this before" and it's "I know I can't do this, it is difficult for me and it's there again" (Assessor 2)

The assessors felt that some participants looked a little confused being asked the same questions during the assessment such as the orientation questions of date, month, year, day and place.

Not feeling comfortable

The assessors felt uncomfortable with the level of challenge of some balance tests with all three assessors commenting on Brief BESTest items 5 and 6 that elicit a compensatory stepping strategy. They felt uncomfortable doing these tests and gave a variety of reasons such as the age of participants, the restricted space if assessing a participant in their room and not feeling it was very safe to do this test. One assessor also commented on testing one leg standing in the SPPB, saying that the participants didn't like it:

A bit tricky like to stand on one leg, they would go "I don't do that usually why would I do that, why are you testing something that I am not even trying to do?" (Assessor 3)

Video

All the video footage was observed to analyse participants' engagement and transitions from one activity to another. The video captured most participants however, as they were sat around a table less than half participants' faces were visible. It was not possible to analyse facial expression or body language for the level of engagement at each session.

There were smooth transitions from one task to another such as from the welcome song to the exercises and the video supported the facilitators' semi-structured interviews and documentation of doing almost all exercises in sitting.

Discussion

The results of the CogEx feasibility study demonstrated that while fall prevention exercises can be incorporated into the CST schedule, the fidelity of the combined programme was poor and other components of the study design need further consideration before evaluation using an RCT would be feasible.

Objective 1. To test recruitment strategy, percentage recruited and the resultant characteristics of PLwD who participated

An ideal recruitment rate was not set prior to the study. Recruitment of PLwD into research trials has been acknowledged as a problem in many countries [40], so the results from this study were to inform recruitment rates for a future study. When designing the study, the numbers of PLwD registered with the NGO was known but not the number of residents with dementia living in the RAC. Recruiting from the community was problematic due to the limited number of CST groups the NGO planned to run annually. Similarly, in RAC all potentially eligible residents were invited by the manager yet after screening less than the 16 were eligible at each facility. Lowering the MoCA score to that used in other CST studies [41] was appropriate for RAC and contributed to a higher number of residents being recruited; however, the percentage recruited at both RAC1 (13%) and RAC2 (21%) was low.

A fully powered fall prevention study requires hundreds of participants [42–44]. To recruit a large enough sample of participants for an RCT, all CST deliverers in Auckland (whether community-based or RAC) would need to be recruited or a multi-centre trial undertaken.

Objective 2. To test the appropriateness of data collection procedures and select secondary outcome measures

The outcome measures used in this study were based on those in Spector et al.'s original pilot study and RCT [45, 46] with the addition of two balance and lower limb measures. However, the MoCA was used instead of the Mini-Mental Scale Evaluation (MMSE) to screen cognition firstly due to the MMSE no longer being freely available [47], and secondly, recent work has identified the MoCA as more sensitive to older adults with mild cognitive impairment [48, 49] and can measure change over time [50, 51]. The assessors and participants noted the repetition between the MoCA and the constructional praxis and orientation sections of the ADAS-Cog-11 and this may have impacted on some participant's performance and agitation with the tests. The MoCA took less time than the ADAS-Cog 11 to administer and needed only the paper copy of the test and a pen while the ADAS-Cog 11 required a large kit of equipment. The MoCA also has banded scores to describe a person's level of cognitive impairment [35] while the ADAS-Cog 11 has a normal score established for healthy older adults but a definitive cutoff score for dementia is still being debated as is what constitutes a meaningful clinical change [52]. Of these two tests, the MoCA is currently the better choice to ascertain a person's level of cognitive impairment for use in future studies unless more detail was required as to the type of cognition being impacted.

The outcome measures did not show change after taking part in CogEx; however, given that only 1 min of exercise in standing was completed this could be expected. The number of participants was also too small for inferential analysis or statistical modelling to be undertaken.

The Brief BESTest was chosen to assess balance as it assesses six subcategories that contribute to the maintenance of balance [32] and therefore provides more insight as to why balance is decreased; this version is also the quickest to complete of all BESTest versions [53]. The assessors felt uncomfortable with the more challenging balance tests (reactive postural response) despite having trained to do the outcome measures and practicing them on each other. The assessors also felt uncomfortable assessing the one-leg stand component of the SPPB because of some participants' reaction to being asked to do something they said they never do.

Assessing balance in frail, older adults who perform fewer incidental activities of daily living in RAC is challenging, as in that environment the population is not homogeneous. Our knowledge of physical tests has not kept up with the global population increase of older adults. There is a lack of normative values in outcome measures for older adults living in RAC as most work to date has been on healthy older adults living in the community [54]. An example of this is of the outcome measures used in this study only three have had a minimal detectable change identified: MoCA 4 points [36]; Brief BESTest 4 points [55]; SPPB total 1 point [56]; however, only the Brief BESTest established this for a population of older adults living in RAC. Consideration should be given to this when selecting measures for future studies.

The battery of assessments took too long and some participants became fatigued or agitated. With the growing evidence of the benefit of CST on cognition and quality of life [6], the number of tests could be reduced to focus purely on changes in physical performance in response to CogEx.

The class record and attendance sheets captured the desired information however asking the facilitators to return them weekly would have given the research team oversight of the level of exercises being delivered and created the opportunity to discuss with the facilitators their choices and possibly intervene.

The focus groups were challenging due to research non-participants taking part. The RAC facilities were offering CST as part of their resident activity programme and agreed for the groups to be used for research. As the RACs hosted the research they retained control of the groups and applied their inclusiveness ethos, which resulted in non-research participants taking part in the groups. This also created an ethical issue as these residents had not given written informed consent.

Focus groups were held immediately after the last session to accommodate for cognitive impairment so that participants knew what group activity and exercises the questions related to. Before the focus groups took place, the researcher explained what questions were going to be asked and why, the use of the voice recorder was explained and the opportunity to leave and not take part was given. Focus groups had been chosen when designing the study in order to generate discussion between participants however some focus group participants had poor hearing, and this made their participation in the focus group challenging. The focus group transcription was anonymised making removal of non-research participant comments impossible. Individual interviews with research participants would address the above problems but remove the creation of information that occurs when participants talk between each other.

Objective 3. To test combining fall prevention exercise into CST

The RAC1 facilitators successfully incorporated the additional exercises and kept the CogEx sessions the same length as CST (1 h). They achieved this by firstly, removing the discussion of topics from the newspaper as they found the group did not engage with this. And secondly, by socialising with morning tea after the session rather than as a form of welcome to the group as CST in the community does. In RAC, morning tea is a part of the daily routine so having morning tea after the session helped CogEx to run within the RAC normal schedule.

Objective 4. To test training of CST facilitators to deliver CogEx

The additional exercise time was scheduled into the CST structure; however, almost no standing exercises were performed. This could be due to CogEx facilitator training being insufficient. Training was a 1 h session working through the manual, discussing the principles of the programme, practicing the different levels of the exercises and practicing using the timer. This pragmatic approach had been used by the research team previously [57] and was how implementation was envisaged in order to prevent training costs being a barrier. Removing any picture or option of sitting exercises from the manual could act to prompt the facilitators to focus on the importance of exercising in standing to improve the participants' balance. One facilitator's comment that it did not matter what the participants did as long as they were moving suggests that the difference between fall prevention exercise and activity was not understood.

The lack of standing exercise could also be due to the industry dynamic referred to by the manager of making sure everyone does the same thing, alluding to accepted cultural norms within a facility. It could be that this group of health care workers are very well trained to err on the side of safety and comfort versus physiotherapists who are trained to encourage people to work to their limits and know challenging balance is important in order to stimulate physiological change. The exercise programme while appearing straightforward requires a skill set that is not an inherent quality of health care workers in RAC who routinely lead activities with large groups of residents in sitting.

Ongoing training such as a physiotherapist attending one session a week to support the facilitator may have helped to grow the confidence and understanding of the facilitators in encouraging participants to stand and progressing the exercises. Increasing the time the physiotherapist is involved with delivering CogEx training and implementation also increases the implementation costs of the programme, but this would be beneficial if they facilitators gained confidence, knowledge and long-term skills to deliver future CogEx programmes independently.

Objective 5. To test intervention fidelity of CogEx delivered by facilitators

This study contained measures of delivery and engagement as categorised by Walton, Spector, Tombor and Richie that when triangulated provided a description of the fidelity of the intervention [58]. Fidelity measures of delivery were the class record sheets (session content) and the facilitator and manager semi-structured interviews, all which illustrated that standing exercise content was minimal. While the video of sessions was recorded, ethical approval was for the video to be used to observe participant engagement and transition from one task to another, not to observe the content of the session or the facilitators. The active ingredient of the intervention (weight-bearing exercise to improve lower limb strengthening and balance) was not delivered as intended and the fidelity of the intervention was poor.

Objective 6. To explore the facilitators' perceptions of delivering CogEx

The facilitators described participants getting more familiar with the programme over time and could see changes in the participants' engagement and ability to stand; they understood that standing was important but were not comfortable encouraging people to stand. One facilitator would have preferred a session of only standing exercises. The large number of residents that attended the sessions also contributed to the facilitators not encouraging more people to stand. The sessions should have had no more than eight participants; however, due to the RAC inclusiveness ethos residents that were not research participants took part. One of the facilitators described 11 people attending one session; with only two staff to supervise that many people balancing exercises may not have been safe.

Objective 7. To explore the participants' experience of CogEx

Participant engagement was measured by their choice to attend and satisfaction with content [59]. Class attendance was higher for CST than CogEx, and participant focus groups revealed mixed thoughts about the exercises.

While exercises that are challenging can be experienced as hard, that is not an ideal starting point. With a more sedentary population such as that in RAC, starting gradually and building confidence and strength over time may be a better approach. What is not known from the study is how the exercises were presented to the participants, i.e. what the facilitators told them or how they encouraged them. The attendance rates were much higher for CST than CogEx. This could be due to participants not liking the exercises although very few standing exercises were performed, or it could be due to the time of day of the session or the room size as suggested by the RAC2 facility manager.

Limitations

There were several limitations to this study. While this study sought to upskill and then utilise a healthcare workforce already in place in RAC, there was no additional funding to pay for the programme delivery. The RACs allowed the research to occur with groups that were planned and as such the RACs retained control of the groups. Both RACs had an inclusion policy so if a resident wanted to take part in an offered activity they could. This resulted in residents who were not research participants taking part in both the CST and CogEx groups, and in most cases, these residents had not been eligible to participate in the research due to being wheelchair-bound, hard of hearing or having a MoCA < 10/30. The non-participant residents' physical capabilities or lack thereof contributed to the facilitators not delivering CogEx as intended (in standing) as they delivered the exercises to the lowest level of physical ability of the group (in sitting).

The outcome measures used were also a limitation. The study initially aimed to test the feasibility of CogEx in community-dwelling and RAC populations and evaluate the appropriateness of the secondary outcome measures. Only one of the outcome measures (Brief BESTest) had normative values for older adults living in RAC, and this poses a challenge for researchers to be able to be confident that changes can be reliably measured and interpreted in this population. The small sample size was too small for inferential analysis or statistical modelling to be undertaken, and so appropriate secondary outcome measures that can be used in the analysis of a larger study remain unknown. However, we found it was reasonably practical to collect a battery of secondary outcome measures in this feasibility study.

A key challenge was the culture of the facilitators to err on the side of caution and not be able to modify the exercise for each individual so that everyone could participate albeit with a variation of the same exercise.

Conclusion

It was not feasible to deliver CogEx (fall prevention exercises embedded in CST) in the way originally conceived for this trial with the workforce currently delivering CST in Aotearoa New Zealand. The RAC environment is complex and while the CogEx programme appears simple implementation was not. Based on the findings from this study, future research needs to firstly explore either modifying the CogEx training package to give the facilitators more support to develop their skills throughout the 7 weeks of the programme or using a different workforce (e.g. physiotherapist) to deliver the fall prevention component of CogEx with a CST facilitator. Importantly, a greater understanding of the complexity of the RAC setting is needed. Each RAC facility is driven by organisational level factors such as organisational priorities, culture, staffing and workflow pressures but must also deliver on obligations to funders and expectations of resident's and their families; all of which combine to make each RAC facility a unique environment. Identification and consideration of these factors are needed for successful intervention implementation.

Supplementary information

Supplementary information accompanies this paper at https://doi.org/10.1186/s40814-020-00646-6.

Additional file 1. The TIDieR (Template for Intervention Description and Replication) Checklist.

Additional file 2. CogEx exercises and the muscles and physiological systems targeted.

Additional file 3. Recording sheets of level of exercise completed in class (circle or tick).

Additional file 4. CogEx participants' change on each outcome measure.

Additional file 5. CST participants' change on each outcome measure.

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Authors' contributions
EB, DT, NK, KP and GC contributed to the design of this study. EB trained the facilitators and RAs, supervised data collection and analysed the data. EB and DT made the initial interpretations of the data. EB drafted the work and all authors critically revised the manuscript. All authors have approved the final manuscript and are accountable for all aspects of the work.

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Availability of data and materials
The manual and de-identified datasets analysed during the current study are available from the corresponding author on reasonable request.

Ethics approval and consent to participate
Ethical approval was gained from NZ Health and Disability Ethics Committee (HDEC) on 23 August 2016 (16/NTB/121) before the trial began. Each RAC gave permission for research to occur within their facility and with their residents.

Consent for publication
Participants gave written informed consent to participate in the trial. The manuscript does not contain data from any individual person that is identifiable.

Competing interests
The authors declare that they have no competing interests.

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Publisher's Note

Appendix H CogEx Additional file 1 (TIDier checklist)

TIDieR Template for Intervention Description and Replication

The TIDieR (Template for Intervention Description and Replication) Checklist*:

Information to include when describing an intervention and the location of the information

Item number	Item	Where located ** Primary paper (page or appendix number)	Other † (details)
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	Line 102	______________
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	Line 51-102, 182-211	Additional file 2 ____________
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	Line 168-178 CST manual	Additional file 3 Manual available on request
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	Line 179-194	_____________
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	Line 169-176	_____________
	HOW		
6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group.	Line 179-189	_____________

	WHERE		
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features.	Line 270-276, L359-360	______________
	WHEN and HOW MUCH		
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose.	Line 179-189	______________
	TAILORING		
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how.	Line 209-211	______________
	MODIFICATIONS		
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how).	N/A	______________
	HOW WELL		
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	Line 229-231, Line 241-245	Additional file 3 ___________
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	Table 4 page 19, Line 367-375, Line 420-497	______________

Appendix I CogEx Additional file 2 (CogEx exercises and muscles and physiological systems targeted)

Table CogEx exercises and the muscles and physiological systems targeted

Exercise	Muscle/group targeted	Physiological effect
Sit to stand	Quadriceps/Hamstrings/ Gluteals	Strengthening
Sideways walking	Hip Abductors/Adductors	Strengthening/balance
Calf raises	Gastrocnemius/Tibialis posterior/soleus	Strengthening/balance
Standing with feet together		Balance
Standing heel to bottom	Hamstrings	Strengthening/balance
Head Nod up/down Turn side/side	Neck extensors/flexors/rotators	Cervical ROM/Vestibular
Focus eyes on own fingertip Move head from side to side Move head up/down	Eye stabilisers/Neck extensors/flexors/rotators	Vestibular ocular reflex
Look at own finger pointing to corner of the room then diagonally to point at the floor		Vestibular ocular reflex
Elbow to opposite knee	Trunk rotators	Spinal rotation ROM/Vestibular
Bend to touch the ground (all in sitting)	Back extensors	Spinal flexion ROM/Vestibular
Backwards chair bends	Truck flexors	Spinal extension ROM/Vestibular
Pass object to neighbour Clockwise anticlockwise	Trunk rotators	Spinal rotation ROM/Vestibular/Balance
Write name on ground with toe		Balance

ROM = range of movement

Appendix J CogEx Additional file 3 (Exercise recording sheets)

Session 1 Date:___________________________

30s of each exercise	Sit to stand	Use both hands to push up Push up with one hand No hand support
	Sideways walking	Support No support
	Calf raises	Support No support
	Standing with feet together	Support No support
	Standing heel to bottom	Support No support
Head Nod up/down Turn side/side	Sitting Standing – support no support	10x each in time to the music. Rotate thru movements for 30s
Focus eyes on own fingertip Move head from side to side Move head up/down	Sitting Standing– support no support	As above
Look at own finger pointing to corner of the room then diagonally to point at the floor	Sitting Standing – support no support	Big slow movements for 30s
Elbow to opposite knee	Sitting Standing – support No support	30s
Bend to touch the ground (all in sitting)	To your toes To the one side then the other To the opposite foot	10x each movement rotate thru movements for 30s
Backwards chair bends (sitting)	Sitting arms crossed over chest Standing arms crossed over chest	Sit up tall as you lift your arms, when arms can go no higher gently lean back
Pass object to neighbour Clockwise anticlockwise	Sitting Standing – support no support	15s one way 15s the other way
Write name on ground with toe	Sitting Standing – support no support	30s
30s of each exercise	Sit to stand	Use both hands to push up Push up with one hand No hand support
	Sideways walking	Support No support
	Calf raises	Support No support
	Standing with feet together	Support No support
	Standing heel to bottom	Support No support

Appendix K CogEx Additional file 4 (CogEx participants' change on each outcome measure)

The tables below demonstrate each CogEx participants' (n = 13) change on each outcome measure. The change scores have been manipulated such that a positive value represents an improvement on a measure while a negative change represents a poorer performance on a measure (in order to be easily visualised across measures). Participant 1 did not complete a reassessment as they were in hospital on the day of reassessment and Participant 2 had stopped going to sessions and declined reassessment.

Table 1 CogEx participants change: MOCA

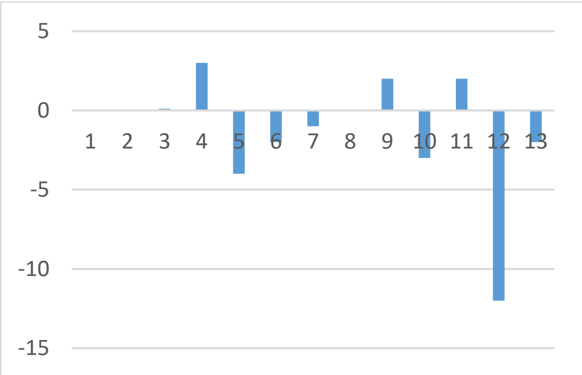


Table 2 CogEx participants change: GDS

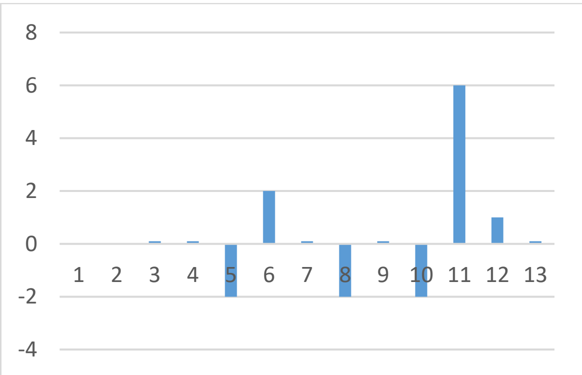


Table 3 CogEx participants change: QoL: AD

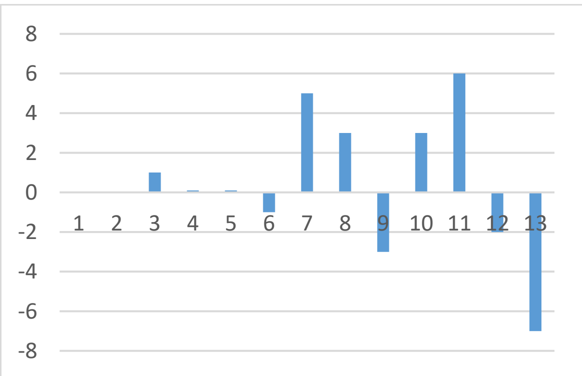


Table 4 CogEx participants change: ADAS-Cog 11

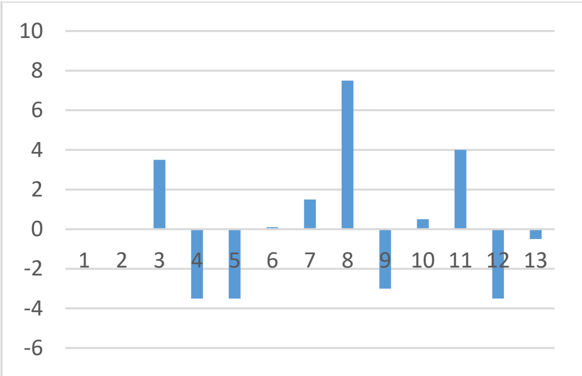


Table 5 CogEx participants change: Brief BESTest

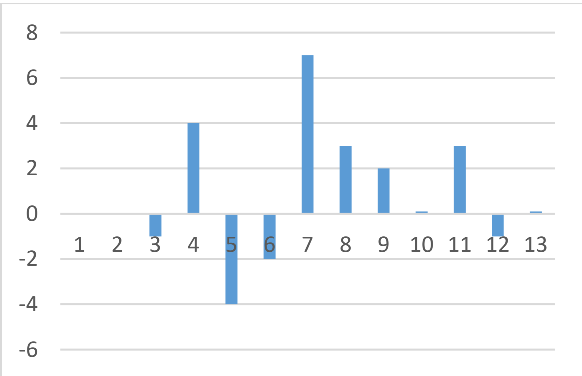
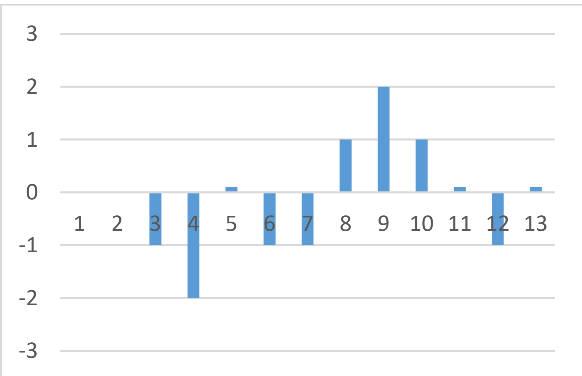


Table 6 CogEx participants change: SPPB



MoCA = Montreal Cognitive Assessment; GDS-15 = Geriatric Depression Scale – 15; QoL: AD = Quality of Life: Alzheimer's Disease; ADAS-Cog 11 – Alzheimer's Disease Assessment Scale – Cognitive; Brief BESTest = Brief Balance Evaluation Systems Test; SPPB = Short Form Physical Performance Battery.

Appendix L CogEx Additional file 5 (CST participants' change on each outcome measure)

The tables below demonstrate each CST participants' (n = 10) change on each outcome measure. The change scores have been manipulated such that a positive value represents an improvement on a measure while a negative change represents a poorer performance on a measure (in order to be easily visualised across measures). Participant 4 did not complete a reassessment as they were emotionally unwell, could not complete the MOCA and the assessment was stopped.

Table 1 CST participants change: MOCA

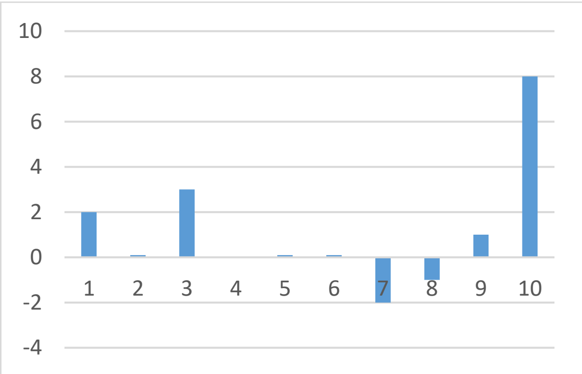


Table 2 CST participants change: GDS

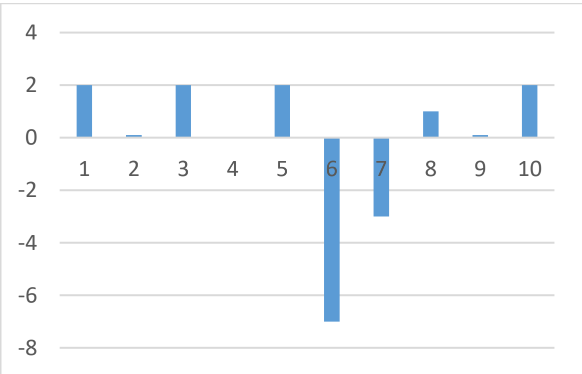


Table 3 CST participants change: QoL: AD

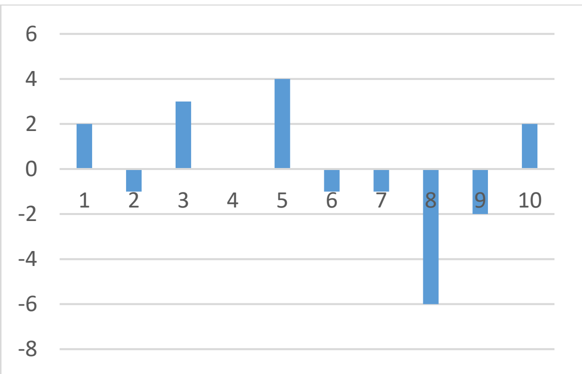


Table 4 CST participants change: ADAS-Cog 11

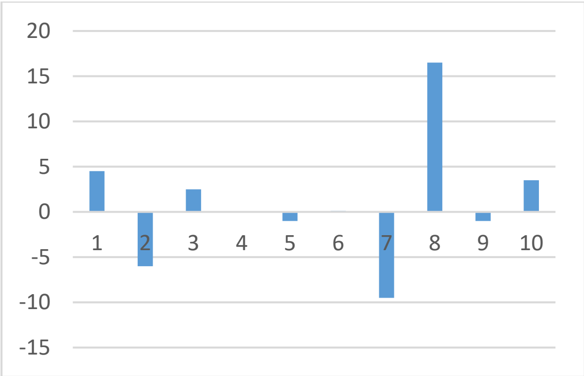


Table 5 CST participants change: Brief BESTest

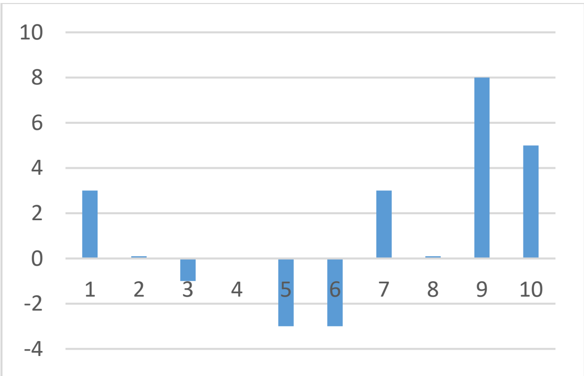
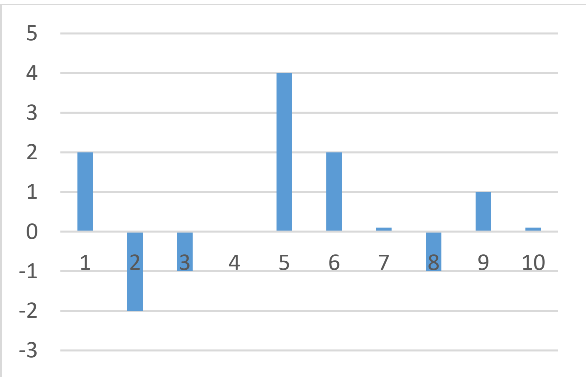


Table 6 CST participants change: SPPB



MoCA = Montreal Cognitive Assessment; GDS-15 = Geriatric Depression Scale – 15; QoL: AD = Quality of Life: Alzheimer's Disease; ADAS-Cog 11 – Alzheimer's Disease Assessment Scale – Cognitive; Brief BESTest = Brief Balance Evaluation Systems Test; SPPB = Short Form Physical Performance Battery.

Appendix M CogEx fidelity published manuscript

SAGE researchmethods cases

Program Fidelity Challenges Discovered During a Feasibility Randomized Controlled Trial of Group Falls Prevention Exercises

Contributors: Elizabeth Binns, Ngaire Kerse, Kathy Peri, Gary Cheung & Denise Taylor
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Methods: Feasibility, Measurement, Intervention studies
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Abstract

This case study focuses on how and when to measure fidelity in a feasibility study. Residential aged care staff who routinely facilitated activity groups were trained to deliver falls prevention exercises embedded within a previously established and manualized group program. The combined intervention (CogEx) was a 1-hr group program delivered twice a week, for 7 weeks. By training residential aged care staff to deliver the program, we aimed to utilize existing resources rather than place further burden on an already poorly resourced sector of health care. A range of measures were used to establish the program fidelity and when triangulated the measures provided a rich description of the intervention as it had been delivered. However, these measures were collected at the end of the intervention as a reflective exercise. At this point, it was revealed that the falls prevention exercises had not been delivered as envisaged by the researchers, and if fidelity measures had been used *during* the study, it may have been possible to intervene.

Learning Outcomes

By the end of this case, students should be able to

- Describe the challenges of delivering research interventions with non-research staff
- Describe fidelity measures and when to use them
- List the fidelity measures used in this study
- Recognize the benefits of using fidelity measures throughout a research trial

Project Overview and Context

A global health problem that is growing with our aging population is falls. The incident rate for falls in community-dwelling older adults is 0.65 falls per person-year, and for older adults living in residential aged care (RAC), this increases to 1.7 falls per person-year (Rubenstein, 2006). Dementia is an independent risk factor for falls, and older people living with dementia (PLwD) are twice as likely to fall and sustain an injury than those without dementia (Suttanon et al., 2010). With the growing proportion of RAC residents living with cognitive impairment (Boyd et al., 2011), falls in PLwD in RAC is an area of serious concern in health care. In Aotearoa New Zealand (NZ), physiotherapy is typically only funded for an RAC resident following a doctor or nurse referral; therefore, the opportunity for physiotherapists to deliver falls prevention in RAC is limited.

Cognitive stimulation therapy (CST) is the only evidence-based treatment recommended for people with mild to moderate dementia in the NICE (National Institute for Health and Clinical Excellence, 2006) dementia guidelines based on evidence that it can improve cognition in people with mild to moderate dementia over and above any medication effects (Kim et al., 2017; Woods et al., 2012). The Dementia Care Framework (Ministry of Health, 2013) in NZ recommends CST as one of only two specific treatments considered as good practice for PLwD. To support this recommendation, a 1-day CST program facilitator training was rolled out and CST is now available nationwide delivered by trained facilitators (Cheung & Peri, 2019).

We designed a mixed-methods feasibility randomized controlled trial (RCT) to explore whether falls prevention exercises could be embedded and delivered in the CST program structure to establish feasibility for undertaking a full-scale RCT to test the effectiveness of CogEx, the combined exercise and CST program, in decreasing falls in PLwD. The rationale underpinning this study was that training a preexisting workforce delivering activity programs (activities staff) in RAC to also deliver falls prevention exercises embedded in the CST structure (CogEx) would address a health need without increasing costs. This article focuses on how study outcome measures when triangulated demonstrated fidelity of the CogEx intervention.

Section Summary

- Falls in older adults is a global problem.
- Staff who do not traditionally deliver falls prevention exercise were trained to do so.

Research Design

The research team was multidisciplinary (physiotherapists, doctors, and a nurse) with expertise in falls prevention exercise, CST training and delivery, caring for people with dementia, and running trials in RAC. A pragmatic approach was taken when designing the trial; this approach values real-world practical considerations as much as theoretical concepts, and in this trial, the potential participants and complex environment the program was going to be delivered in were important considerations (Frampton, 2018). The specific objectives of the feasibility study were as follows:

1. To test recruitment strategy, percentage recruited, and the resultant characteristics of PLwD who participate;
2. To test the appropriateness of data collection procedures and the outcome measures;
3. To test combining falls prevention exercise into CST;
4. To test training of CST facilitators to deliver CogEx;
5. To test intervention fidelity of CogEx delivered by facilitators;
6. To explore the facilitators' perceptions of delivering CogEx;
7. To explore the participants' experience of CogEx.

Participants and Setting

The study was conducted at two RAC facilities. The residents invited to take part in this study met the criteria of being 65 years or older, diagnosed with mild to moderate dementia, mobile with or without an assistive device, a Montreal Cognitive Assessment (MoCA) score between 15 and 26 out of 30, able to hear and see well enough to take part in the group discussion, and likely to remain in a group for 1 hr. The inclusion criteria were based on those used in previous CST studies and aimed to be as inclusive as possible of the RAC population in NZ.

Residents gave consent and their next of kin gave assent. Participants were randomized to take part in the CST or CogEx group within their facility. All participants completed baseline and post-intervention assessments.

CogEx Training

Activities staff who had completed the 1-day master class CST training (Cheung & Peri, 2019) were invited by their manager to train and deliver the CogEx program. CogEx was CST (Spector et al., 2006) with aerobic and progressive strength and balance exercises embedded and followed the CST structure of an hour-long group session twice a week for 7 weeks. The falls prevention exercises were designed to challenge and improve balance, be done in standing, and progressed by decreasing hand support. They were progressive in nature incorporating increasing movement amplitude and speeds as well as including basic vestibular exercises. Progressions were based on an individual's ability. A seated option was available for each exercise so that everyone could participate. A CogEx manual was developed and included the program principles, session structure, photos of exercises with instructions and progressions, and a one-page exercise sheet for each session that could be used to plan and record the exercises for each session. Groups of facilitators were trained as their work schedules allowed and this involved theory and practice: working through the manual, doing each exercise and progression, practicing with the interval timer, and doing a 3-min exercise sequence that was part of the program. The trainer (E.B.) was available for ongoing support during the 7 weeks of the program via telephone or email. We had used a similar training structure previously with physiotherapists in an earlier fall prevention trial. Both groups were run to the CST format of 1 hr of group activity run by a facilitator and an assistant, twice a week for 7 weeks (Spector et al., 2006).

Outcome Measures and Data Collection

There was concern within the research team that participants may not be able to transition between activities in the CogEx group. Video was chosen as a tool to observe how participants managed the transitions as well as their engagement with the program in both CogEx and CST groups, that is, were they awake, engaged with the activity or other group members, and so was used to explore the participants' experience of CogEx (Objective 7).

When designing the study, Objective 5 was explicitly regarding fidelity; however, after completion of the study, we realized that only Objectives 1 and 2 did not contribute to measuring fidelity. Therefore, all study outcome measures and forms of data collection by objective are listed below:

- Objective 1: Descriptive statistics to describe the number of residents recruited and group demographics at baseline.
- Objective 2: Pre- and post-intervention clinical measures and change in outcome measures (MoCA, Geriatric Depression Scale–15, Quality of Life: Alzheimer's Disease, Alzheimer's Disease Assessment Scale–Cognitive 11, Brief Balance Evaluation Systems Test, and Short Form Physical Performance Battery). Semi-structured interviews with assessors.

- Objectives 3–5: Length of each class. Record of class content.
- Objective 6: Semi-structured interviews with facilitators. Length of each class.
- Objective 7: Video. Participant semi-structured group feedback immediately following the last group. Class attendance sheets.

Fidelity Measures

Measures used for Objectives 3 to 7 contributed to assessing intervention fidelity and can be categorized as measures of delivery and engagement (Walton et al., 2017). Fidelity measures of delivery were the session content, attendance sheets (intervention records), and the facilitator semi-structured interviews. While video (observation) of sessions was recorded, the intent was to observe how the participants engaged with the exercises and transitioned from one task to another, not to observe the content of the session. Therefore, participant engagement was measured by attendance and focus groups (participant experience; Bartlett et al., 2019).

Section Summary

- A pragmatic approach to study design and intervention delivery was taken to confidently answer the question of feasibility.
- Measures of fidelity are specific to the trial being undertaken.
- Fidelity measures can be categorized, and this study used measures of delivery and engagement.

Research Practicalities

When doing research in a real-life setting, there is a lot that is outside of your control. This is compounded when you only have funding for the blinded assessors and your research relies on goodwill and professional networks and relationships. However, everyone involved in this project had the shared passion of working for the residents. This was not the first study we had conducted within RAC, so the practicalities encountered and reflected on below are a mix of earlier learnings being reinforced as well as some new learnings.

You Are a Guest

The RAC facilities generously hosted the research and were not paid. Both facilities planned to offer CST in their resident activity program and agreed for the groups to be used for research. The day-to-day running of the groups (day, time, location) were decided by the facility with only the group content set by the researchers. Residents who wanted to take part in the research gave informed consent; however, the facilities had an ethos of inclusiveness, so if a resident wanted to participate in an offered activity, they could. This resulted in residents who were not research participants participating in the CST and CogEx groups, and in most cases these residents were excluded from the research due to being wheelchair bound or having a MoCA <10/30.

Your Research Is Not Part of Their Job

Knowing that nobody enjoys paperwork, we designed study forms to be minimal. The attendance sheet was one page and the facilitator had to enter the date, session number, attendees' names, and whether they attended or not. A session sheet for each class (14 in total) was in the manual and the facilitator had to date the sheet and tick which exercises and what level were performed. These forms were all on paper.

How to Use Video

A video camera was set up by the facilitator on a tripod in the corner of the room and remained there for the duration of the trial as it was impractical for the researcher to set up the camera for each class. This also maintained the group dynamic by not introducing another person into the group environment to set up the video camera. The position of the camera was intended to be as unobtrusive as possible.

In a Pragmatic Trial Does Diagnosis Matter?

We learnt that residents may have cognitive impairment or dementia but not be formally assessed and diagnosed if this developed after admission to RAC, as in this environment it would not necessarily change their treatment or management. The study criteria were expanded to include "staff identified cognitive problems" and "self-identified memory problems."

Section Summary

- Funding may dictate what you can control in your study.
- Great relationships with all research stakeholders (participants, staff, host institutions, assessors, etc.) are vital.

Method in Action

After completion of the study during data analysis, we realized how most of the measures contributed to a rich description of fidelity. Below is a discussion of the fidelity measures of delivery and engagement, coupled with our learnings gained with the benefit of hindsight.

The Video

Video was approved by ethics for observing participants in the group. We viewed the 14 group sessions after all had been completed. The camera captured all the participants; however, as they were sat around a table, less than half participants' faces were visible, so it was not possible to view whether everyone was engaged, for example, awake, facial expression, or body language. As we began to search the literature to guide coding the video observations, we realized the "fly on the wall" approach we had taken with a group was not common. Generally, environments are set up for observations with the camera facing participants and whatever task they were undertaking. In hindsight, the "fly on the wall" approach provided invaluable information about the delivery of the class; however, we did not have ethics approval to use the video to observe the facilitators delivering the program. In future studies, we would invite the facilitators to also be study participants and gain ethics approval to use the video as a record of what the facilitators did.

Facilitator Paperwork (Attendance and Session Sheets)

The paperwork was collected after completion of the 14 sessions. One facility had complete paperwork for all CogEx and CST sessions. The other facility kept attendance sheets for 12/14 CogEx sessions and no CST sessions. This was also the facility that did not deliver CogEx after Week 2 or 3 reverting to CST; however, without paperwork, it is not possible to know exactly when the exercises stopped. The completed session sheets demonstrated that 1 min of standing exercise occurred in the 10-min exercise segment with almost all exercises done in sitting.

The attendance and session sheets worked well, when completed. Being able to quantify the dose of standing exercise in minutes is novel in falls prevention research. In hindsight, we would have asked the facilitators to send paperwork to us at the end of each week (i.e., after every two sessions). While this is asking more of the facilitators, that level of program oversight would have enabled us to know what was being delivered and to intervene with support.

Facilitator Interviews

The facilitators that delivered CogEx were honest with their feedback; however, they were not critical. The facilitators perceived no negativity for delivering the exercises predominantly in sitting and were encouraged to explain their choices. Both interviewees were very experienced in delivering activity groups in sitting and this was their strength, being able to engage participants. They were very well versed in erring on the side of safety and comfort as opposed to physiotherapists who are trained to encourage people to work to their limits knowing that challenging balance is important to stimulate physiological change and traditionally deliver falls prevention exercise (Sherrington & Tiedemann, 2015). In hindsight, using a researcher not known by the facilitators to be involved with the program would have created an opportunity for them to feel comfortable to be critical when interviewed; however, they understood that this was a pilot study and that their feedback was vital to refining the program—also the researcher remaining inquisitive/curious in the interview and not judging facilitator choices was crucial for them to express why they did what they did.

The manager of the facility where the CogEx program was stopped asked that her staff were not interviewed as the perception of the facilitators could be that they had failed. This was respected. In hindsight, word choice was crucial; the facilitators had not failed, they had made a choice and it had greatly informed the study. While interviewing the manager was not planned, they offered industry insight that the facilitators did not.

Participant Focus Groups

To accommodate for cognitive impairment, focus groups were held immediately following the last group so that participants knew what the questions related to. Due to the inclusive ethos of the facilities, non-research participants took part in the focus groups rather than being asked to leave. The focus groups were challenging as not everyone could hear and rather than being a group conversation, at one facility it was reduced to asking each participant what they thought. It had been envisaged that from the focus groups, individuals could be selected and asked to give their views in an interview, but with the level of cognitive impairment of participants, this was not pursued. All comments made in the focus group were transcribed and used in the analysis as it was not possible to identify and remove non-participants. In hindsight, we are still unsure of a better way to elicit the thoughts of people with cognitive impairment. While attendance could be a proxy measure of satisfaction, this may not be so when people live in an environment where staff may strongly encourage attendance at activities.

Section Summary

- Apply to the ethics committee for amendments to be able to use data in previously unconsidered ways.
- Consider how data collection tools may have to be tailored to your study population, that is, children and people with cognitive impairment.
- Unplanned observations can inform your thinking—be open to them and take time to reflect.

Practical Lessons Learned

The feasibility study question was answered. It was not feasible to deliver CogEx (falls prevention exercises embedded in CST) in the way originally conceived with the workforce currently delivering CST in NZ. So why was the intervention not delivered how we thought it would be?

The trial design aimed to elicit acceptability of the program to the participants and facilitators and whether falls prevention exercises fitted in the CST structure. It was triangulating the results that provided a rich description of fidelity, but not only the "what" was delivered but a step further to trying to unpack the "why." The analysis of "why" the intervention ran the way it did taught us the following.

Know Your Tribe

We had previously worked in RAC so were comfortable in this environment and felt we knew and understood staff roles well. It was during the interview with the manager that they described there being an industry dynamic in RAC of the activities staff feeling sorry for a person who cannot do something. Staff like everyone to do the same so no one feels left out; so if one person can't do an activity, nobody does it and a different activity is undertaken. In a group exercise environment, this is the complete opposite of how a physiotherapist would tailor an exercise to the individual, so within the group everyone could be working at their own level of capability; this program was set up so that each exercise had different levels of challenge to allow for individual variation. The facilitator interviews also revealed that they understood standing was important but were not comfortable encouraging people to stand. The culture of activities staff is to promote resident engagement, comfort, and safety; they are also highly skilled in delivering group activity in sitting and this is what they reverted to.

Teaching a New Skill or Changing Practice?

With the knowledge gained regarding the industry dynamic, in hindsight 1 hr of training was insufficient to change practice. We could have attend the first two classes to assist the facilitators in on-the-job training and build their confidence with standing exercises, but would the facilitators have stepped back and let us take over if we were present rather than lead the exercises with our support? How much ongoing input is needed to change usual practice significantly? Would a video of the exercise program have enabled the participants to follow along and facilitators to be available to assist people to try a little less hand support? The above options all have cost implications, and the driver for this study was delivering fall prevention programs in RAC without increasing costs.

Maintain Weekly Contact With Facilitators

Collecting the paperwork weekly would have been light touch but have given us oversight of what exercises were being delivered. We could have then responded to the lack of standing exercises and determined how to intervene to encourage the facilitators to deliver the standing exercises. A regular weekly phone call or email from the trainer would have been another light touch way to check the delivery of the program with the facilitator. Neither of these options would have greatly increased program costs. A class visit to do a fidelity check after four sessions could also have been used to start a conversation with the facilitators about the level of exercises being delivered.

Section Summary

- Use fidelity measures during your study so you have oversight of what is being delivered.
- What level of oversight do you need of your study? Be aware that your presence could change the intervention.

Conclusion

The triangulation of multiple fidelity measures provided a rich description of the study intervention, which not only answered the question of feasibility but enabled us to look past the "what" was delivered to reflect on the "why" of delivery. Our learnings from conducting a feasibility study were greatly enhanced through developing objectives that required qualitative and quantitative methods. On reflection, in our pragmatism to run the trial as we envisaged it to be delivered, we lacked oversight of what was being delivered. A light touch measure of fidelity (research paperwork) would have brought to our attention that the intervention was being delivered predominantly in sitting. Measuring fidelity should not necessarily be left to the end of a trial.

For researchers conducting trials in a real-world environment, an understanding of the "why" an intervention was successful or not is critical as the environment is complex and many factors are in play. Therefore, planning to measure fidelity will provide data, which can demonstrate a rich description of "what" and prompt thinking as to the "why." Otherwise, there is a possibility that an intervention could be completely disregarded when in fact only one factor needed changing or conversely one factor is changed when many needed addressing.

Section Summary

- Measuring fidelity during a trial can be beneficial.
- Multiple fidelity measures can be triangulated to give a rich description.
- The "what' and the "why" are equally important.

Classroom Discussion Questions

Classroom Discussion Questions

1. What is a pragmatic clinical trial?
2. What fidelity measures would you use to determine what content of an exercise program was delivered?
3. How would you draw out the thoughts about taking part in an intervention from a person with cognitive impairment?

Funding

The study was funded by Brain Research New Zealand, a government-funded national Centre of Research Excellence.

Declaration of Conflicting Interests

The Authors declare that there is no conflict of interest.

Further Reading

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Appendix N SUp HDEC ethical approval

Health and Disability Ethics Committees

Health and Disability Ethics Committees
Ministry of Health
133 Molesworth Street
PO Box 5013
Wellington
6011

hdecs@health.govt.nz

23 November 2020

Prof Ngaire Kerse
GP&PHC, SoPH
University of Auckland
SOPH, Private Bag 92019,
Ponsonby 1011

Dear Professor Kerse,

Re:	**Ethics ref:**	**18/NTB/151/AM04**
	Study title:	Staying Upright in Residential Care

I am pleased to advise that this amendment has been *approved with non-standard conditions* by the Northern B Health and Disability Ethics Committee. This decision was made through the HDEC Expedited Review pathway.

The main issues considered by the HDEC in giving approval were as follows.

1. Sub-study to explore views of stakeholders on the intervention assessed in the main study

Non-standard conditions:

2. Please ensure participants are given the option of reviewing and correcting interview transcripts.
3. If it is planned that quotes be used in published reports / results, this should be stated in the relevant PISCFs.
4. Please amend the protocol to state how the audio recordings will be managed post transcription.
5. Eliciting the views of adults without consent capacity who have taken part in the programme might also be considered under best interest as respecting their autonomy in so far is possible. Should their views be considered valuable to the sub-study, please amend the protocol and submit a further amendment application

Non-standard conditions must be completed before commencing any changes as a result of this amendment, however they do not need to be submitted to or reviewed by HDEC.

If you would like an acknowledgement of completion of your non-standard conditions you may submit a post approval form amendment through Online Forms. Please clearly identify in the amendment form that the changes relate to non-standard conditions and ensure that supporting documents (if requested) are tracked/highlighted with changes.

CHIEF EXECUTIVE INFORMATION SHEET

Study Title: Understanding context for Staying Upright in Residential Care: a sub study

Ethics Committee Reference:

Locality: AUT University

Lead Investigator: Liz Binns

Contact Number: 09 921 9785

Dear XXX

My name is Liz Binns, I am a Senior Research Officer and PhD candidate at AUT University, responsible for training and supporting the facilitators delivering the intervention groups in the Health Research Council of New Zealand funded Staying UpRight in Residential Care study that <a number of your company's homes> OR <your home> is taking part in.

I would like to invite you, members of your management team, as well as staff and residents (and their family/ whānau) who are participating in the research at <name of care home/s> to take part in a sub study to share your thoughts about falls prevention in Residential Care and how the main study intervention ran within the home/s.

While I am inviting you to take part in this research, I am also asking for your permission to invite the homes mentioned above to participate however, taking part in this study is their choice.

The findings of this research may be used for academic publications and presentations. This study will also be one of a number contributing to my PhD.

The other people involved in this study are: Dr John Parsons, Dr Lynne Taylor, Dr Denise Taylor (all physiotherapists interested in residential aged care) and Dr Kathy Peri (academic nurse researcher interested in gerontology).

This information sheet tells:

- why we are doing the study, what taking part would involve for yourself, staff and residents
- what the benefits and risks might be, and what will happen at the end of the study

You will be given a copy of both this information sheet and consent form to keep.

This document is 6 pages long. Please read this information sheet. It is important that you understand all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

The Staying Upright in Residential Care study is evaluating 2 exercise programmes to see how they strengthen, improve function, and prevent falls in people living in residential aged care using physical measures. This sub study looks to capture the opinions of people involved in the study through all levels of the business, residents and their family/ whānau.

The findings from the sub study will give context to the main study findings as well as identifying barriers and facilitators, opportunities for improvement and refinements required if the classes were to be made widely available. The host institution for the sub study is AUT University with researchers from the University of Auckland also.

Please contact Liz Binns 09 921 9785 if you have any questions.

This study has been approved as an amendment to the main study by The Health and Disabilities Ethics Committee, Reference Number: 18/NTB/151/AM04.

WHAT WILL PARTICIPATION IN THE STUDY INVOLVE?

A researcher will interview yourself and your staff (Clinical Director/Operations Manager, Care Home Manager, Clinical Leader) individually either at work or via zoom. The interview will be no longer than an hour. Indicative questions will be sent with the participant information sheet as the topics covered differ slightly depending on the role of staff in the organisation. Following the interview, you will be sent a copy of the transcription to review. At this point you can correct any errors or delete any part you would like to withdraw. If possible, we ask if the review can be completed within 2 weeks.

Facilitators of the exercise groups will be invited to take part in a focus group facilitated by a researcher either at the workplace or via zoom. The focus group will be no longer than an hour. Similarly, the residents will be invited to take part in focus group immediately following one of the research exercise classes.

Residents in the focus group will be asked if they give consent for the family/ whānau to be contacted and invited to be interviewed about their thoughts about the research exercise classes.

Interviews and focus groups will be audio recorded and transcribed verbatim however any identifying information (e.g. people's names, the name of the home) will be removed prior to analysis.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

The benefit to participating in the study is the opportunity to give your opinion regarding falls prevention in residential aged care and how service delivery can be optimised. Similarly, for your staff and residents it is an opportunity to share their opinion with the researchers regarding the research exercise classes. The wider benefit to the community is if the research exercise classes are made widely available they would have been refined following the research.

The risks in taking part in this study are small. The organisation, staff and care homes taking part will be confidential to the research team. Quotes from your interview may be used in published reports/ results but will be deidentified and, no names or identifiers will be used in publications or presentations. However, given the small size of the residential aged care in Aotearoa New Zealand it is possible that others may guess your organisation's involvement therefore only limited confidentiality is possible.

WHAT COSTS ARE ASSOCIATED WITH THE STUDY?

The only cost associated with the study is time. Staff interviews will take up to an hour, as will the facilitator and resident focus groups. Transcript revision may take up to 30 minutes. Interviews will be in the workplace or via zoom and so there is no travel cost/time.

WHAT ARE MY RIGHTS?

Taking part in this study is voluntary for you, your organisation, staff and residents.

Your participation in this research is your choice and whether or not you choose to participate will neither advantage nor disadvantage you. You are able to withdraw from the study at any time. If you choose to withdraw from the study, then you will be offered the choice between having any data that is identifiable as belonging to you removed or allowing it to continue to be used. However, once the findings have been produced, removal of your data may not be possible.

All the information collected will be kept confidential, organization and individual's details and any identifying information will be removed, and only the researchers will look at the information collected. A professional transcriber may be used and they will be asked to sign a confidentiality agreement.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

The sub study data will be stored in a locked cabinet at AUT University throughout the duration of the study and all computer files and e-records about the study are password protected. At the end of the study the data will be stored in a secure place in the Physiotherapy Department at AUT University. It will be kept for 6 years and then destroyed.

A summary of the study findings will be presented back at a public meeting within 2 years of completion of the study and articles in health journals and books will be written about the study.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Liz Binns, liz.binns@aut.ac.nz 09 921 9785

John Parsons, j.parsons@auckland.ac.nz 09 373 7999

Denise Taylor, denise.taylor@aut.ac.nz 09 921 9680

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050

Fax: 0800 2 SUPPORT (0800 2787 7678)

Email: advocacy@hdc.org.nz

You can also contact the Health and Disability Ethics Committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS

Email: hdecs@moh.govt.nz

GROUP FACILITATORS INFORMATION SHEET

Study Title: Understanding context for Staying Upright in Residential Care: a sub study

Ethics Committee Reference:

Locality: AUT University

Lead Investigator: Liz Binns

Contact Number: 09 921 9785

Hello

My name is Liz Binns, I am a Senior Research Officer and PhD candidate at AUT University, responsible for training and supporting the facilitators delivering the intervention groups in the Health Research Council of New Zealand funded Staying UpRight in Residential Care study your care home is taking part in.

I would like to invite you as one of the research exercise group facilitators in the Staying UpRight study to take part in a sub study to share your thoughts about falls prevention in Residential Care and the main study exercise classes.

The Care Home Manager has given permission for staff and residents to be invited to take part in this research, however, taking part in this study is your choice.

The findings of this research may be used for academic publications and presentations. This study will also be one of a number contributing to my PhD.

The other people involved in this study are: Dr John Parsons, Dr Lynne Taylor, Dr Denise Taylor (all physiotherapists interested in residential aged care) and Dr Kathy Peri (academic nurse researcher interested in gerontology).

This information sheet tells:

- why we are doing the study and what taking part would involve
- what the benefits and risks might be, and what will happen at the end of the study

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This document is 6 pages long. Please read this information sheet. It is important that you understand all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

The Staying Upright in Residential Care study is evaluating 2 exercise programmes to see how they strengthen, improve function, and prevent falls in people living in residential aged care using physical measures. This sub study looks to capture the opinions of people involved in the study through all levels of the organisation, residents and their family/ whānau.

The findings from the sub study will give context to the main study findings as well as identifying barriers and facilitators, opportunities for improvement and refinements required if the classes were to be made widely available. The host institution for the sub study is AUT University with researchers from the University of Auckland also.

Please contact Liz Binns 09 921 9785 if you have any questions.

This study has been approved as an amendment to the main study by The Health and Disabilities Ethics Committee, Reference Number: 18/NTB/151/AM04.

WHAT WILL PARTICIPATION IN THE STUDY INVOLVE?

Facilitators of the exercise groups are invited to take part in a focus group facilitated by a researcher not involved with the exercise classes either at the workplace or via zoom. A focus group is a group of people discussing topics. The number of facilitators taking part in the focus group will vary according to availability, but it is likely that facilitators from other homes will be in the same focus group. The focus group will be no longer than an hour. Similarly, the residents will be invited to take part in focus group immediately following one of the research exercise classes.

Focus groups will be audio recorded and transcribed verbatim however any identifying information (e.g. people's names, the name of the home) will be removed prior to analysis.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

The benefit to participating in the study is the opportunity to give your opinion regarding falls prevention in residential aged care and how service delivery can be optimised and to share your opinion with the researchers regarding the research exercise classes. The wider benefit to the community if the classes are made widely available will be refinement following the research.

The risks in taking part in this study are small. The organisation, staff and care homes taking part will be confidential to the research team. Quotes from the focus group may be used in published reports/ results but will be deidentified and, no names or identifiers will be used in publications or presentations. However, given the small size of the residential aged care in Aotearoa New Zealand it is possible that others may guess your care home's involvement therefore only limited confidentiality is possible.

WHAT COSTS ARE ASSOCIATED WITH THE STUDY?

The only cost associated with the study is time. Facilitator focus groups will take up to an hour and as they will be in the workplace or via zoom there is no travel cost/time.

WHAT ARE MY RIGHTS?

Your participation in this research is voluntary (it is your choice) and whether or not you choose to participate will neither advantage nor disadvantage you. You are able to withdraw from the study at any time. If you choose to withdraw from the study, then you will be offered the choice between having any data that is identifiable as belonging to you removed or allowing it to continue to be used. It may not be possible to destroy all records of the focus group discussion of which you were part of and once the findings have been produced, removal of your data may not be possible.

All the information collected will be kept confidential, organisation and individual's details and any identifying information will be removed, and only the researchers will look at the information collected. A professional transcriber may be used and they will be asked to sign a confidentiality agreement.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

The sub study data will be stored in a locked cabinet at AUT University throughout the duration of the study and all computer files and e-records about the study are password protected. At the end of the study the data will be stored in a secure place in the Physiotherapy Department at AUT University. It will be kept for 6 years and then destroyed.

A summary of the study findings will be presented back at a public meeting within 2 years of completion of the study and articles in health journals and books will be written about the study.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Liz Binns, liz.binns@aut.ac.nz 09 921 9785

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Denise Taylor, denise.taylor@aut.ac.nz 09 921 9680

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You can also contact the Health and Disability Ethics Committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS

Email: hdecs@moh.govt.nz

CARE HOME MANAGER INFORMATION SHEET

Study Title: Understanding Context for Staying Upright in Residential Care: a sub study

Ethics Committee Reference:

Locality: AUT University

Lead Investigator: Liz Binns

Contact Number: 09 921 9785

Dear XXX

My name is Liz Binns, I am a Senior Research Officer and PhD candidate at AUT University, responsible for training and supporting the facilitators delivering the intervention groups in the Health Research Council of New Zealand funded Staying UpRight in Residential Care study that your care home is taking part in.

I would like to invite you, members of your staff and residents (and their family/ whānau) who are participating in the research to take part in a sub study to share your thoughts about falls prevention in Residential Care and how the main study intervention ran within the home.

The CEO has given permission for staff and residents to be invited to take part in this research, however, you and the home you manage taking part in this study is your choice.

While I am inviting you to take part in this research, I am also asking for your permission to invite the staff and residents (and their family/ whānau) mentioned above to participate however, taking part in this study is their choice.

The findings of this research may be used for academic publications and presentations. This study will also be one of a number contributing to my PhD.

The other people involved in this study are: Dr John Parsons, Dr Lynne Taylor, Dr Denise Taylor (all physiotherapists interested in residential aged care) and Dr Kathy Peri (academic nurse researcher interested in gerontology).

This information sheet tells:

- why we are doing the study, what taking part would involve for yourself, staff and residents
- what the benefits and risks might be, and what will happen at the end of the study

You will be given a copy of both this information sheet and consent form to keep.

This document is 6 pages long. Please read this information sheet. It is important that you understand all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

The Staying Upright in Residential Care study is evaluating 2 exercise programmes to see how they strengthen, improve function, and prevent falls in people living in residential aged care using physical measures. This sub study looks to capture the opinions of people involved in the study through all levels of the organisation, residents and their family/ whanau.

The findings from the sub study will give context to the main study findings as well as identifying barriers and facilitators, opportunities for improvement and refinements required if the classes were to be made widely available. The host institution for the sub study is AUT University with researchers from the University of Auckland also.

Please contact Liz Binns 09 921 9785 if you have any questions.

This study has been approved as an amendment to the main study by The Health and Disabilities Ethics Committee, Reference Number: 18/NTB/151/AM04.

WHAT WILL PARTICIPATION IN THE STUDY INVOLVE?

A researcher will interview yourself and your Clinical Leader (with their consent) individually either at work or via zoom. The interview will be no longer than an hour. Indicative questions accompany this information sheet so you know the topics that will be asked to share your opinions on. Following the interview, you will be sent a copy of the transcription to review. At this point you can correct any errors or delete any part you would like to withdraw. If possible, we ask if the review can be completed within 2 weeks.

Facilitators of the exercise groups will be invited to take part in a focus group facilitated by a researcher either at the workplace or via zoom. The focus group will be no longer than an hour. Similarly, the residents will be invited to take part in focus group immediately following one of the research exercise classes.

Residents in the focus group will be asked if they give consent for the family/ whanau to be contacted and invited to be interviewed about their thoughts about the research exercise classes.

Interviews and focus groups will be audio recorded and transcribed verbatim however any identifying information (e.g. people's names, the name of the home) will be removed prior to analysis.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

The benefit to participating in the study is the opportunity to give your opinion regarding falls prevention in residential aged care and how service delivery can be optimised. Similarly, for your staff and residents it is an opportunity to share their opinion with the researchers regarding the research exercise classes. The wider benefit to the community is if the research exercise classes are made widely available they would have been refined following the research.

The risks in taking part in this study are small. The organisation, staff and care homes taking part will be confidential to the research team. Quotes from your interview may be used in published reports/ results but will be deidentified and no names or identifiers will be used in publications or presentations.

However, given the small size of the residential aged care in Aotearoa New Zealand it is possible that others may guess your care home's involvement therefore only limited confidentiality is possible.

WHAT COSTS ARE ASSOCIATED WITH THE STUDY?

The only cost associated with the study is time. The interview will take up to an hour, as will the facilitator and resident focus groups. Transcript revision may take up to 30 minutes. Interviews will be in the workplace or via zoom and so there is no travel cost/time.

WHAT ARE MY RIGHTS?

Taking part in this study is voluntary for you, your care home, staff and residents.

Your participation in this research is your choice and whether or not you choose to participate will neither advantage nor disadvantage you. You are able to withdraw from the study at any time. If you choose to withdraw from the study, then you will be offered the choice between having any data that is identifiable as belonging to you removed or allowing it to continue to be used. However, once the findings have been produced, removal of your data may not be possible.

All the information collected will be kept confidential, organisation and individual's details and any identifying information will be removed, and only the researchers will look at the information collected. A professional transcriber may be used and they will be asked to sign a confidentiality agreement.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

The sub study data will be stored in a locked cabinet at AUT University throughout the duration of the study and all computer files and e-records about the study are password protected. At the end of the study the data will be stored in a secure place in the Physiotherapy Department at AUT University. It will be kept for 6 years and then destroyed.

A summary of the study findings will be presented back at a public meeting within 2 years of completion of the study and articles in health journals and books will be written about the study.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact:

Liz Binns, liz.binns@aut.ac.nz 09 921 9785

John Parsons, j.parsons@auckland.ac.nz 09 373 7999

Denise Taylor, denise.taylor@aut.ac.nz 09 921 9680

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

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Email: advocacy@hdc.org.nz

You can also contact the Health and Disability Ethics Committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS

Email: hdecs@moh.govt.nz

Permission form for Chief Executive/Clinical Director

Study Title: Understanding context for Staying Upright in Residential Care: a sub study

Sub study Project Lead: Liz Binns

Team: Dr John Parsons, Dr Denise Taylor, Dr Kathy Peri, Dr Lynne Taylor

5 November 2020

I have read and I understand the Information Sheet.	☐
I understand that this organisation, care homes and staff taking part in this study is voluntary and that I may withdraw them from the study at any time without this affecting any care to residents.	☐
I understand that participation in this study is confidential and that no material, which could identify this organisation or staff personally, will be used in any reports on this study.	☐
I know who to contact if I have any questions about the study.	☐
I understand the responsibilities of study participation.	☐

Please tick to indicate you give permission to the following

I give permission for staff to be invited to take part in interviews	Yes ☐	No ☐
I wish to receive a summary of the results from the study.	Yes ☐	No ☐

Declaration by management:

I hereby give permission for this rest home and staff facilitating this study.

Organisation's name:

Chief Executive's/Clinical Director's name:

Signature: Date:

Declaration by researcher:

I state that I have fully explained the study and the Chief Executive has the capacity to give informed consent.

Researcher's name:

Signature: Date:

Approved by the Health and Disability Ethics Committee (HDEC) on 23 November 2020, HDEC Reference number 18/NTB/151/AM04

Permission form for care home management

Study Title: Understanding context for Staying Upright in Residential Care: a sub study

Sub study Project Lead: Liz Binns

Team: Dr John Parsons, Dr Denise Taylor, Dr Kathy Peri, Dr Lynne Taylor

5 November 2020

I have read and I understand the Information Sheet.	☐
I understand that this care home and staff taking part in this study is voluntary and that I may withdraw the care home from the study at any time without this affecting any care to residents.	☐
I understand that participation in this study is confidential and that no material, which could identify this care home or staff personally, will be used in any reports on this study.	☐
I know who to contact if I have any questions about the study.	☐
I understand the responsibilities of study participation.	☐

Please tick to indicate you give permission to the following

I give permission for staff facilitating study exercise groups to be invited to take part in a focus group.	Yes ☐	No ☐
I wish to receive a summary of the study results.	Yes ☐	No ☐
I give permission to the research team to invite residents participating in the main study to take part in a focus group	Yes ☐	No ☐
With permission of the residents I will give researchers access to next of kin contact details.	Yes ☐	No ☐

Declaration by management:

I hereby give permission for this care home and staff participating in this sub study of the Staying UpRight in Residential aged care trial.

Care home name:

Manager's name

Signature: Date:

Declaration by researcher:

I state that I have fully explained the study and the manager has the capacity to give informed consent.

Researcher's name:

Signature: Date:

Approved by the Health and Disability Ethics Committee (HDEC) on 23 November 2020, HDEC Reference number 18/NTB/151/AM04

Consent form for Chief Executive/Management

Study Title: Understanding context for Staying Upright in Residential Care: a sub study

Sub study Project Lead: Liz Binns

Team: Dr John Parsons, Dr Denise Taylor, Dr Kathy Peri, Dr Lynne Taylor

5 November 2020

I have read and I understand the Participant Information Sheet.	☐
I have been given sufficient time to consider whether or not to participate in this study.	☐
I have had the opportunity to use a legal representative, whānau/ family support or a friend to help me ask questions and understand the study.	☐
I am satisfied with the answers I have been given regarding the study and I have a copy of this form and information sheet.	☐
I understand that notes will be taken during the interview and it will also be audio-taped and transcribed.	☐
I understand that if I withdraw from the study then I will be offered the choice between having any data that is identifiable as belonging to me removed or allowing it to continue to be used.	☐

However, once the findings have been produced, removal of my data may not be possible.	
I understand that participation in this study is confidential and that no material, which could identify me, this organisation, the care homes or staff personally, will be used in any reports on this study.	☐
I know who to contact if I have any questions about the study in general.	☐
I understand the responsibilities of study participation.	☐

Please tick to indicate you consent to the following

I consent to taking part in an interview.	Yes ☐	No ☐
I wish to receive a summary of the results from the study.	Yes ☐	No ☐

Declaration by management:

I hereby consent to participate in this study.

Organisation name:

Chief Executive's name

Signature:	Date:

Declaration by researcher:

I state that I have fully explained the study and the manager has the capacity to give informed consent.

Researcher's name:

Signature: Date:

Approved by the Health and Disability Ethics Committee (HDEC) on 23 November 2020, HDEC Reference number 18/NTB/151/AM04

Consent form for care home management

Study Title: Understanding context for Staying Upright in Residential Care: a sub study

Sub study Project Lead: Liz Binns

Team: Dr John Parsons, Dr Denise Taylor, Dr Kathy Peri, Dr Lynne Taylor

5 November 2020

I have read and I understand the Participant Information Sheet.	☐
I have been given sufficient time to consider whether or not to participate in this study.	☐
I have had the opportunity to use a legal representative, whānau/ family support or a friend to help me ask questions and understand the study.	☐
I am satisfied with the answers I have been given regarding the study and I have a copy of this form and information sheet.	☐
I understand that notes will be taken during the interview and it will also be audio-taped and transcribed.	☐
I understand that if I withdraw from the study then I will be offered the choice between having any data that is identifiable as belonging to me removed or allowing it to continue to be used.	☐

However, once the findings have been produced, removal of my data may not be possible.	
I understand that participation in this study is confidential and that no material, which could identify me, this care home or staff personally, will be used in any reports on this study.	☐
I know who to contact if I have any questions about the study in general.	☐
I understand the responsibilities of study participation.	☐

Please tick to indicate you consent to the following

I consent to taking part in an interview.	Yes ☐	No ☐
I wish to receive a summary of the results from the study.	Yes ☐	No ☐

Declaration by management:

I hereby consent to participate in this study.

Care home name:

Manager’s name

Signature:	Date:

Declaration by researcher:

I state that I have fully explained the study and the manager has the capacity to give informed consent.

Researcher's name:

Signature: Date:

Approved by the Health and Disability Ethics Committee (HDEC) on 23 November 2020, HDEC Reference number 18/NTB/151/AM04

Consent form for participants who are exercise group facilitators:

Study Title: Understanding context for Staying Upright in Residential Care: a sub study

Sub study Project Lead: Liz Binns

Team: Dr John Parsons, Dr Denise Taylor, Dr Kathy Peri, Dr Lynne Taylor

5 November 2020

I have read and I understand the Participant Information Sheet.	☐
I have been given sufficient time to consider whether or not to participate in this study.	☐
I have had the opportunity to use a legal representative, whānau/ family support or a friend to help me ask questions and understand the study.	☐
I am satisfied with the answers I have been given regarding the study and I have a copy of this form and information sheet.	☐
I understand that taking part in this study is voluntary and that I may withdraw from the study at any time without this affecting my work.	☐
I understand that notes will be taken during the focus group and it will also be audio-taped and transcribed.	

I understand that if I withdraw from the study then, while it may not be possible to destroy all records of the focus group, I will be offered the choice between having any data that is identifiable as belonging to me removed or allowing it to continue to be used. However, once the findings have been produced, removal of my data may not be possible	☐
I understand that identity of my fellow participants and our discussions in the focus group is confidential to the group and I agree to keep this information confidential.	☐
I understand that participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.	☐
I know who to contact if I have any questions about the study general.	☐
I understand the responsibilities of study participation.	☐

Please tick to indicate you consent to the following

I consent to participate in the study focus group	Yes ☐	No ☐
I wish to receive a summary of the results from the study.	Yes ☐	No ☐

Declaration by facilitator:

I hereby consent to participate in this study.

Participants name:

Signature: Date:

Declaration by researcher:

I state that I have fully explained the study and the facilitator has the capacity to give informed consent.

Researchers name:

Signature: Date:

Approved by the Health and Disability Ethics Committee (HDEC) on 23 November 2020, HDEC Reference number 18/NTB/151/AM04

Confidentiality agreement

Study Title: Understanding context for Staying Upright in Residential Care: a sub study

Sub study Project Lead: Liz Binns

Team: Dr John Parsons, Dr Denise Taylor, Dr Kathy Peri, Dr Lynne Taylor

5 November 2020

- ○ I understand that all the material I will be asked to transcribe is confidential.
- ○ I understand that the contents of the tapes or recordings can only be discussed with the researchers.
- ○ I will not keep any copies of the transcripts nor allow third parties access to them.

Transcriber's signature...

Transcriber's name...

Transcriber's Contact Details (if appropriate):

....

....

....

....

Date:

Note: The Transcriber should retain a copy of this form.

Approved by the Health and Disability Ethics Committee (HDEC) on

23 November 2020, HDEC Reference number **18/NTB/AM04**

Appendix X SUp published manuscript

Binns *et al. BMC Geriatrics* (2023) 23:14
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BMC Geriatrics

RESEARCH **Open Access**

"It's all about the money": an interpretive description of embedding physical therapy-led falls prevention group exercise in long-term care

Elizabeth Binns[1,2*], Felicity Bright[1,3], John Parsons[4,5], Kathy Peri[4], Lynne Taylor[6], Ngaire Kerse[6] and Denise Taylor[2,7]

Abstract

Background Falls prevention interventions are effective for community dwelling older adults however, the same cannot be said for older adults living in long-term care (LTC). The Staying UpRight (SUp) randomized controlled trial was designed to test the effectiveness of a progressive strength and balance group exercise program delivered to LTC residents. This paper explores the factors impacting LTC providers' decisions to continue the program on completion of the funded trial period.

Methods A qualitative study using an Interpretive Description approach. Semi-structured interviews and focus groups were conducted with 15 LTC staff involved in the randomized controlled trial. Data were analysed using conventional content analysis.

Results Practice change occurred following participation in the trial with some facilities starting exercise groups, some increasing the number of exercise groups offered and physical therapists selecting elements of the program to adopt into their practice. Decisions about continuing with SUp as designed were constrained by organizational decisions regarding funding and resources. Three factors were identified which informed decision-making: business models and philosophies, requirements for evidence, and valuing physical therapy.

Conclusions Managers and facilitators adapted SUp by selecting and delivering components of the program in response to the changes they had observed in participating residents. However, our findings highlight that while SUp was valued, the tight financial environment created by the current funding model in New Zealand did not support funding physical therapist delivered falls prevention exercise programs in LTC. This study may provide policy makers with important information on changes needed to support falls prevention service delivery in LTC.

Trial registration This study is a sub-study of a randomized controlled trial which was registered to the Australian New Zealand Clinical Trials Registry ACTRN12618001827224 on 09/11/2018. Universal trial number U1111-1217-7148.

Keywords Falls prevention, Older adults, Long-term care, Qualitative research

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Background

The fall rate for older adults living in long-term care (LTC) is higher than community dwelling older adults [1, 2], which is a reflection of residents' high levels of physical frailty and disability; both high risk factors for falls [3]. The LTC environment may compound physical impairment through staff limiting the physical activity of residents they consider to be fall-prone or considering 'walking' to be the domain of physical therapists, leading to increased sedentary behaviour and lower limb muscle weakness in residents [4, 5].

To be admitted into LTC, an older adult is assessed as no longer able to live independently at home [6]. The International Resident Assessment Instrument (interRAI) Home Care is a mandated component of this assessment and determines what level of care is needed [7]. A national contract (Age-Related Residential Care Services Agreement [8]) between the national health authority (New Zealand Ministry of Health) and LTC facilities defines the Government funded care services provided to a resident. Services covered by the agreement include an individualized care plan based on the interRAI LTC facilities assessment. The agreement specifies a facility must have a falls prevention policy and assess, prevent and manage falls however, it does not require that there is physical therapy input into falls prevention [9, 10].

The Staying UpRight (SUp) falls prevention exercise program was developed to address the fall risk factors of decreased lower limb strength and impaired balance in older adults living in LTC. The program was informed by clinical experience, previous falls prevention research, and an understanding of the physiological systems of balance and principles of rehabilitation (task specificity, progression and overload) [11–14]. The SUp exercise program (intervention) was delivered by physical therapists and the dose matched chair exercise program, Flex and Stretch (control), was delivered by LTC activities staff. A pilot study found improvements in physical function, no adverse events, and that the program was acceptable to participants and staff [15].

There is limited evidence regarding the sustainability of falls prevention programs in LTC. There is a lack of evidence from the experience of different levels of staff within the same LTC facility (senior management, onsite management, and frontline staff) examining the sustainability of falls prevention interventions. The field of implementation science currently focusses more on the initial uptake of evidence-based practice rather than whether it is sustained. This means we lack an understanding of what happens over time [16]. The limited evidence from community falls prevention programs suggests that health practitioners experience personal and interpersonal influences, clinical barriers and limitations of research evidence as barriers to implementation [17]. At an organizational level funding has been identified as a critical factor for sustainability [18].

This paper reports a qualitative study completed as part of an effectiveness-implementation hybrid type 1 study [19]. This study ran alongside the Staying UpRight (SUp) randomized controlled trial (RCT) which assessed the effectiveness of a 12-month strength and balance group exercise program compared with a control program (Flex and Stretch) [20]. The RCT findings will be published separately. Qualitative studies are the most common design used to evaluate sustainability of evidence-based interventions [21]. Our qualitative study explored what factors influenced the maintenance of SUp as usual practice. In this paper, we report the perspectives of managerial and clinical LTC staff.

Methods

Study design

This study utilises an Interpretive Description (ID) [22] methodology. This qualitative approach seeks to provide insight into practice-oriented issues and generate findings which could be applied in practice settings. The study is reported in accordance with the Standards for Reporting Qualitative Research [23]. Ethical approval was given by the New Zealand (NZ) Health and Disability Ethics Committee (HDEC) (18/NTB/151/AM04). This study is a sub-study of the RCT which was registered to the Australian New Zealand Clinical Trials Registry ACTRN12618001827224 on 09/11/2018. Universal trial number U1111-1217-7148.

Sampling and recruitment

Three NZ LTC organizations involved in the RCT were purposively sampled, seeking variation across business structure: one publicly listed ('for-profit') company, one private company ('for-profit') and one charitable organization (charity). Grouping facilities by organization enabled exploration of whether organizational influence impacted SUp being embedded in facilities. The sample were staff from the three organizations. Once organization consent was gained, researchers sampled for maximum diversity in participants by job role: senior management, onsite management and clinical staff. Eligible staff were emailed an invitation to participate by researchers. All participants gave written informed consent. All methods were carried out in accordance with relevant guidelines and regulations.

Data collection

Interviews and focus groups took place between April and August 2021 in person or via Zoom. Two experienced qualitative researchers (JP and KP) who were not involved in the trial conducted the interviews and focus groups. Interviews were conducted with senior management and onsite management staff. These allowed for detailed exploration of organizational contexts and discussion of commercially sensitive information. Focus groups were held with exercise group facilitators to allow exploration of a breadth of experiences and explore similarities and differences across practice settings. Separate focus groups were held specific to the exercise group (SUp and Flex and Stretch). One physical therapist had an individual interview as no other therapists attended the planned focus group. Three unplanned focus groups occurred when management and clinical staff at the same facility chose to be interviewed together. Questions followed an interview guide informed by Curran [19], supplemented with follow up questions and prompts to deeply explore participant experiences (Additional file 1). In response to low facilitator participation and COVID lockdowns, an amendment was approved by HDEC on 23 September 2021 (ref 2021 AM 7851), to use facilitator emails sent during the RCT that discussed the classes, as data.

Data analysis

Interviews and focus groups were recorded and transcribed. Transcripts and high-level summaries were sent back to participants for confirmation of accuracy and meaning intent [24]. De-identified transcripts were organised and coded in NVivo, release 1.0 (QSR International, Melbourne, Australia) [25]. We used conventional content analysis and followed the steps of listening to the recordings, reading, re-reading, coding individual transcripts, and refining codes as data analysis progressed. These were defined within a codebook. We worked across multiple transcripts and inductively formed categories [26]. Emails were also organised and coded in NVivo. Conventional content analysis was used and followed the steps of reading and re-reading, coding with codes generated from the interview and focus groups analysis and further code development. Once coded, initial themes were generated by category handling, specifically, writing themes on paper and manually arranging them [27]. These were represented in a concept map for final discussion between research team members [28]. Direct quotes were used to illustrate points made to ensure confirmability. Maximum variation sampling enabled data triangulation of interviews with multiple participants and constant comparison was used to ensure not privileging one account over another.

To aid rigour, a reflexive approach was taken throughout the analysis process to acknowledge the researcher's professional training, clinical experience, previous research, and role in developing the RCT exercise programs. The involvement of independent interviewers and co-authors with methodological expertise added rigour, as did processes such as negative case analysis, triangulation, journaling and constant reference to raw data.

Results

Fifteen people took part (Table 1). Five interviews were held, lasting between 15 and 34 minutes and five focus groups, lasting between 19 and 41 minutes. Twenty-four facilitators ($n=19$ SUp facilitators and $n=5$ Stretch and Flex facilitators) gave retrospective consent for their emails to be included in the data analysis. Quotes are reported with a participant identifier; SM (senior management), Mgmt (onsite management) and FAC (exercise group facilitator).

The decision-making of management staff was key in embedding falls prevention in organizations. The decisions made regarding use of resource and funding influenced what types of falls prevention approaches were used and who they were delivered by. Decision-making regarding how individual programs were delivered

Table 1 Characteristics of the interview and focus group participants ($n=15$)

Characteristics	n (%)
Gender	
Male	1 (7)
Female	14 (93)
Role	
Senior Management	4 (27)
Onsite Management	5 (33)
Staying UpRight Facilitator (physical therapist)	4 (27)
Flex and Stretch Facilitator	2 (13)
Professional background	
Nurse	8 (53)
Physical Therapist	6 (40)
- facility Employee (NZ registered)	1
- facility Employee (overseas trained, not NZ registered)	2
- contractor (NZ registered)	3
Unknown	1 (7)
Years working in LTC	
<5	3 (20)
5-10	6 (40)
10+	5 (33)
Unknown	1 (1)

Table 2 Summary of findings

Themes	Sub-themes
Business models and philosophies	Driven for profit versus being driven by care No specified model of care
Requirements for evidence	Knowledge of results required for financial investment Anecdotal evidence informed practice change
Valuing physical therapy	The invisible skillset Time equals money and money equals time

happened at clinician level – the activities co-ordinator or physical therapist. Decision-making appeared to be informed by several factors: business models and philosophies, requirements for evidence, and valuing the contribution of physical therapy. Table 2 illustrates the main factors and subtopics that emerged from the interview, focus group and email data.

The influence of business models and philosophies on embedding SUp

An organization's ability and, perhaps more significantly, willingness to embed SUp as a sustained usual care program appeared to be informed by their business model and philosophy.

Being driven by the need to generate a profit versus being driven to provide care

For-profit organizations needed to make a profit for shareholders and required their facilities to be "fiscally responsible" (SM#2). Government funding was considered insufficient, with one senior management participant saying: "the amount we get per day doesn't look after the residents right now" (SM#1). Some facilities were not financially viable. Organizations used profits from the sale of independent units co-located in the retirement village (self-care apartments and villas) for facility operational costs however, doing so decreased organization profits. One senior management participant observed that "...unless the government recognises (the shortfall), there's gonna be a lot of providers go out of business. Particularly those that don't have villages. [to embed SUp in practice] We would have to actually think about how we funded it in the tight environment that we're in at the moment". In this financial context, physical therapist delivery of SUp was perceived as a cost. This brought tensions. Whilst valued for being "resident focused and quality of life focused" (SM#1), delivery of SUp was balanced against organizational finances, with participants saying "we have to be able to afford them [SUp classes] and not go down the gurgler" (SM#1) and "I would absolutely love to have something like this (SUp) in, but it's the matter of the money" (SM#2). Another senior management participant discussed weighing up the increase of a resident's wellbeing against their length of stay in a facility to determine the return on investment in SUp, "should it be an investment that we make to ensure that our rest home level care residents are more well? But then do we get them all well and they go home? (laughter) That's one side of the coin, but the other side of it is, get them all well and more mobile so that their quality of life is better and they live longer in a lovely environment with us" (SM#3). This comment was immediately followed by an expression discomfort about basing a decision to improve a person's quality of life on financial gain, "[it] sounds pretty horrible" (SM#3).

In contrast to the for-profit organizations, the charity LTC organization received government and charitable funding. The charity required only that the organization provide care for those in need. This saw the organization foreground the well-being of residents alongside prudent financial management. Business decision-making was guided by principles of "promoting well-being" (Mgmt#5) and feedback gathered through surveys and resident focus groups. This created an environment where management did not feel financially constrained and could approach the Board for new initiative funding. The Board's view on the positive contribution made by physical therapy to resident's wellbeing was well known. The management participant reflected on the possibility of continuing SUp as designed if it was found to be effective, "is there a really good argument now to actually increase physio not just hold status quo" (Mgmt#5).

The for-profit organizations drive for profitability meant management had an acute awareness of cost. This led to tight budgeting which constrained the uptake of any new initiatives in the absence of specific funding. The charity organization's drive for resident well-being led to regular review of service delivery. Services were updated as part of business as usual to deliver better resident outcomes. The charity, in contrast to the for-profit organizations, had a mechanism for management to gain financial support for new initiatives if needed.

No model of care specified to determine the delivery of care

The NZ Government service specifications outline *what* is to be delivered in LTC but not *how* it should be delivered. Whilst a falls prevention policy was a requirement, the assessment and management of falls was determined by the LTC facility. This included to what extent physical therapy was involved.

Organizations were acutely aware of the NZ Government service specifications and what they were paid to provide. They also knew that the configuration and delivery of services were not dictated by the Government. A senior management participant quoted the service specification almost word for word, "there's a responsibility to ensure that older people remain active and have access to doing active things...there's not a specific model of care, if you like. And so the variation in the sector, not just for [organization name] but for everyone, is significant" (SM#1). Management participants knew that physical therapy was not in the service specifications. Most facilities had access to physical therapy however, this was variable within and across organizations, "physio is a bit of a challenge in the aged care sector and for us particularly it's quite variable. So it is something that I think has more, has value, but there isn't a really clear program of how physios would actually interface with aged care" (SM#1).

Usual therapy for residents was planned and supervised by physical therapists but often delivered by unregistered health professional staff: "[We] do a thorough physio assessment on them and then at facilities where we have assistants, we hand on to them mostly, for the ongoing care" (FAC#3). A management participant echoed "[physical therapist name] is more of like overseeing what's happening in the care home. So that's why she has a physio assistant. So the physio assistant can continue the plan. She's like the brain and the physio assistant is the skills" (Mgmt#3). Several participants expressed the personal conflict experienced by knowing what residents needed wasn't necessarily provided, "it comes back to my core values and belief that we don't have a reablement pathway in aged residential care at the moment. And it's not even everybody that needs it, is it? But for those that do, I think it's unfair that they don't really get that" (SM#3). Similarly, another said: "they [residents] often come in very deconditioned and we build them up. So being able to actually do some really good physio intervention as part of that gets them into a much better health state. So it should be part of what we do, frankly" (SM#2).

Senior and management participants' desire to care for people revealed the ethos of their clinical background. They understood how the service specifications impacted on service delivery through what was and wasn't specifically funded and how this effected outcomes for residents in their care.

Requirements for evidence

All participants considered SUp was valuable, but they wanted evidence that falls were prevented in order to support a case for SUp being integrated into everyday practice. This was needed for organizational resourcing, and to support individual therapists to change their practice.

Knowledge of results required for financial investment

For organizations to support routine SUp provision, participants in management roles needed to "see what the results are first" (SM#2). They stated that having data would strengthen a business case for ongoing funding. A manager said, "it would be tremendous to see the results of the overall research because it always just reinforces that you're on the right track with something. And it should drive business decisions," (Mgmt#5) and knowing that "(SUp) would be evidence based and proven" (SM#4) would be crucial to being able to fund the delivery of SUp after the program of research finished. There was also an awareness of the economics of being able to deliver the program in a group setting: "I think group exercise session is probably a much better bang for your buck, because you're covering off a large group" (SM#2). This perhaps reflects the dominant discourse of evidence-based practice entrenched in health care services.

Anecdotal evidence informed practice change

Clinicians, predominantly, considered the practice-based evidence they observed through participating in the RCT was sufficient to support using SUp in usual care. In particular, they drew on observations of individual residents, referring to changes in (1) residents' capabilities: "one of the ladies walked all the way up from the downstairs wing and walked back - previously she was using a wheelchair to get to and from the class" (FAC#4); (2) increased fitness and balance: "I was very pleasantly surprised how rapidly I could get them up to 60 minutes of exercise and how far I could get in the difficulty of exercises challenging their balance" (FAC#8); and (3) resident engagement: "residents had asked for more exercises" (FAC#6). Some physical therapy participants built on this, adding classes to usual care where previously none were available or increasing the number of classes offered and applying concepts from SUp within these: "It's hard to teach an old dog new tricks, but we have learnt some... it has made us realise that we can push them" (FAC#2). The engagement of the physical therapists themselves was seen as positive and convinced some management participants to support practice change, with one reflecting: "physios don't change stuff without good evidence" (Mgmt#5), while another requested the physical therapist run more classes. While physical therapy SUp facilitators could see changes in individual residents' functional abilities, management participants needed to measure the change across all those who took part in the SUp program and were specifically focused on the falls prevention outcome. Observing changes in participants and perceiving the program produced better outcomes for residents resulted in clinicians being more open to change. However, this resulted in clinicians incorporating concepts of SUp into usual care rather than management looking for additional funding to continue the SUp program.

Valuing the contributions of physical therapy in falls prevention

Physical therapists were part of the multidisciplinary team in all facilities, but their skillset was utilised differently between the for-profit and charity organizations. In the for-profit organizations their input in falls prevention was minimal.

The invisible skillset of physical therapy in LTC

Physical therapy input was viewed positively at the charity, reflected by the manager observing "it's such a drawcard for lots of families, having such a proactive physio team" (Mgmt#5). However, in the for-profit organizations physical therapists were predominantly "limited to assessment and advice" (FAC#4), contributing to multidisciplinary resident assessments and care plans. A senior management participant observed that "the physios do more paperwork than they do time with the residents doing walking programs" (SM#4). This perhaps meant managers and other staff did not experience and understand what falls prevention skills physical therapists had. Instead, falls prevention practices were a set of discrete tasks completed by a nurse or caregiver, mainly focused on the physical environment. If residents were having recurrent falls, physical therapists were sought for advice on how to manage the environment rather than for therapeutic intervention, as one manager illustrated: "when the resident had a fall, usually the clinical team will send an email to [physio name], "Can you please review this transfer plan? Is there something else that we can do?"" (Mgmt#3). This then contributed to senior management participants' expectations not being met and they questioned the value of physical therapy. One commented: "Whenever I ... do any clinical reviews of [residents], their physio assessments and the physio input into their plan is nothing like what I think it could be or should be. So it comes down to telling them, 'Yes, carry on with the walker'. Well the nurse could've figured that out. So I don't see a great depth of investment. Or individual planning." (SM#3). The clinical reasoning of physical therapists appeared to be invisible to managers but was evident when physical therapists described how demanding it was to challenge a participant "to their level". Observations and ongoing clinical decisions needed to be made during each SUp class, "you need to make a quick assessment of who is safe to stand up and try standing on one leg" (FAC#4). This demonstrated how assessment and clinical reasoning skills are central to individualising SUp and supporting individual progress. However, if this skillset is not usually recognised within an organization, this may not be 'seen' by those who make the financial decisions.

Time equals money and money equals time

All physical therapists in the for-profit organizations were contracted on an hourly basis. Any increase in physical therapist time had budgetary impact. The SUp research funded the physical therapists' time and enabled physical therapists to prioritise SUp classes in their workload. In everyday practice, often group classes were cancelled or given to an assistant to take: "an exercise class is often the first thing to go off my list if I have lots of new referrals or someone very acute" (FAC#4). One physical therapist reflected on the possibility of continuing to provide SUp, saying "there's no way they would be likely to allow me an hour out of my contracted hours... I couldn't afford that much time. I would just get way too far behind on all my other stuff" (FAC#3). However, in the charity, physical therapy was available to all with the onsite physical therapy gym open to treat residents in the morning. In the afternoon physical therapists visited residents who "needed to be seen individually" (FAC#2). There appeared to be no cost sensitivity in the charity. The value the Board placed on physical therapy was reflected in physical therapists being employed on staff and well resourced. As such, the cost of physical therapy was already incurred "...we just know we fund physio... our team have just absorbed it" (Mgmt#5); this perhaps made it easier to make changes to physical therapist programs and for SUp to be maintained after the research program finished.

To deliver SUp without additional funding in the for-profit organizations, management participants looked for workarounds that would mean the program was not delivered by physical therapists as designed and tested in the RCT. Even when value was seen, the cost was considered: "...I think there's absolute value in it, it's just about how we do it, what the workforce's availability is and what the cost is to the sector" (SM#1). To this end, the management preference was to deliver SUp using diversional therapists or activity coordinators already employed so they wouldn't have to pay for a physical therapist. When a physical therapist SUp facilitator asked a manager about SUp continuing: "...he [the manager] said yes to carrying on [SUp] but he thought that his activity coordinators were able to take over both sessions a week so he wouldn't have to pay for a physio" (FAC#7). Another appeared resigned, saying "It is a bit of a pity but what I expected as they don't like spending money on physio" (FAC#5). This led to not wanting to deliver the program with FAC#5 saying, "I don't imagine [name] will pay for me to continue sadly as the classes literally double the hours I get there!". Contracted physical therapists were acutely aware of their time costs and the impacts of funding. The contrast of contracting versus employing physical therapists to work in facilities demonstrated spending as little as possible to meet the requirements of the service agreement and create a profit versus not being profit driven. This highlights how business models and philosophies shaped care decision-making.

Discussion

The study results revealed that organizational budgets, and underpinning contractual and financial requirements, influenced whether managers and/or physical therapists considered it was possible to embed a falls prevention exercise program as standard practice in LTC after the cessation of the research program. Identifying these factors highlights to designers of future falls prevention initiatives that on-going funding, as an aspect of delivery and maintenance, must be considered. This evidence also illustrates to policy makers that service specifications are used as drivers of care delivery and that identifying and addressing key health issues such as falls prevention should be considered in the wording of contractual documents.

Healthcare can be considered a complex adaptive system, as it comprises different components that are dynamically inter-related, changing in response to events. In this study facilities, organizations and the Government are system components however, each is also its own system. With this in mind, a complex adaptive systems view was taken and SUp considered as an event occurring in the complex adaptive system of the NZ health system [29]. While the study findings are contextual to NZ due to the funding model, the findings may be translatable to other countries when considering service delivery of falls prevention programs in LTC.

In NZ, means testing is used to determine the amount of government subsidy paid to a LTC facility for a person's residency. Most residents receive a form of subsidy [30]. Government funding varies for residents assessed as requiring low dependency, high dependency and dementia level care, but is not based on the individual care needs of the resident as assessed by the interRAI. All study participants with budget responsibility described not only the cost of physical therapy as a barrier but also the larger issue of insufficient government funding for the increasing level of care residents needed. Their experiences echo an industry report that sought to update the funding model for LTC from the current three broad levels of low dependency, high dependency and dementia level care [31]. This report proposed a case-mix funding model and validated the use of interRAI Resource Utilisation Group (RUG-III) data to better reflect the need and funding required to care for each resident [31]. Following publication of the report, a NZ Government commissioned review of the LTC funding model recommended the use of interRAI RUG-III as a more sensitive model for allocating funding [32]. With each resident assessed with the interRAI 6 monthly, adopting a case-mix funding model would match the resident's current care needs on an ongoing basis [33]. The review recommendations have not yet been adopted. The rationalisation of health resources in the face of an ageing population will be an ongoing pressure as LTC is increasingly used for end of/late life care, with residents living in LTC for an average of 18 months but the mortality rate within 1 month of admission reported as high as 36.5% in NZ [32, 34]. Providing the level of care needed at this stage of life is resource intensive. The senior management participants' call for more funding to embed SUp rather than redistributing resources to falls prevention is understandable.

Considering the financial environment, growing care demands from increasingly frail residents and the drive for fiscal responsibility, if physical therapy is not understood and valued, it is likely that management either will seek cheaper methods of delivering SUp or not continue it at all. Delivering SUp without increasing costs saw participants adapting the intervention for their context [35]. Physical therapist participants adapted SUp content by selecting elements of the program and integrating concepts in their current workload, while management participants' adapted SUp delivery by using unregistered (cheaper) healthcare professionals. Using unregistered healthcare professionals to deliver falls prevention exercise is not uncommon in the community and can be effective [36, 37]. However, in previous LTC research, unregistered healthcare professionals were trained to deliver a manualised falls prevention exercise program and exercised participants in sitting "for safety", removing the element of standing balance, a critical component of falls prevention exercise [38, 39]. This suggests that more physical therapist input may be required to train and maintain program delivery by unregistered healthcare professionals, negating cost savings by not using physical therapists to deliver programs. The lack of parameters for physical therapy service in LTC creates the potential for providers to deliver to the minimal contractual obligation. A NZ survey of 373 facilities reported only 16 physical therapists were employed but 55 assistant physical therapists and 895 activities co-ordinators [40]. However, the annual NZ physical therapy workforce survey reported 111 physical therapists working in LTC [41]. Rather than employ physical therapists like the charity in this study, it appears that most facilities contract physical therapists and employ activities co-ordinators to carry out physical therapy plans and provide "activity" to meet government service specifications. This may also reflect the shift from socially oriented and charitable providers to large corporations now providing the majority of LTC beds and needing to generate investor profit [42]. A lack of parameters to guide delivery of physical therapy services in LTC is not unique to NZ and has been found to vary widely between countries [43]. The Netherlands utilised physical therapy the most; with a focus on rehabilitation and the goal of discharging people back to their own homes from LTC. In Canada, UK, Denmark, Italy and Japan some LTC facilities had no physical therapy services. Government funding appears to be the common denominator for determining physical therapy utilisation with the Netherlands Government fully funding physical therapy and the UK, Canadian and NZ governments only partially funding physical therapy in LTC [43, 44].

The research funding allowed the delivery SUp to be prioritised; that the program ceased when funding ended was not surprising. When an intervention (SUp) is introduced to a complex system (LTC), the system realigns to accommodate the new event, often at the expense of another component within the system. In the LTC facilities that ran exercise programs prior to SUp, they were typically only 30 minutes long. For the SUp classes to be accommodated, these class times were gradually increased. In facilities that had not run classes prior, the SUp classes were additional as the extra staff time was paid for and the physical therapist's usual case load was not affected. When funding was stopped status quo returned to the system (LTC), with physical therapist applying some elements of SUp to their work but not delivering SUp as designed. The sustainability of falls prevention programs beyond external funding is an ongoing problem [45]. Partnerships and collaborations, supported by policy have been identified as critical elements for sustainability [46]. What is not clear in the literature is why there appears to be an expectation that falls prevention can be delivered without appropriate ongoing financial resourcing. With the large cost of falls to the health system being known, surely it is cheaper to prevent a fall than pay to deal with the consequences.

Strengths and limitations

A strength of this study was the sample of staff through the levels of LTC organizations from senior managers in corporate offices to clinicians providing care for residents in facilities. This diversity of roles represented in the sample enabled experiences of SUp to be explored from different perspectives and triangulated to gain a fuller understanding of what might help or hinder embedding SUp in everyday practice in LTC. These findings will contribute to program implementation decision making should SUp prove to be an effective falls prevention exercise program. While it was planned to include residents and their families, the sample did not include residents as the NZ COVID-19 restrictions impacted this study. During this time visitors were not being permitted to LTC facilities and therefore researchers were not able to run resident focus groups or gain resident permission to contact their family. Lockdown protocols also increased staff workload and some participants chose to be interviewed together, saving time, and resulting in unplanned focus groups. Power relationships from the staff hierarchy (nurse manager, nurse) may have played out with participants not speaking as freely as they may otherwise have in an interview.

Conclusions

The results of this study suggest that if SUp is effective in preventing falls in LTC it may not become embedded within everyday practice, as designed, without additional funding support. This study identifies that policies that underpin funding decisions need to support physical therapy-led falls prevention exercise programs to be embedded in LTC. To be funded and resourced appropriately, the LTC facility service specifications need to be updated to recognise the health issue of falls in this population and current best practice evidence in LTC falls prevention. However, if status quo remains and funding is not attainable, the essential components of SUp need to be identified and a complexity informed approach taken to work with individual facilities to adapt SUp to suit.

Abbreviations

FAC	Exercise group facilitator
HDEC	Health and Disability Ethics Committee
ID	Interpretive Description
interRAI	International Resident Assessment Instrument
LTC	Long-term care
Mgmt	Onsite management
NZ	New Zealand
RCT	Randomized controlled trial
RUG-III	Resource Utilisation Group
SRQR	Standards for Reporting Qualitative Research
SUp	Staying UpRight
SM	Senior management

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12877-022-03722-z.

Additional file 1. Interview guides. The semi-structured interview guides that were used for interviews and focus groups.

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Authors' contributions
Study concept and design: EB, JP, DT, and LT. Recruitment strategy and data collection: JP and KP. Analysis and interpretation of data: EB, FB and DT. Drafting of manuscript: EB, FB and DT. Critical revision of the manuscript for important intellectual content: EB, FB, NK, JP, KP, DT and LT. All authors read and approved the final manuscript.

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Declarations

Ethics approval and consent to participate
Ethics approval was granted by the New Zealand Health and Disability Ethics Committee (HDEC) (18/NTB/151/AM04). Written informed consent was gained from all participants. Participants were informed that they were able to withdraw from the study at any stage up until the findings were produced. To ensure confidentiality, data was deidentified and given a study code and securely stored. All methods were carried out in accordance with relevant guidelines and regulations.

Consent for publication
Not applicable.

Competing interests
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Publisher's Note

Appendix Y SUp Additional file 1 (Interview guides)

Additional file 1. Interview guide for interviews and focus groups

Senior manager interview

How many years have you been in this role?

How many years have you been with the business?

o Can you tell me why you agreed to [name of organisation] taking part in the trial?

o Can you tell me what support was needed for the trial to run in [name of organisation]?

o How did staff feel about the trial/Was there any pushback from the staff about taking part? If yes how managed?

o Can you tell me what happened when the trial funding changed from external to within the organisation?

o Would you continue the Staying UpRight classes after the study?

o What are your views on making this programme sustainable within [name of organisation]? What changes would need to be made?

o Has there been any policy change as a result of this study?

o Can you tell me about any experiences/learnings from the COVID-19 pandemic that will be used in the future?

o Any other comments about the trial/intervention?

Onsite Management interview

How many years have you been in this role?

How many years have you been with the business?

o Can you tell me why you agreed to [name of of facility] taking part in the trial?

o How were you informed about the trial?

o Can you tell me how your facility got involved in the study?

o Can you tell me what support was needed for the trial to run in [name of of facility]?

o How did staff feel about the trial/Was there any pushback from the staff about taking part? If yes how managed?

o What are your views on falls prevention?

o What does your organisation value?

o Would you continue the Staying UpRight classes after the study?

o What are your views on making this programme sustainable within [name of of facility]? What changes would need to be made?

o What are your views on what Staying UpRight offers residents compared to what is routinely offered to residents?

o Did you share with other homes how the trial was working in your home?

o Can you tell me about any experiences/learnings from the COVID-19 pandemic that will be used in the future?

o Any other comments about the trial/intervention?

<u>Exercise group facilitator Flex & Stretch Focus Groups</u>

How many years have you been in this role?

How many years have you been with the business?

What is your professional background?

o What are your views on the training to deliver the class? (length of time? Manual? Ongoing support?)

o What else would you prefer?

o What are your views of the exercise classes in the trial? (content, duration, any different from usual classes?)

o How did the exercise groups affect workload, burden, and space (resource)?

o What were the factors that determined the length of the class?

o Can you tell me about what changes had to occur for the Staying UpRight group to run?

o Would you/What are your thoughts about continuing the Staying UpRight classes after the study?

o What changes did you see in the residents taking part over the course of the trial?

o Can you tell me what changes need to be made to the classes if they were to continue?

o Can you tell me about any experiences/learnings from the COVID-19 pandemic that will be used in the future?

o What went well and what were the barriers to the classes?

o What strategies did you use to address those barriers?

o Any other comments about the intervention?

<u>Exercise group facilitator Staying UpRight Flex & Stretch Focus Groups</u>

How many years have you been in this role?

How many years have you been with the business?

o What are your views on the training to deliver the class? (length of time? Manual? Ongoing support?)

o What are your views of the exercise classes in the trial? (content, duration, any different from usual classes?)

o How did the exercise groups affect workload, burden, and space (resource)?

o What did you think did/not contribute to the class running smoothly?

o What are your views on what Staying UpRight offers residents compared to what is routinely offered to residents?

o What changes did you see in the residents taking part over the course of the trial?

o Would you/What are your thoughts about continuing the Staying UpRight classes after the study?

o Can you tell me what changes need to be made to the classes if they were to continue?

o Can you tell me about any experiences/learnings from the COVID-19 pandemic that will be used in the future?

o Any other comments about the intervention?