Exercise in residential aged care – effects on falls, physical performance, quality of life and health care costs.

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This work is dedicated to the memory of my father, Terry Lawson, who passed away two years ago, he was my mentor, confidante and dear friend.

“Walk on

Walk on

With hope in your heart

And you’ll never walk alone

You’ll never walk alone”

Gerry and the Pacemakers

Candidate's Statement

I, **Jennifer Hewitt**, hereby declare that the work contained within this thesis is my own and has not been submitted to any other university or institution as a part of whole requirement for any higher degree.

I, **Jennifer Hewitt**, hereby declare that I was the principal researcher of all work included in this thesis, including work published with multiple authors. I was responsible for: contributing to the design of all chapters and studies; collecting the data for both the cluster randomised controlled trial and cost effectiveness studies; managing the day to day running of the studies and research assistants; contributing to data analysis and interpretation and writing of the initial draft of the manuscript. I did not receive any external grants to fund this work.

In addition, ethical approval from the University of Sydney Human Ethics Committee was granted for the studies presented in this thesis. Participants were required to read the participant information statements and informed consent was gained prior to all data collection.

I understand that if I am awarded a higher degree from this thesis, "Exercise in residential aged care -effects on falls, physical performance, quality of life and health care costs", being lodged herewith for examination, the thesis will be lodged in the University Library and be available immediately for use. I agree that the University Librarian (or in the case of a department, the Head of Department) may supply a photocopy, electronic copy or microform of the thesis to an individual for research or study or to a library.

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Publications and presentations

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Peer reviewed papers

Hewitt J, Refshauge K, Goodall S, Henwood T, Clemson L. Does progressive resistance and balance exercise reduce falls in residential aged care? Randomized controlled trial protocol for the SUNBEAM program. *Clinical Interventions in Aging* 2014; 9:369-376.

Accepted for publication

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Submitted

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Published abstracts

Hewitt J, Refshauge K, Henwood T, Goodall S, Clemson L. Falls prevention and quality of life in residential aged care: using exercise to grow bold not old. *JAPA* 2016; (24): Supp: S21.

Henwood T, Keogh J, Senior S, Hewitt J. Sarcopenia in the aged care setting: Prevalence, Consequences and the impact of resistance training. *JAPA* 2016; (24): Supp: S8-9.

Conference Presentations - podium

2012

November **ERA (Emerging Researchers in Ageing), Brisbane.**

Falls prevention in residential aged care: Making an impact by averting impact

2013

May **3rd Biennial National Falls Prevention Summit, Brisbane.**

Falls prevention in residential aged care: The research and its practical application.

November **ERA, Sydney.**

Enabling active ageing in residential aged care.

2014

November **Sydney Medical School Anniversary Event, Sydney.**

Exercise for falls prevention in residential aged care.

2016

May **NSW Falls Prevention Network Forum, Sydney.**

Exercise for falls prevention in residential aged care

June **World Congress on Active Ageing, Melbourne.**

Falls prevention and quality of life in residential aged care: Using exercise to grow bold not old.

November **Australian Association of Gerontologists Annual Conference, Canberra.**

Re-imagining physiotherapy in residential aged care: Exercise, falls prevention, re-ablement.

2017

October **Australian Physiotherapy Association National Conference, Sydney.**

Challenging physiotherapy in residential aged care: Moving away from pain management to exercise, falls prevention, and re-ablement. (Awarded Runner-up for best presentation – Gerontology).

Poster Presentation

Higher Degree Research Conference the University of Sydney, Sydney.

Progressive resistance and balance exercise for falls prevention in residential aged care, (awarded an Honorary Mention).

Abstract

The aims of this thesis were to investigate falls in the residential aged care setting, to develop an intervention based on best available evidence and to conduct studies on its efficacy and cost effectiveness. The issue of falls in older people forms the opening chapter and the paucity of evidence for effective falls prevention strategies in residential aged care is highlighted. Recommendations from the World Health Organisation and the Australian Aged Care Policy Review are introduced.

A literature review then explores the epidemiology of falls in older age, from a global perspective (Chapter 2). Interventions to prevent falls are presented and the disparity in findings for effective programs between community and residential aged care settings is examined. The relative scarcity of evidence concerning exercise as a potentially inexpensive and scalable approach is outlined and forms the rationale for the studies conducted in the thesis.

The first study is a cluster randomised controlled trial designed to test the effectiveness of an exercise program developed using the exercise type and dosage contained in best practice guidelines for community dwellers but applied to a residential care setting. The methodology of the trial is presented in Chapter 3. A cluster randomised controlled trial design was selected (clusters were residential aged care facilities) and the rate of falls was the primary outcome measure, over a 12-month follow-up period. A range of secondary outcomes were taken with the aim of developing a broader understanding of exercise in this setting (including quality of life (QOL), physical performance, functional mobility, fear of falling and cognition).

The trial was conducted between July 2012 and March 2016 and is presented in Chapters 4-6. Chapter 4 describes the implementation of the trial and results of the primary outcome of falls rate. While the secondary outcomes are reported in chapter 4, they are discussed in greater depth in chapter 5. The trial included 16 clusters and 221 residents included in the trial, 8 clusters (113 participants) were randomly allocated to receive the exercise program (called the Sunbeam Program) and 8 clusters (108 participants) received usual care. Aged care facilities (clusters) were included if they had: a mix of high-care residents ("nursing home" residents who required daily care by – or under the supervision of – registered nurses) and/or low-care residents ("hostel" residents who needed some assistance but did not have complex health care needs). Mean age of participants was 86 years (SD = 7.0), 65% of participants were female and 77% relied on a mobility aide for walking), and 49% had a diagnosed cognitive impairment.

The Sunbeam program differed from previous exercise tested in this setting as it specifically incorporated key components of best practice guidelines for effective falls prevention programs in community dwellers. The exercise was delivered in a group setting. Progressive resistance and balance training was individually prescribed and upgraded over 50 one- hour sessions provided twice weekly for 25 weeks. The progressive resistance training component was performed using pneumatic resistance equipment (HUR Health and Fitness Equipment) to challenge knee flexion/extension, hip abduction/adduction, triceps, leg press, and abdomen/back, all in a seated position. The balance component included high level balance exercises performed in standing with close supervision.

After 12-months follow-up, there was a significant reduction of 55% in the rate of falls for those in the Sunbeam Program (incidence rate ratio = 0.45 (95% confidence interval 0.17 to 0.74). This is equal to an overall incidence of falls in the exercise program of 1.31 per person years, compared to 2.91 in the usual care group. Participants were also more likely to fall multiple times (>5) in the usual care group (n=20 participants: 19%) than in the exercise group (9 participants: 8%). There were 72 injurious falls in the intervention group and 157 injurious falls in the usual care group. These findings are important as this is the first trial that provides strong evidence for exercise as an effective counter measure to falls in the residential aged care setting.

Secondary outcomes of the trial, including physical performance, mobility, QOL, fear of falling, and cognition, are reported in Chapter 5. A significant improvement was demonstrated in physical performance at 12 months in the exercise group (p = 0·02). Some improvements can be seen for other secondary outcomes scores, except fear of falling, however none of these reached statistical significance. Future research adequately powered to assess QOL, cognition and fear of falling is recommended. Further investigation of the validity and reliability of tools to measure these outcomes in residential care is also warranted.

Findings of the cost effectiveness study form Chapter 6, including the incremental cost effectiveness ratio (ICER) for the acute costs of falls. The Sunbeam Program cost $AUD 463 per person to deliver and the ICER per fall avoided was $AUD 22. These outcomes are compared to other falls prevention programs and demonstrate that the program is cost effective. This may be attributed to the strongly significant reduction in falls rates found in the intervention group as well as the Sunbeam Program being delivered in a group format which is less expensive than individualised programs. Scenario analyses provide further evidence of cost benefit particularly when the upfront cost of the exercise equipment has been accounted for and when the long-term costs of the sequelae of falls are included in the calculations.

The closing chapter is used to synthesise findings and make suggestions for the application of the results. The key discovery is that the Sunbeam program significantly reduced falls rate and improved physical performance in residents of aged care facilities. The program was also found to be cost effective. The studies contained within the thesis have important implications for the residential aged care sector as the intervention is relatively simple to scale with the potential to improve health outcomes as well as reduce healthcare costs. Findings may also be used to contribute to the health policy debate regarding public funding in the residential aged care sector.

Chapter 1

Introduction

1.1 Background

Falls are the leading cause of preventable deaths in residential aged care[1] and occur three times more often in residential aged care facilities than in the community dwelling aged care.[2,3] Approximately 60% of every care facility's residents will fall each year and this figure is rising faster than fall rates among those living in the community.[2] The number of hospitalisations from injurious falls is also increasing in older people from both settings.[4]

Falls can have a major impact both on individuals and on society. The consequences for individuals may include reduced independence, injury or even death.[3,5] The burden of falls on society is also substantial, Australian data show that while representing approximately 7% of the older population, residents of aged care account for more than 20% of fall-related hospital in-patient costs.[6] In New South Wales (NSW) the estimated annual treatment cost associated with falls is $AUD 558.5 million.[7] The proportion of the oldest-old is rising dramatically in most developed countries,[8] leading to projections of increases in the number of people living in long term aged care, the number of fall-related hospital admissions, and costs of follow-up care.[9] It is projected that without preventive action the costs to the health system from injurious falls will become unsustainable.[7] The World Health Organization (WHO) has therefore highlighted the prevention of falls as an international priority.[10] Furthermore, the Australian Institute of Health and Welfare (AIHW) has strongly advocated for interventions designed specifically for the residential aged care because the difference in injury risk between residents and community dwellers continues to widen.[2]

There is a plethora of research in the arena of falls prevention for older people living in the community, however little conclusive evidence is available for reducing falls among residents of aged care facilities. Interventions that are effective for reducing falls in a community setting do not return the same outcomes in residential care.[3,11] Exercise programs, for example, are recommended in best practice guidelines for older adults living outside residential care, however authors of these guidelines report that there remains limited and inconsistent evidence for exercise programs for residents living within residential care.[11] It has been reported that falls prevention exercise programs have been abandoned by aged care facilities worldwide subsequent to a Cochrane review that reported limited evidence of benefit.[3,12]

A position statement on exercise for falls prevention in older people[13] identified a set of key components for effective exercise programs in a community setting that form current best practice guidelines, however none of the exercise trials included in the Cochrane review specific to residential care had implemented the type or dosage recommended. It is possible therefore that it is not exercise itself that is ineffective, but the specific type of exercise programs tested so far.

1.2 Current Australian Context

The practical application of exercise programs in the Australian residential aged care setting may be impeded by two barriers; the Government funding mechanism and a risk averse culture. In Australia residential aged care facilities are funded under the Aged Care Funding Instrument (ACFI).[14] The ACFI consists of a number of categories that guide the level of funding an aged care facility receives for each resident, based on their individual level of comorbidity, disability and care needs. There is no specific provision within the ACFI for funding of any form of exercise program delivery and if an exercise program is implemented and the resident's mobility improves, the funding provided to the facility for that resident's care is reduced.

Risk aversion and the concept of a "trade off" between falls and mobility have been documented previously in the residential care setting.[15] Falls may be reduced by a resident limiting his/her mobility, but this may adversely impact physical performance and quality of life.[17] Residents are often encouraged to avoid risks and instead to wait and ask for assistance to be safe. Stimulating such extreme caution was the observation by Barker and Colleagues[16] that "improving the mobility of residents with severe mobility impairment may enhance their independence but paradoxically increase their risk of falls." It is understandable that such statements are highly likely to engender fear among clinicians about working with residents to improve mobility, lest a resident consequently suffer an injurious fall.

1.3 Aims of the thesis.

This thesis was designed to examine the available evidence regarding exercise in the residential care setting, to develop and implement a program and to measure its concurrent effects on fall rates, physical performance, mobility, confidence, quality of life and cognition. A subsequent study was also performed to examine the cost effectiveness of the program.

Specifically, the research questions are:

1. Does an exercise program, designed using best practice guidelines and delivered with adequate safety, reduce the primary outcomes of fall rates and falls in residential aged care?
2. Does the program improve the secondary outcomes of physical performance, mobility, quality of life, fear of falling and cognition?
3. Is the program cost effective?

1.4 Structure of the thesis

The thesis is comprised of seven chapters. Chapter 2 is designed to provide context, broadly presenting the epidemiology of falls in older adults on a global scale before narrowing the focus to those in residential aged care. Research on interventions to prevent falls in this setting is also reviewed, and gaps are identified in current knowledge regarding exercise as a falls prevention strategy.

Chapter 3 describes the protocol of a cluster randomised trial designed to compare a progressive resistance and balance exercise program (Sunbeam Program) with usual care. Outcomes measured were falls, physical performance, mobility, quality of life, confidence and cognition. This body of work has been published in *Clinical Interventions in Ageing*.

Chapter 4 reports the findings of the Sunbeam Program trial, which was conducted between August 2012 and March 2016, and included 16 residential care facilities and 221 participants. Findings include between-group comparisons of baseline and 12-month follow up data. The paper presented here has been accepted for publication in the *Journal of the American Medical Directors Association (JAMDA).* While the secondary outcomes are reported in chapter 4, they are discussed in greater depth in chapter 5.

Chapter 5 examines the secondary outcomes of the trial. The Sunbeam trial is the first to measure the concurrent effects of exercise on falls prevention in residential aged care and physical performance, functional mobility, quality of life, confidence and cognition. Findings are synthesised and compared to other randomised controlled trials that reported at least one of these measures. Recommendations for future research are presented here.

Chapter 6 presents the cost effectiveness study. The health economic aspects of the Sunbeam program are compared to usual care, including incremental cost effectiveness ratios, as well as probabilities of cost effectiveness. Recommendations regarding generalisability and scalability are also presented. This work has been submitted for publication in *JAMDA*.

Chapter 7 summarises and synthesises the information provided in previous chapters and discusses the implications for clinical practice and policy. The Australian Government has commissioned a Legislated Aged Care Review to identify clinical and cost-effective health care delivery methods as part of an Aged Care Reform project.[17] Findings from the studies contained within this thesis will contribute to the health services debate regarding funding models for therapy in residential aged care. Suggestions for further research are also presented.

The thesis includes one published article, one article currently *in press* and one articles currently under review for publication. Author guidelines for relevant journals are included as appendices, and chapters containing work prepared for publication have their own reference list in accordance with these guidelines. Ethics approval was obtained for all research from the Human Research Ethics Committee of the University of Sydney prior to commencement of any data collection.

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Chapter 2

Falls in older adults – a global issue

2.1 Population ageing

For the first time in history most people, worldwide, can expect to live into their sixties and beyond.[1] In high income countries, increases in life expectancy are predominantly attributed to declining mortality among those who are older.[1] In low income countries this is largely the result of reduced mortality during child birth, childhood or from infectious diseases.[2] Worldwide, the number of persons over 60 years is growing faster than in any other age group.[3] Figure 1 shows that Japan is currently the only country where the proportion of people aged at least 60 exceeds 30%, however by 2050 many countries will have similar proportions (Figure 2).

Figure 1 Proportion of population aged 60 years or older, by country, 2015[1]

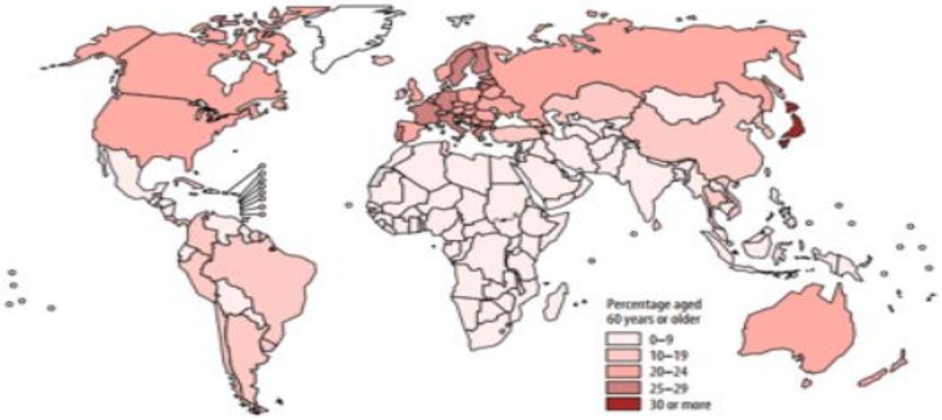
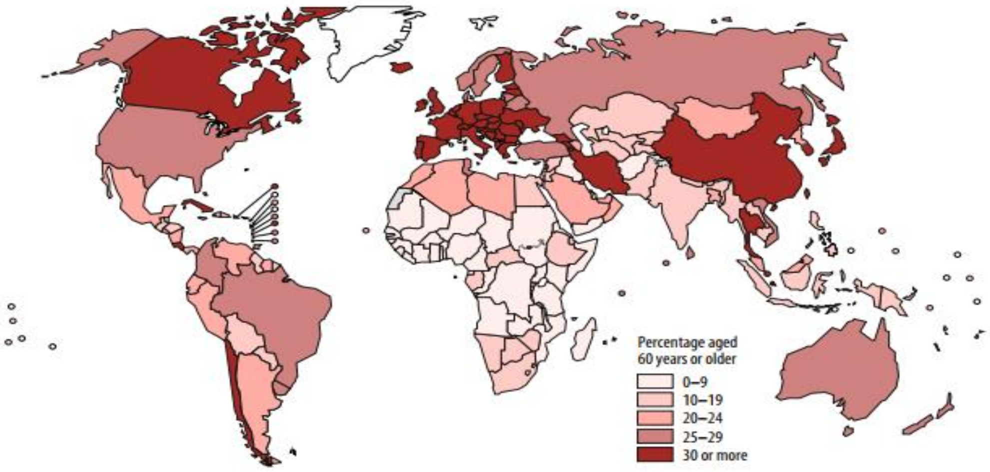


Figure 2 Proportion of population aged 60 years or older, by country, 2050 projections[1]



It has been traditionally accepted that the entry point for older age is 65 years, however in developed countries with rapidly increasing life expectancies, the diversity of definitions of older age differs by approximately 40 years. The United Nations has therefore further categorized the older age group into: “young-old” (65-74 years); “old-old” (75-84) and “oldest-old” (85 years and older).[4] The oldest old currently constitute 8% of the world’s population and is projected to increase by 351% by 2050.[5]

An increase in life expectancy ranks as one of society’s greatest achievements, however a comprehensive, global public-health response to population ageing is needed to cater for the specific needs of this changing demographic.[1] With increasing age, numerous underlying physiological changes occur, often resulting in disability and impairments. The major burdens of disability arise from sensory impairments, back and neck pain, chronic obstructive pulmonary disease, depressive disorders, diabetes, dementia and, in particular, from falls.[1] The World Health Organization has specifically highlighted the prevention of falls among older people as an international priority because falls are the leading cause of both fatal and non-fatal unintentional injuries for those aged over 65 years.[3,4]

2.2 Definition of a fall

Historically, there has been ambiguity around the definition of a fall.[4] Some early studies reported falls only if they resulted in contact with the ground,[6] whereas others reported falls only when a trial participant interpreted and recorded an event as a fall. The WHO therefore led a consensus agreement on an operational definition of a fall, with explicit inclusion and exclusion criteria. Since 2007, the WHO definition of a fall has been “an event which results in a person coming to rest inadvertently on the ground or lower level.”[3] A faller is defined as “a person who has fallen [at least] once in a specified time frame.”[3] These definitions are used throughout this thesis.

2.3 Measuring falls

A recent systematic review of methods used to measure falls in randomised controlled trials found considerable heterogeneity in reporting systems and in the follow up period.[6] Measurements included: self-report; prospective reporting using calendars, diaries or postcards; retrospective reports using questionnaires,[6] telephone calls or interviews;[4] and abstraction from health care records[6] and more recently, technology such as video surveillance or inertial wearable devices.[7,8] Each method presents advantages and disadvantages. Self- report measures (either prospective or retrospective), while being relatively simple to collect, may under-estimate falls if participants do not record an event contemporaneously, or misinterpret the definition of a fall.[4] Scheduled telephone calls, interviews and questionnaires may also be impeded by compromised retrospective recall, depending on the length of the recall period.[6] There may also be disincentives for older people to record falls, because of embarrassment or fear of consequences, such as loss of independence.[4] Data obtained from incident forms or progress notes in an institutional setting may be inaccurate due to under-reporting, possibly related to staff time pressures and a perception of blame.[9] Video surveillance is an accurate way of identifying falls[8] however only those falls occurring in view of the cameras will be captured. Recent use of satellite monitoring for wearable inertial monitoring devices provides a solution to the accurate capture of falls, however the devices pose greater expense than the other methods.[8]

2.4 Incidence of falls and fall related injuries

Although falls may occur at any age, the risk and incidence of falls increases with advancing age, and outcomes may take on greater significance due to elevated susceptibility to injury.[4] The incidence of falls and fall related injuries varies between nations, populations and settings. There is relatively sparse data from developing countries,[3] however studies from Hong Kong, Japan and Barbados report that approximately 20% of older adults fall each year whereas figures from the United States of America, The United Kingdom, Australia, New Zealand, Spain, The Netherlands and Chile report figures of approximately 30%.[3,4] The reasons for these differences are not yet well understood, although it is possible that differences in methods of measuring and recording falls, and cultural differences in activity levels throughout the lifespan may be at least partly responsible.

Internationally, those living in permanent residential aged care fall 3-5 times more often than people of the same age who live in the community[3,4,10] and the incidence of falls in residents of aged care has increased over the past decade to 60%.[11]

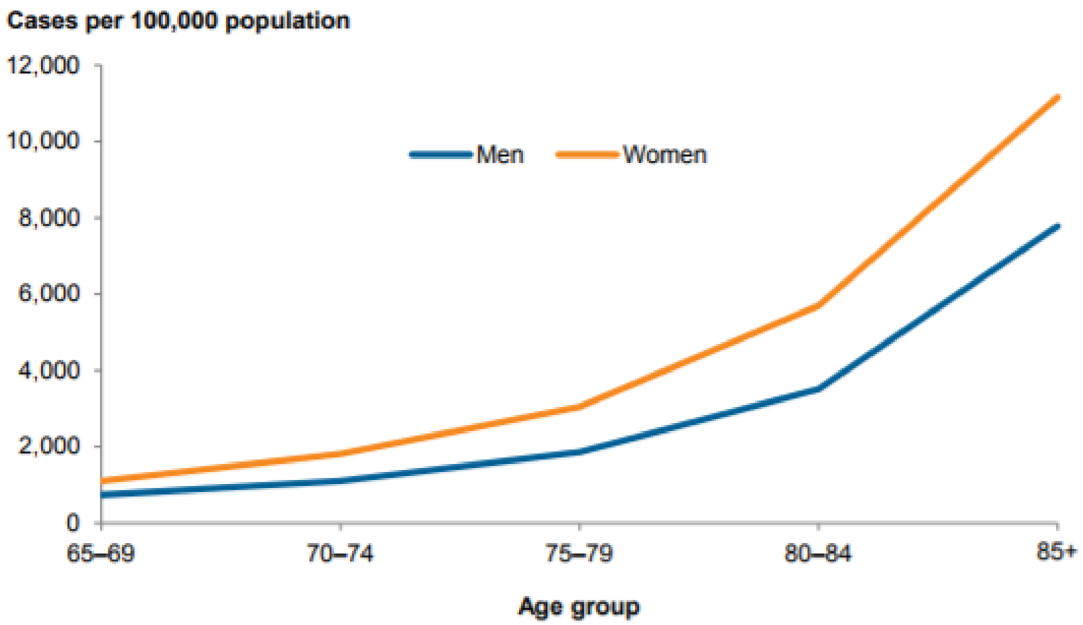
2.5 Consequences of falls in older adults

Falls are the leading cause of both morbidity and mortality among people aged over 65 years,[10,12] accounting for 40% of injury-related deaths and 80% of injury-related hospital admissions.[3] In the residential aged care setting, falls are now reported to be the most common cause of preventable deaths.[13] Injurious falls occur 3.5 as many times in people aged 65 and over as in those aged 45-64.[13] The rate of hospital admission for older people due to falls in Australia, Canada, and The United Kingdom range from 1.6 to 3.0 per 10 000 people.[3] In NSW, Australia falls result in approximately 30 000 hospitalisations and 300 deaths each year, for people over 65 years.[14] The major underlying causes for fall-related hospital admission are hip fracture, traumatic brain injury and upper limb injuries[3,13] Other consequences of falls may include pain, injury, a decline in function, independence and quality of life.[10,15] Self- imposed activity restriction and loss of confidence in the ability to ambulate safely following falls has been shown to contribute to feelings of helplessness and social isolation.[16]

Women are more likely to fall than men throughout older age.[17] In 2013-2014, 1.4 million of the Australian hospital bed days and 67% of hospital admissions were for injurious falls among women aged over 65 years.[13] Figure 3 demonstrates fall rates by age and sex in Australia in 2011-12.[18]

Figure 3: Age specific rates of injurious fall (cases) by age group and sex, 2011-

12 in Australia.



Source: Australian Institute of Health and Welfare **[18]**

Women are reported to have a 40-60% higher rate of fall-related injury than men which may be attributed to higher rates of osteoporosis among women, making them more susceptible to fractures.[19] Despite this finding, men are more likely to sustain fatal falls than women,[17] possibly because men present with more co-morbid conditions than women of the same age,[3] sustain a higher incidence of fall related head injuries,[20] and have an increased tendency to engage in risk taking behaviours.[17]

2.6 Time and location of falls

Most falls (80%) occur during the day. Night time falls tend to occur between 9 pm and 7 am when people wake to use the bathroom.[18] The mechanism of falls is difficult to ascertain from the literature: "unspecified fall" was the descriptor for the highest frequency of falls from the Australian Institute of Health and Welfare report for 2011-12,[18] however falls on the same level (slip, trip or stumble), from a chair or from the bed were the next most common types of falls.[18]

Outdoor falls are more likely to occur in those aged under 75 years, most likely because this group are more active and mobile.[18] Men are more likely to fall outdoors while women tend to fall indoors.[17] In a residential aged care setting, people are at increased risk of falling on the first day of moving in to the facility, possibly due to disorientation caused by a new environment.[16,17]

2.7 Economic impact of falls

The economic and health impact of falls is critical to community and society.[3] In Australia, falls cost the health economy more than any other form of trauma, including motor vehicle accidents.[20] In NSW, the estimated annual treatment cost associated with falls is $AUD 558.5 million.[14] The proportion of the oldest-old is rising dramatically in most developed countries,[4] leading to projections of increases in the number of people living in long term aged care, the number of fall-related hospital admissions, and costs of follow-up care.[21] It is projected that without preventive action the costs to the health system from injurious falls will become unsustainable[14] and the prevention of falls has been highlighted by The World Health Organisation as an international priority.[3]

2.8 Risk factors for falls

Falls are not considered to be purely accidental events. Studies report they occur from the interaction between increased individual susceptibility to hazards arising from the accumulated effects of ageing and chronic diseases, risk taking behaviours and identifiable environmental hazards.[4,16,26,23]

Normal ageing is associated with declines in several physiological systems including, musculoskeletal, cardiovascular, visual, vestibular and proprioception, coordination, slowed postural responses, and cognitive function (especially dual tasking and executive function), all of which have been shown to increase the risk of falls. The risk of falls may be predicted from the interplay between these and other identifiable risk factors classified as intrinsic (person specific) or extrinsic (environmental) factors.[4,16,17,22]

Intrinsic Risk Factors

Intrinsic risk factors include those that relate to the effects of disease, ageing and co-morbid conditions. The following intrinsic factors have been identified as strongly increasing falls risk: gait and balance disturbance, muscle weakness, visual impairment, fear of falling and cognitive impairment. Gait and balance disorders have been consistently reported in multiple reviews as the strongest risk factors for falls.[4,16,17,22] Specific diseases of the nervous system, circulatory and respiratory systems may contribute to gait and balance dysfunction by exacerbating impairments in postural control, reaction speed, and height of stepping, all of which also decline with age and impair the ability to avoid a fall.[16,22]

Lower limb muscle weakness is another important risk factor. In a meta-analysis of 30 studies, Moreland and colleagues found that the combined odd ratio for the association of lower limb muscle strength and falls was 1.76 (95% CI 1.31-2.37).[24] Muscle weakness may be attributed to ageing and disease process however increased sedentary behaviour in older age may also play a part.[16,25]

Visual impairment is also an important risk factor, impoverished visual input, balance control and obstacles avoidance become impaired. This may be due to misjudgement of depth or distance, misinterpretation of spatial information and an inability to detect hazards.[22,26]

Fear of falling has been identified as an important psychological factor associated with falls in older adults. [27] Disparities bewteen perceived and physiological fall risk have been shown to influence the probability of falling. Those who worry about falling may have a higher falls rate despite low physical risk and conversely, those with a low perceived risk may have increased falls if this coincides with high physical risk.[27]

Cognitive impairment features in the research as an important individual risk factor,[17] however its role is less clearly understood.[22] Reduced executive function, reaction speeds, and disorientation are considered likely contributors to the increased risk.[28] A diagnosis of dementia, in both community and residential care dwelling older adults, confers a high risk of falls.[22]

Other intrinsic factors include Vitamin D deficiency, foot pain, incontinence (particularly urgency), poor nutrition, and cardiovascular disease. Serum levels of Vitamin D < 75nmol/L result in increased falls risk, because low Vitamin D levels are thought to be related to reduced calcium absorption, bone density, and neuro-muscular function.[29] Foot pain may result in changes to gait and balance thereby also increasing falls risk.[30] Urological co-morbidities such as benign prostatic hyperplasia and overactive bladder are associated with increased falls risk.[31] An explanation for this association is that individuals may need to rush to the bathroom, and if this urgency exists in combination with poor balance and gait may contribute to increased risk of falls.[32] Nutritional status has been found to be an independent predictor of falls[33] most likely because malnutrition is associated with gait abnormalities, impaired muscle function, and reduced cognitive function.[33] In terms cardiovascular disorders, syncope and orthostatic hypotension are documented risk factors,[34] as is carotid sinus hypersensitivity.[12]

Each of the conditions described above are individual risk factors for falls, however if they occur in combination, the risk is magnified.[22] Higher prevalence of these conditions occurs with advancing age and may contribute to the finding that falls among people aged 80 years and older are more likely to be associated with intrinsic factors.[22,35]

Risk taking behaviours also contribute to increased falls risk and may include walking without a prescribed aide, walking in reduced lighting, over-reaching, and ladder climbing.[4,16,18] Wearing inappropriate shoes (loose fitting or high heels), alcohol misuse and sedentary behaviour resulting in deconditioning are also considered to be risk taking behaviours.[36]

Extrinsic Risk Factors

Extrinsic factors encapsulate issues related to the environment, including home hazards, hazardous features of the public environment and some classes of medication.[3,4 22] Narrow stairs, slippery floors, loose rugs, poor lighting, the absence of handrails, cracked or uneven ground surfaces and icy conditions are all associated with increased falls.[3,37] Falls risk medications include antipsychotics, antihypertensive agents, diuretics, β blockers, sedatives and hypnotics, neuroleptics, antidepressants, benzodiazepines, narcotics and non- steroidal anti-inflammatories.[23,38-40]

2.9 Interventions to prevent falls in older adults

The effect of interventions aimed at reducing falls in older adults has been widely studied,[10,12] although most research has been directed at community dwellers aged 65 years or older.[12] There are fewer studies that focus on the oldest-old and permanent residents of aged care facilities. The Cochrane review on interventions for the prevention of falls in community dwelling older adults[12] identified 159 relevant trials whereas the review conducted in hospitals and nursing facilities (residential aged care) identified 41 trials.[10] Research has generally focussed on testing the efficacy of interventions that target the extrinsic and intrinsic risk factors for falls, and may have addressed one factor in isolation or a combination of factors. Due to the complexity of reporting and comparing heterogenous research, a taxonomy has been developed to assist in classifying interventional research.[41] Categories include: single interventions (targeting one risk factor); multiple interventions (targeting more than one risk factor); and multifactorial interventions (individualising interventions to the participant's risk factors). Tables 1 and 2 summarise the findings from a meta-analysis of studies performed in the community dwelling and residential aged care settings, respectively. Differences in interventions and outcomes in each setting are introduced.

Table 1. Interventions that reduced falls rate in community dwelling older adults; summary of results from Cochrane Review[12]

Intervention	Falls Rate Reduction	Falls Risk Reduction
Gradual withdrawal of psychotropic medication	RaR[a] 0.34 95% CI 0.16 – 0.73 1 trial 93 participants	Not significantly reduced
Individualised podiatry	RaR 0.64 95% CI 0.45 – 0.91	Not significantly reduced
Cataract surgery	RaR 0.66 95% CI 0.45-0.95 1 trial 306 participants	Not significantly reduced
Multi-component home-based exercise	RaR 0.68 95% CI 0.58 – 0.8 7 trials 951 participants	RR[b] 0.78 95% CI 0.64 – 0.94 22 trials 714 participants
Multi-component group exercise	RaR 0.71 95% CI 0.63-0.82 16 trials 3622 participants	RR 0.85 95% CI 0.76 – 0.96 22 trials 5333 participants
Tai Chi	RaR 0.72 95% CI 0.52 – 1.00	Not significantly reduced
Pacemaker (for carotid hypersensitivity)	RaR 0.73 95% CI 0.57 - -0.93 3 trials 349 participants	Not significantly reduced
Multi-factorial (individualised falls risk assessment and targeted management plan)	RaR 0.76 95% CI 0.67 – 0.86 19 trials 9503 participants	Not significantly reduced
Home safety assessment and modification	RaR 0.81 95% CI 063-0.97 6 trials 4208 participants	RR 0.88 95% CI 0.8-0.96 7 trials 4051 participants

a = rate ratio b = risk ratio

Table 2. Interventions to reduce falls outcomes in older people living in nursing care facilities; summary of results from Cochrane Review [10]

Intervention	Falls Rate Reduction	Falls Risk Reduction
Prescription of Vitamin D	RaR[a] 0.72 95% CI 0.55 – 0.95 5 trials	Not significantly reduced
Exercise programs	Not significantly reduced 11 trials	Not significantly reduced
Multi-factorial (individualised falls risk assessment and targeted management plan)	Not significantly reduced 7 trials 2997 participants	Not significantly reduced
Medication management	Not significantly reduced 2 trials	Not reported
Multiple Interventions (exercise + management of urinary incontinence + fluid therapy)	Borderline significant RaR 0.62 95% CI 0.38 – 1.00 1 trial	Not significantly reduced

a = rate ratio

Summary of findings.

Pooled data from eligible randomized controlled trials (RCT) and found the most effective falls prevention programs for community dwelling older adults included; gradual withdrawal of psychotropic medications, anti-slip shoes in icy climates, podiatry for those with foot pain, cataract surgery, multicomponent home-based exercise, multicomponent group exercise (targeting balance and strength), Tai Chi, provision of a cardiac pacemaker in people with carotid hypersensitivity, multifactorial interventions customised to target relevant risk factors, and home safety assessment and modification (Table 1). Vitamin D supplementation did not improve falls outcomes in this setting. Pooled data from other interventions that tested cognitive behavioural interventions, participant education, and withdrawal of multi-focal glasses, returned no significant improvement in fall rates.[12]

Systematic review and meta-analysis of studies in the residential aged care settings[10] returned results that differed from those in community settings (Table 2). Pooled data from 5 RCTs that tested Vitamin D supplementation as a single intervention found a significant reduction in the rate of falls.[10] Exercise as a single intervention found no reduction in rate of falls or risk of falling in residential care, however when included in one multiple-intervention study[42] the reduction in falls rate reached borderline significance. Inconsistent results from trials comparing medication review to usual care also led the authors to report that there is little evidence to support pharmacist-led medication reviews on reducing fall rates in the residential aged aged care setting.[10]

2.10 Scope of the thesis

This thesis was undertaken to focus on risk factors that may be modifiable with simple, inexpensive and scalable allied health practice. The intrinsic risk factors of gait and balance disorders and muscle weakness have been cited as important risk factors that may be amendable to targeted exercise. Exercise as a single intervention has been shown to prevent falls in older community dwellers[12] (Table 1) however it is not clear if exercise is effective in the residential care setting (Table 2)[10]. Of the studies that met the eligibility criteria for inclusion in the Cochrane review: two found a reduction in fall rates and/or fallers, two found no between-group differences following the intervention, and four studies found an increase in fall rates.[10] The authors were therefore unable to determine the value of exercise intervention in this setting. Other reviews have also reported that there is insufficient evidence to support exercise as a counter-measure to falls in residential care.[16,43] It has been reported by Silva and colleagues[44] that exercise has subsequently been abandoned by many aged care facilities worldwide. They note however that not all included studies included in the reviews had used exercise as the sole intervention, and that falls were not always the primary outcome measures, thereby limiting the validity of findings.[44]

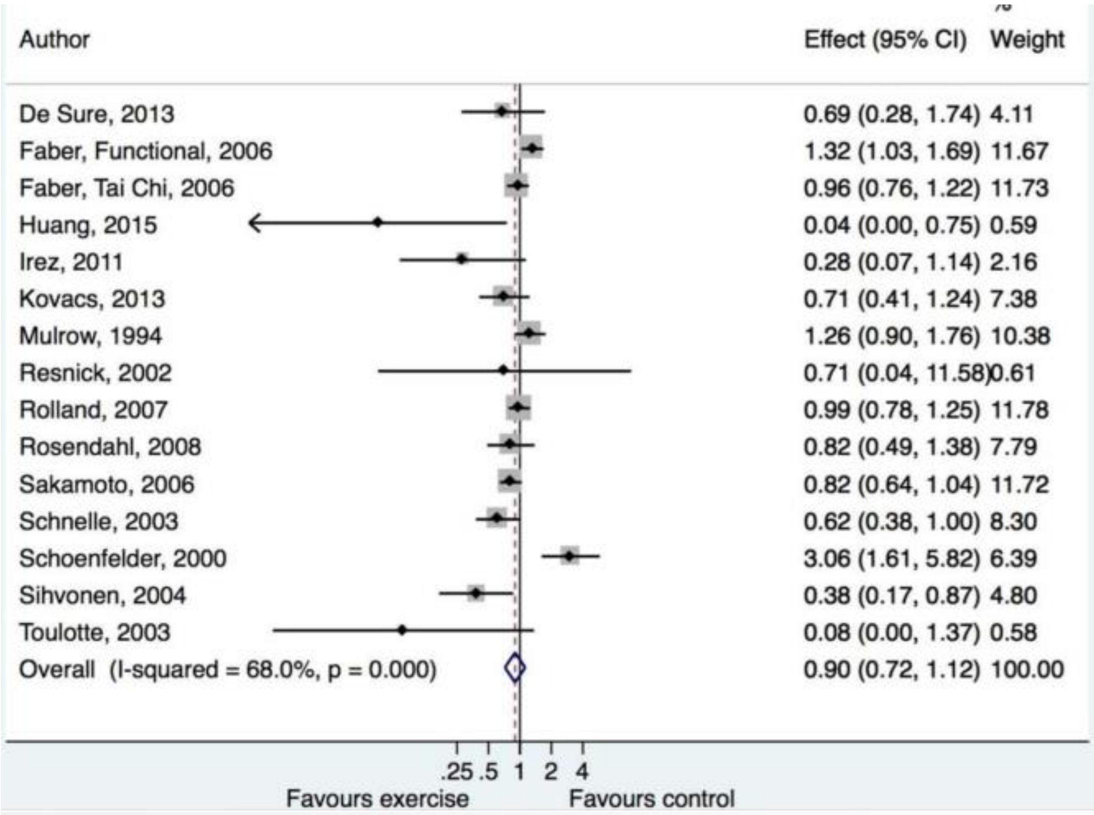
Another important factor in conclusively evaluating the efficacy of the exercise programs tested in residential care is to examine the type, dosage and intensity of exercise implemented, and to match this against best practice falls prevention exercise recommendations.

2.11 Exercise programs for the prevention of falls in residential aged care

It is unknown whether interventions that are effective in community-dwelling adults will also be effective in residents who live in long-term care.[45,46] A Cochrane Review of interventions to prevent falls in long-term residential care and hospitals identified eleven trials of supervised exercise as a single intervention.[10] The findings from the meta-analysis of these studies were equivocal. When evaluated by type of exercise performed, pooled data from two trials[47,48] found that mechanical balance perturbation reduced falls; two[49,50] found that using standing balance did not change falls; and pooled data from four studies[51-54] found that using functional exercise and walking increased falls. The remaining trials did not provide sufficient data to be included in the meta-analysis. The inconsistency of these findings prevented the authors from determining the value of exercise in residential aged care.

A recent systematic review[43] identified a further four trials on exercise as a single intervention for falls prevention in residential aged care. The pooled effect of exercise on fall rates, expressed as a rate ratio, was 0.90 (95%CI 0.72-1.12; p=0.35, I^2 =65%). This represents a 10% reduction in falls rate which was not statistically significant.[43] Figure 4 is a forest plot of the mean (95% confidence intervals) outcome for each trial in this review, demonstrating the degree of heterogeneity in findings that led to the overall pooled result.

Figure 4 Forest plot of trials of exercise to prevent falls in residential aged care settings[42]



It is possible that the inconsistent falls outcomes in these trials were related to the type and dosage of exercise implemented. For community dwelling adults, a set of key components for falls prevention exercise programs has been identified and form current best practice guidelines.[43,46] These include a combination of: high challenge balance training; moderate to high intensity progressive resistance training (PRT) for those who are deconditioned; and a total of at least 50 hours of exercise over 6 months. Among the trials included in reviews specific to residential care,[10,16,43] there was a large variation in exercise type and dosage, however none implemented balance and PRT at the recommended dosage.

There is therefore a gap in the current literature regarding whether an exercise program designed using the key components of successful falls prevention programs in the community setting will also result in reduced falls and fall rates in residents of aged care. The studies presented in this thesis were designed to test the efficacy of an exercise program that incorporates both balance and PRT, individually prescribed and progressed by a practitioner trained to assess and accommodate for co-morbid conditions. The program included moderate intensity exercise training for 50 hours over 6 months. A randomised cluster design was used to test the hypothesis that fall rates and number of falls would be reduced in the group allocated to receive the exercise program compared to usual care. Secondary outcomes (physical performance, quality of life, functional mobility, fear of falling and cognition) were also hypothesised to improve. Furthermore, to understand the scope for scaling the program, a cost effectiveness analysis was conducted. The protocol and results of these studies are presented in the following chapters.

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Chapter 3

Does progressive resistance and balance exercise reduce falls in residential aged care? Randomized controlled trial protocol for the SUNBEAM Program.

Preamble

This chapter describes, in detail, the cluster randomised controlled trial (reported in Chapter 4). The aim was to develop a cluster randomised controlled trial to test the efficacy of an exercise program in a residential aged care setting. The program incorporated each of the recommended key elements derived from effective falls prevention programs for community dwell older people. The methodology was described using the taxonomy recommended by the European Prevention of Falls Network[1] to allow for international comparison and effective pooling of data by future researchers.

A cluster randomised controlled trial design was selected to test the research hypothesis that the number of falls and the falls rate would be reduced in the clusters allocated to receive the exercise program (called the Sunbeam Program), compared to usual care. Each aged care facility represented a cluster. This design was chosen to reduce the potential risk of contamination from participants within a facility choosing to join the exercise program during the intervention period, irrespective of group allocation.

During recruitment we worked closely with facility staff (usually the registered nurse on duty) who provided a list of residents that were eligible and either consented to join the trial or asked to speak with the research team directly. In the event of a resident being ineligible to sign the consent form themselves, the facility staff member also provided us with the contact details of the person responsible for signing. Direct contact was made by the research team or the facility staff to explain trial participation and seek written consent from him/her.

As a courtesy, the documented "next of kin" for each participant was also informed about the trial and invited to contact the research team if they had any questions (we advised participants that this was our protocol at the time of the baseline measures and adhered to their wishes is they asked us not to proceed with this process).

The paper is presented in the format in which it was published in *Clinical Interventions in Ageing*.[2]

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METHODOLOGY

Does progressive resistance and balance exercise reduce falls in residential aged care? Randomized controlled trial protocol for the SUNBEAM program

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Introduction: Falls are common among older adults. It is reported that approximately 60% of residents of aged care facilities fall each year. This is a major cause of morbidity and mortality, and a significant burden for health care providers and the health system. Among community dwelling older adults, exercise appears to be an effective countermeasure, but data are limited and inconsistent among studies in residents of aged care communities. This trial has been designed to evaluate whether the SUNBEAM program (Strength and Balance Exercise in Aged Care) reduces falls in residents of aged care facilities.

Research question: Is the program more effective and cost-effective than usual care for the prevention of falls?

Design: Single-blinded, two group, cluster randomized trial.

Participants and setting: 300 residents, living in 20 aged care facilities.

Intervention: Progressive resistance and balance training under the guidance of a physiotherapist for 6 months, then facility-guided maintenance training for 6 months.

Control: Usual care.

Measurements: Number of falls, number of fallers, quality of life, mobility, balance, fear of falling, cognitive well-being, resource use, and cost-effectiveness. Measurements will be taken at baseline, 6 months, and 12 months.

Analysis: The number of falls will be analyzed using a Poisson mixed model. A logistic mixed model will be used to analyze the number of residents who fall during the study period. Intention-to-treat analysis will be used.

Discussion: This study addresses a significant shortcoming in aged care research, and has potential to impact upon a substantial health care problem. Outcomes will be used to inform care providers, and guide health care policies.

Keywords: balance, strength, training, falls, nursing care, cost-effectiveness

Introduction

The size of the population aged 75 years and older is projected to grow to more than double in the next 20 years.[1] The number of people living in residential aged care, the number of fall-related hospital admissions, and the costs of follow-up care are also expected to rise.[2] Identification and implementation of effective interventions to reduce falls in this setting has the potential to significantly benefit older individuals, and to reduce the health care burden.

To date, the majority of studies have focused on falls among community-dwelling older adults. However, the number of falls among residents of aged care facilities is reported to be three times greater.[3] The consequences of falls are often traumatic, and include reduced independence, injury, and death.[3,4] The burden upon society is also substantial. Australian data show that, while residents of aged care facilities form only one-eighteenth of the older population, the cost of their falls is greater than one-fifth of the total cost of falls, to the health system.[5] Therefore, a recent economic evaluation of projected costs of health care recommended urgent action, to prevent falls in aged care facilities.[2,6]

Falls are not considered to be purely random events, but can be predicted to arise from a number of risk factors, including: visual impairment, vitamin D deficiency, foot pain, incontinence (particularly urgency), poor nutrition, psychoactive medications, cardiac arrhythmia, reduced lower limb muscle strength, and impaired balance and gait.[7–10] There have been many randomized controlled trials, Cochrane Collaboration reviews, and other systematic reviews conducted, to explore the effectiveness of a range of fall prevention strategies, including single interventions (targeting one risk factor), multiple interventions (targeting more than one risk factor), and multifactorial interventions (individualizing the interventions to the participant's risk factors).[3] There is evidence that exercise, as a single intervention, can prevent falls in older community dwellers.[9,11–15] A recent review from the Cochrane Collaboration that examined fall prevention interventions in residential aged care facilities (RACFs) and hospitals identified eleven studies which had tested exercise as a single intervention. The pooled results returned inconsistent data; it was concluded that carefully-designed research into supervised exercise for falls prevention in this setting is essential.[3] Clinical practice guidelines currently recommend the following key components for exercise programs: high-challenge balance training, moderate-to-high intensity progressive resistance training (PRT), and a total of at least 50 hours of exercise.[12]

Therefore, this study aims to test whether the SUNBEAM program (Strength and Balance Exercise for Aged care), which is based on key components of successful community-based programs, will reduce falls in the high-risk group of residents of aged care facilities.

The key research questions are:

- Is a supervised, group-based, PRT and balance exercise program more effective than usual care for the prevention of falls among residents, during a 12-month follow-up period?
- Does the program result in improvements in secondary outcomes: quality of life, cognition, mobility, and confidence?
- Is the program cost-effective?

Method

Design

This will be an assessor-blinded, two-group, cluster-randomized, controlled trial. It will be funded by a donation from Domain Principal Group (Sydney, NSW, Australia), and in-kind support from HUR Health and Fitness Equipment (Birkdale, QLD, Australia). Concealed allocation and intention-to-treat analysis will be used. Measurements will be taken at baseline, immediately following the intervention (6 months), and at 12 months after randomization, to examine the maintenance of any intervention effects. The study protocol has been approved by The University of Sydney Ethics Committee (Approval number 14995), and has been registered in the Australia and New Zealand Clinical Trials Registry (Registration number: ACTRN12613000179730). The trial's results will be reported using domains and categories described in the taxonomy developed by the Prevention of Falls Network Europe, to allow future synthesis of evidence, or study replication.[16] A flowchart of the trial design is provided in Figure 1.

Residential aged care facilities and participants

We will recruit 300 residents and 20 RACFs from northern New South Wales and South East Queensland, Australia. The inclusion criteria for RACFs are: 1) to have a mix of high-care residents ("nursing home" residents, who require daily care by – or under the supervision of – registered nurses) and/or low-care residents ("hostel" residents, who need some assistance, but do not have complex health care needs); 2) to be likely to have 15 residents willing to participate; and 3) the facility manager consents to participation in the trial and to the allocation of staff time. Staff will assist with generating a list of potential participants (using the trial's inclusion/exclusion criteria), approaching potential participants, to invite them to volunteer for the trial, and (where relevant) will assist with supervision of the exercise sessions over the 12-month trial period. Enduring power of attorney holders, where present, will be contacted by mail, for each potential participant.

Participants will include men and women who permanently reside in residential aged care and are able to understand English to a level where they can comprehend the participant information statement, complete the consent form, and carry out self-report outcome measures without an interpreter. Residents with a terminal or unstable illness, significant advanced cognitive decline (Mini Mental State Examination[17] $\leq$15), or physical symptoms that preclude

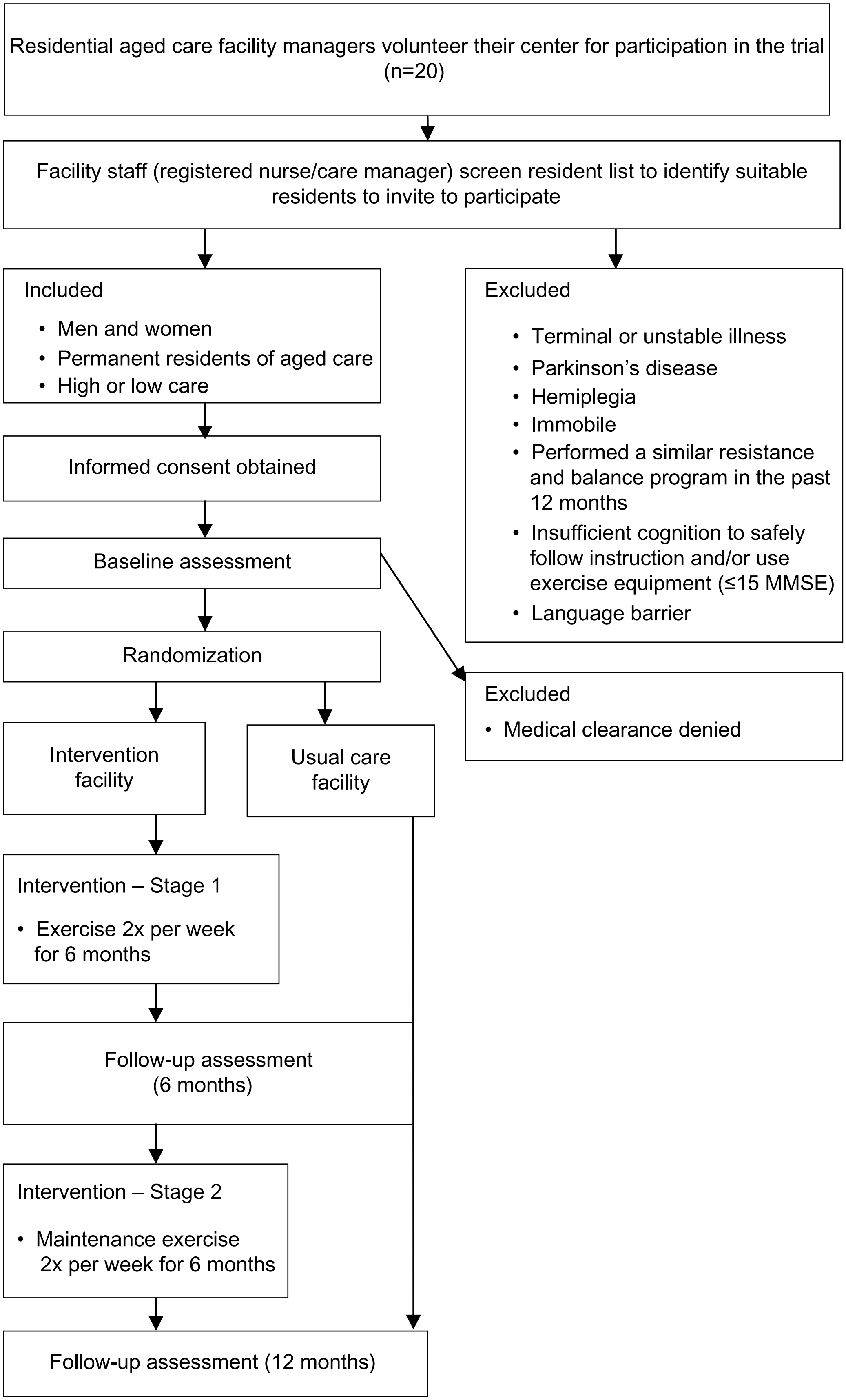

Figure 1 Flowchart of study design.
Abbreviation: MMSE, Mini Mental State Examination.

the safe use of exercise equipment in a group setting (eg, Parkinson's Disease or hemiplegia) will be ineligible. Other criteria will exclude those who are permanently wheelchair- or bed-bound, and those who have performed a similar balance and/or resistance training program within the previous 12 months.

Outcome measures

Data will be collected at baseline, 6 months, and 12 months by blinded assessors. Baseline measurements will be taken as soon as possible after recruitment, and before randomization. In addition to falls data, a range of demographic information and known risk factors for falls will be recorded at each assessment, including comorbid conditions, medications, environmental hazards, use of a mobility aid, and incontinence.[7,9,18]

Primary outcome

The primary outcomes will be the proportion of residents who fall (fallers), and the number of falls for each participant (fall rate), during the 12-month trial period. The definition of a fall will be: "an unexpected event in which the participant comes to rest on the ground, floor, or lower level", as derived by consensus statement[19] and used in recent reviews by the Cochrane Collaboration.[9] Individual falls will be recorded every month for the 12-month study period, by auditing aged care facility incident reports.[20–22] In addition, at the time of each assessment, participants will be asked directly if they have fallen. It is acknowledged that it would be preferable to incorporate multiple approaches to collecting falls data, to improve accuracy. However, this is beyond the resources available to this study.

Secondary outcomes

Quality of life (QOL): The aim will be to describe what aspects of QOL are affected, and to what extent, if any, QOL is improved in the Intervention group. QOL will be measured using the 36- item short form health survey (SF-36) and the EuroQol -5 dimension - 5 level (EQ-5D-5L) instruments. The SF-36 is the most widely used measure of general health.[23] EQ-5D-5L is a 5-level version of the widely used EQ-5D scale. EQ-5D-5L is cognitively undemanding and takes only a few minutes to complete; it is potentially ideal for the RACF population.[24] We will test the validity and acceptability of using the EQ-5D-5L, relative to the SF-36, in the RACF setting.

Measures of balance and gait will be taken, as these have been identified as potential risk factors[9] for falls, that may be remediable with exercise.[7,12] The Short Physical Performance Battery (SPPB)[25] will be used to evaluate balance, gait, strength, and endurance. The Step Test[26] will be used to assess dynamic balance and agility.

The University of Alabama, Birmingham Life-Space Assessment will be used to assess extent of mobility and frequency of movement.[27,28] The scores represent how much an individual actually mobilizes over a 4-week period (rather than the distance that they are capable of).

Fear of falling will be measured using the Falls Efficacy Scale International (FES-I),[29] which evaluates confidence in avoiding falls when performing basic activities of daily living, and has been shown to maintain good measurement properties in persons with or without moderate cognitive impairment and, when administered in an interview format, in frail older persons.[30]

Cognition will also be assessed, as cognitive impairment has been identified as a risk factor for falls.[31] A recent systematic review and meta-analysis of the effects of exercise training on older people with cognitive impairment and dementia found that training resulted in improvements in health-related physical fitness and cognitive function.[32] Cognitive status will be measured using the Addenbrooke's Cognitive Examination Revised (ACE-R), a brief cognitive test that assesses five cognitive domains: attention, memory, verbal fluency, language, and visuospatial abilities.[33]

Intervention (SUNBEAM program)

Participants allocated to the Intervention group will perform an exercise program, conducted in group settings (of approximately 10 participants) in two stages during the 12-month trial period. The first stage (0–6 months) will comprise of progressive resistance (strength) training, with static and dynamic standing balance exercises.[7,11,34,35] The exercises will be prescribed, and supervised by an exercise professional, such as a physiotherapist or an exercise physiologist. An RACF staff member (diversional therapist or physiotherapy assistant) will cosupervise during this period, to help maintain safety. If there are several participants in an exercise group who demonstrate a need for close supervision (eg, lower cognitive functioning; very poor dynamic balance), an extra supervisor will be recruited.

The second stage (7–12 months) will consist of a maintenance program of resistance, weight-bearing balance, and functional exercises.[12] Each group will continue to be supervised by the RACF staff member who worked with the group during the initial intervention stage. Exercise doses for this stage will be prescribed by the exercise professional on completion of the initial training stage.

Stage 1 (0–6 months): PRT and balance exercise

PRT will target large muscle groups in the lower and upper limbs and trunk, using specialized pneumatic resistance equipment (HUR Australia Pty Ltd, Birkdale, QLD, Australia). Specifically, the resistance devices to be used include: knee extension, knee flexion (leg curl), abdominal curl, back extension, hip abduction, hip adduction, elbow and shoulder extension (dip), and leg press. Dosages will be individually prescribed, so as to enable each participant to achieve 2–3 sets of 10–15 repetitions of each exercise.[7,36] Dosages will be gradually adjusted as participants' abilities change throughout the course of the program.[12] If an individual has a specific comorbid condition that precludes them from safely using an item of equipment, a substitute exercise will be prescribed, using resistance bands to target the same muscle groups. Elbow and shoulder flexion exercises will be performed using resistance bands.

Balance exercises will include a combination of heel and toe raises, stepping in different directions, single leg standing, step-ups, and task-specific balance work (eg, reaching outward from the base of support while standing, sitting, and standing and turning). Balance exercises will be upgraded by: 1) reducing hand support and/or 2) narrowing the base of support, and/or 3) introducing a cognitive challenge (eg, counting backwards while performing exercise) or performing exercise with the eyes closed.[7,12]

Sessions will be of 1-hour duration, and will be conducted twice per week over a 6-month period.[7,12] After 6 months, the resistance training equipment will be moved to the next-included RACF of the Intervention group.

No structured or standardized sessions of education for falls prevention will be conducted during Stage 1. However, if a participant shows unsafe behavior during sessions (eg, wearing unsafe footwear; attempting to walk without mobility aid), the supervisory exercise professional will provide specific feedback that is consistent with standard practice and their duty of care.

Stage 2 (7–12 months): Maintenance exercise

A maintenance program that includes resistance exercise (using bands), balance, weight-bearing, and functional exercises will complete the remaining 6 months of the study. Participants will be asked to sign their names in a book at each visit, to record attendance. Sessions will be supervised by the RACF staff member (diversional therapist or physiotherapy assistant) who was involved in cosupervising the initial training sessions (Stage 1) and a volunteer, if deemed necessary by the exercise professional. The exercise program will include: 1) performance of the standing and sitting balance exercise at the level safely achieved by the end of the initial 6-month training, using a setup designed to optimize safety; 2) sit-to-stand exercises; and 3) resistance band exercises for the trunk and upper limbs (sitting or standing). Classes will be conducted twice per week for 30 minutes per session.

The total number of exercise sessions attended in both Stage 1 and Stage 2, as well as the exercises performed at each session by each participant, will be recorded. Acceptability will be determined by participant adherence to the program; information about acceptability will be determined by exit interviews.

Control group

Participants who are allocated to the control group will continue with usual care, without the introduction of the SUNBEAM program. Usual care may include activities, games, and hobbies, which will be recorded at each assessment.

Procedure

A list of all RACFs within northern New South Wales and South East Queensland was generated in 2012, by Internet searching and using local telephone directories. A letter was sent to each facility to invite expressions of interest. In addition, presentations were given by a research team member at relevant industry forums, to explain the trial objectives and protocol, and to answer any questions.

Staff at participating RACFs will use the inclusion and exclusion criteria to generate a list of eligible residents. All eligible residents will be informed by RACF staff that participants are being recruited for a long-term exercise study, to take place across multiple sites, and will be provided with a participant information sheet. Residents who consent to volunteer for the trial will be contacted by the research team, to organize final screening and a baseline assessment. Letters will be sent to potential participants' medical practitioners, to seek medical clearance. Each participant's next of kin (or enduring power of attorney) will also be advised, by mail, of the participant's consent to join the trial. After baseline measures are completed, the RACFs will be randomized (to receive either the SUNBEAM Program or usual care) by a researcher, independent of baseline assessment, using a computer-generated randomization schedule.

Falls will be recorded monthly for the duration of the trial. All other outcome measures will be taken at 6 months (ie, immediately post-intervention) and at 12 months, by assessors blinded to group allocation.

Residents of the first included RACF were recruited in August 2012. It is anticipated that recruitment will continue over the next 4 years.

Data analysis

Effectiveness of intervention

The primary analysis will be based on an intention-to-treat approach. This will be compared to per-protocol analyses. Summary outcomes will be presented at the cluster level, using standard measures. Analyses will also be conducted at the participant level, but adjusted appropriately for clustering of participants within RACFs, using mixed models. A logistic mixed model will be used to analyze the number of residents who fall during the study period (binary outcome). The number of falls (a count outcome) will be analyzed using a Poisson mixed model. To adjust for loss of follow-up, which may be significant in this cohort, a multilevel survival analysis will be conducted, with the outcome being time to first fall (and first fracture). All regression models will include the treatment group as an explanatory variable, and also a random effect for RACFs, to adjust for any clustering effects. Baseline characteristics will be compared between the two groups; any potential confounding factors that are found not to be balanced among groups, such as age, will be included as covariates in the regression models. Model assumptions will be tested, and appropriate adjustment to the analysis, such as logarithmic transformation of skewed variables, will be made as necessary.

Pre-specified subgroup analyses will be performed on the following variables: 1) level of care; 2) previous faller; 3) number of falls in the 12 months prior to inclusion, 4) program adherence, and dosage of exercise completed; 5) age; and 6) presence of other known risk factors for falls. Interactions between falls and ability to mobilize,[37] physical performance measures,[8] fear of falling, and QOL will also be examined.

Cost-effectiveness analysis

A recent Cochrane Collaboration review has identified a need for economic evaluation of falls prevention interventions.[34] A stepped cost benefit analysis will be undertaken, to examine the costs of providing the exercise program, and any cost offsets due to reduced health services use resulting from fall incidents. Program costs will include the capital cost of exercise equipment, the cost of any additional training material, and the costs of the exercise professional and supervisory staff. Health service use during the 12-month trial period will be determined from monthly auditing of RACF records, to extract data specific to fall incidents; these will include: 1) any medical services utilized, such as medical practitioner visits; 2) transfers to hospital; 3) hospital admissions; 4) number of nights admitted; 5) procedures performed; 6) follow-up visits; 7) rehabilitation; and 8) pharmaceutical drug usage. The total health service costs will be derived by multiplying the units of resource used by the relevant factor: the Australian Government's Medicare Schedule Benefit item fee, Pharmaceutical Benefits Scheme price, or the Australian Refined Diagnosis-Related Group cost.[38,39,40]

An incremental cost-effectiveness ratio will also be calculated, relative to the control group, as cost per quality of life year gained. To perform this analysis, the health benefits associated with the program will be estimated using the SF-36. A preference-based single utility measure, using Australian preference weights, will be derived from SF-36 using the Short Form-6 Dimensions (SF-6D) as described by Norman et al.[41] A supplementary analysis using the EQ-5D-5L will also be conducted.[42] A within-trial time horizon will form the base case analysis. Extrapolations beyond the trial period (eg, a 5-year time horizon) will be based on various assumptions about the sustainability of the treatment effect. Sensitivity analyses will be undertaken, to explore the robustness and validity of the cost-effectiveness data, and to test any assumptions used in the economic model.

Sample size

The study has been powered with respect to the primary outcome: falls. It is estimated that approximately 60% of participants in the usual care group will sustain at least one fall during the 12 months of follow-up.[8] Meta-analysis of pooled community and residential aged care studies of incorporating high-dose exercise (>50 hours) and high level balance training have demonstrated a reduction in fall rates of 38%.[12] The intervention in this study will contain these components, but will be specific to residents of RACFs. Assuming that participation reduces the proportion of falls and fallers, the exercise program will be considered successful if, at 12 months after randomization, only 40% of the intervention group have fallen – an absolute difference of 20%.

Twenty RACFs (clusters) will be recruited, with outcomes to be collected for an average of 15 residents per facility. Several studies of RACFs[11,43] indicate that the intracluster correlation coefficient (ICC) is close to zero (<0.01). ICCs for clinical and physical activity variables ranged between 0–0.08 in three cluster trials of residential health care.[43] With a zero ICC, we would need to recruit 194 residents of RACFs, in order to detect a 20% difference, with 80% power, at a 5% two-sided significance level. We will recruit 300 residents, to allow us to detect a 20% absolute difference, with 80% power, if ICC =0.01, allowing for a conservative 25% dropout (given the participants' ages and the presence of comorbid conditions).

Discussion

Despite a plethora of research into the area of falls prevention, there is little conclusive evidence available to show effective ways of reducing falls in adults in residential care. This trial utilizes an intervention that has been proven to be effective in community-dwelling older people, and tests whether these results can be extrapolated to the residential care setting within a more supervised and supported environment. If the intervention is shown to be effective, there is potential for this study to have both immediate and long-term impact, in terms of benefits to older individuals, and decreased direct health care costs.

For older people living in RACFs, potential direct benefits of this exercise program are reduced probabilities of falling and the sequelae of falls, such as increased mortality, morbidity, injury, hospitalization, and loss of confidence, along with reduced mobility and reduced quality of life.

For the health care system, fewer fall-related hospital admissions will reduce costs to society, and help to improve access to hospitals. Benefits for health departments will be realized if the exercise program is cost-effective, and if the program is accepted by RACFs and their residents.

Finally, the intervention is simple for RACFs: it can be rolled out easily, to have far-reaching impact. Its implications may include reducing the health care burden of falls, improving the well-being of residents of RACFs, and contributing to the health policy debate, by challenging current residential aged care funding models.

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Disclosure

None of the authors has any actual or potential conflict of interest to disclose, including any financial, personal, or other relationships with other people or organizations that could inappropriately influence this work.

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Chapter 4

Progressive resistance and balance training for falls prevention in long term residential aged care: A cluster randomised trial of the Sunbeam Program

Preamble

Chapter 4 presents the results of the cluster randomised controlled trial, focussing on the primary outcome, falls rate. The work included in this chapter has been accepted for publication in the Journal of the American Medical Directors Association and formatting reflects the publishing requirements of that journal (Appendix 2). Chapters 5 and 6 present the secondary outcomes of the trial in more detail.

Progressive resistance and balance training for falls prevention in long term residential aged care: A cluster randomised trial of the Sunbeam Program

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Progressive resistance and balance training for falls prevention in long term residential aged care: A cluster randomized trial of the Sunbeam Program.

Abstract

Background: Falls prevention is an international priority, and residents of long term aged care fall approximately three times more often than community dwellers. There is a relative scarcity of published trials in this setting.

Objectives: Our objective was to undertake a randomized controlled trial to test the effect of published best practice exercise in long term residential aged care. The trial was designed to determine if combined moderate intensity progressive resistance and balance training (the Sunbeam Program) is effective in reducing the rate of falls in residents of aged care facilities.

Method: A cluster randomized controlled trial of 16 residential aged care facilities and 221 participants was conducted. The broad inclusion criterion was permanent residents of aged care. Exclusions were diagnosed terminal illness, no medical clearance, permanent bed- or wheelchair-bound status, advanced Parkinson's Disease or insufficient cognition to participate in group exercise. Assessments were taken at baseline, after intervention and 12 months. Randomization was performed by computer-generated sequence to receive either the Sunbeam program or usual care. A cluster refers to an aged care facility.

Intervention: The program consisted of individually prescribed progressive resistance training plus balance exercise performed in a group setting for 50 hours over a 25- week period, followed by a maintenance period for 6 months.

Outcome Measures: The primary outcome measure was the rate of falls (falls per person year). Secondary outcomes included physical performance (Short Physical Performance Battery), quality of life (SF-36), functional mobility (University of Alabama Life Space Assessment), fear of falling (Falls Efficacy Scale International) and cognition (Addenbrooke's Cognitive Evaluation – revised).

Results: The rate of falls was reduced by 55% in the exercise group (IRR = 0.45 (95% CI 0.17 to 0.74), an improvement was also demonstrated in physical performance ($p = 0.02$). There were no serious adverse events.

Conclusion: The Sunbeam Program significantly reduced the rate of falls and improved physical performance in residents of aged care. This finding is important as prior work in this setting has returned inconsistent outcomes resulting in best practice guidelines being cautious about recommending exercise in this setting.

This work provides an opportunity to improve clinical practice and health outcomes for long term care residents.

Introduction

A dramatic increase in life expectancy ranks as one of society's greatest achievements. People aged 85 or older now constitute 8% of the world's population, this figure is projected to increase by 351% by 2050.[1] A comprehensive, global public-health response to population aging is recommended to transform systems and align them with the population they will serve.[2] The World Health Organization has warned that continuing current public health responses will be insufficient to cater for the needs of the aging population, and highlighted falls prevention among older people an international priority.[1] Falls are the most common cause of injury-related death and fracture,[3] and are estimated to cost the health economy more than any other form of trauma, including motor vehicle accidents.[4] Fall rates increase with advancing age. Figures estimate that 30% of community-dwelling older people aged 65 years or older and 50% of those aged over 85 years fall each year.[4,5] These figures have remained largely unchanged for decades.[6] Those in long-term aged care fall approximately three times more often,[5] and falls are the main cause of preventable deaths in this setting.[3]

The risk of falling may be predicted from a number of risk factors, including: age; sex; visual impairment; vitamin D deficiency; foot pain; incontinence (particularly urgency); poor nutrition; psychoactive medications; cardiac arrhythmia, cognitive impairment; Parkinson's Disease; stroke; reduced lower limb muscle strength, and impaired balance and gait.[5,7-10] Trials have been conducted to explore the effectiveness of a range of strategies to address these factors and most research into falls prevention focuses on community-dwelling older adults.[5,9] Interventions that are effective in reducing falls in community-dwelling adults do not all have the same effect in residential care.[9,11] For example, exercise as a single intervention[8] prevents falls in older community-dwellers[7,10,11] however, this result is not consistently demonstrated in residential care.[5,12] A Cochrane review analyzed pooled data from trials in this setting: two demonstrated a reduction in fall rates; two showed no change in falls; and data from four studies returned an increase in fall rates. Authors were therefore unable to determine the value of exercise for falls prevention in residential care and such programs were subsequently abandoned by multiple aged care institutions worldwide.[13]

It is possible that inconsistent falls outcomes in these trials related to the type and dosage of exercise implemented. For community-dwelling adults, a set of key components for successful falls prevention exercise programs has been identified and form current best practice guidelines.[9,10] These include a combination of:

high challenge balance training; moderate to high intensity progressive resistance training for those who are deconditioned; and a total of at least 50 hours of exercise over 25 weeks. None of the trials included in the Cochrane Review in residential care incorporated each of these components.[5] This study therefore reports on a trial designed to test the efficacy of an exercise program formulated using these key elements in a residential care setting. We tested the hypothesis that the falls rate and number of falls would be reduced in the group allocated to receive the program compared to usual care. Secondary outcomes (physical performance, quality of life, functional mobility, fear of falling, cognition) were also hypothesized to improve.

Material and Methods

A pragmatic cluster randomized controlled trial was performed to compare exercise with usual care in 16 long-term residential aged care facilities in New South Wales and Queensland, Australia. A cluster refers to a residential aged care facility. Ethics approval was granted by The University of Sydney Human Research Ethics Committee (Approved protocol 14995). The published protocol[14] can be found at http://dx.doi.org/10.2147/CIA.S53931 and is registered with the Australia and New Zealand Clinical Trial Registry (Registration number: ACTRN12613000179730).

Included facilities were those that: housed a mix of high care residents (who require daily care by, or under the supervision of, a registered nurse) and low care residents (who need some assistance but do not have complex health care needs); and would allocate staff time to assist with recruitment and exercise supervision should the facility be randomized to the intervention.

Residents were recruited prior to cluster randomization and were eligible for inclusion if they were aged at least 65 years, permanently residing in care, and understood sufficient English to comprehend the participant information statement and complete the consent form. Exclusion criteria were: a diagnosis of a terminal or unstable illness; medical clearance for participation denied; having participated in a similar resistance and balance training program in the previous 12 months; deemed unable to participate safely in a group gym-based exercise program for the following reasons: permanently bed- or wheelchair-bound; advanced Parkinson's Disease (where symptoms precluded safe inclusion in group exercise) ; insufficient cognition (defined as ≤15/30 using the Mini-mental State Exam, MMSE).[15] Written consent was provided by facility management, individual participant consent was obtained in writing from each participant and an enduring power of attorney, if directed by management. Facilities were identified using local telephone registries and internet searches, and a mailed invitation and telephone contact was made to invite participation. Facilities were recruited in pairs and baseline data were collected on participants from both facilities prior to randomization. A research investigator not involved in baseline assessment measures or recruitment of facilities (SG) used a computer-generated algorithm (in Microsoft Excel) to randomly assign facilities (1:1) to receive either the intervention or no intervention (usual care). Facilities were stratified by size (number of beds) and proportion of low and high care residents. Results of the randomization were passed onto a research team member (JH) who liaised directly with facility management and organized the gymnasium equipment to be delivered to the facility randomized to receive the intervention.

Falls outcomes were measured by auditing incident records kept as standard practice in all facilities. The process of recording falls incidence was a routine already existing within the facilities prior to their involvement in the study. Secondary outcomes were measured by assessors blinded to group allocation, blinding of participants was not possible however due to the nature of the intervention.

Participants allocated to the intervention performed an exercise program in a group setting of up to 10 participants supervised by two trained staff (either a physiotherapist (PT) and activities officer (AO) from the facility, or two AO). The trial period was 12 months which consisted of 25 weeks performing the intervention (Sunbeam Program) followed immediately by a maintenance program for 6 months.

The Intervention: *Stage 1 The Sunbeam Program (0-25 weeks)*

The Sunbeam program consisted of individually prescribed progressive resistance training (PRT) plus balance exercise performed for one hour twice per week over for 50 hours[9,10,16,17] (Figure 1). PRT targeted large muscle groups using pneumatic resistance equipment that resisted both concentric and eccentric contractions throughout range and had the capacity to be progressed by increments of 100 grams (HUR Health and Fitness Equipment). The devices selected were predominantly for lower limb exercise plus one each for the upper limbs and the trunk (Figure 1). Exercises were run in a circuit, as each participant completed one exercise s/he moved onto the next free exercise station. An exercise station was either a HUR device or a balance station that consisted of a chair or table with a card describing the exercise and a second chair behind for safety (Figure 1). Dosage was individually prescribed by a PT trained in the use of the equipment and the balance exercise protocol. Dosage was prescribed to accommodate comorbidities and minimize the risk of harm. Participants were asked to achieve 2-3 sets of 10-15 repetitions for each exercise at a self-determined “moderate” intensity, defined as 12-14/20 using the Borg Scale of Perceived Exertion.[9,10,18] Dosage was reviewed fortnightly and gradually adjusted by the PT as participants' abilities changed throughout the course of the program. The ratio of leaders: participants was 1: 5, when there were more than 10 participants in a cluster, a second class was run with a smaller group. Participants requiring more assistance due to physical, cognitive or behavioural impairment were scheduled to attend the smaller session.

Balance exercises included a combination of complex static and dynamic balance exercises performed with close supervision to maximise safety. All balance exercises were progressed by: reducing the base of support or hand support; increasing the speed of the activity; and/or performing the action with the eyes closed (Figure 2). Relevant stretches were performed on completion of each session. A total of 50 hours of exercise was offered at each cluster allocated to the intervention group, scheduled as two, one-hour sessions per week over a 25-week period.[9,10] Participants were advised to expect some degree of delayed onset muscle soreness as a normal response to unaccustomed exercise. Physiotherapists monitored reported symptoms closely and if necessary modified exercises by adjusting the dosage or range of motion performed on the gym equipment, or providing alternative exercises targeting the same muscle groups (Figure 1).

Figure 1. Resistance exercises and progression schedule used in Stage 1.

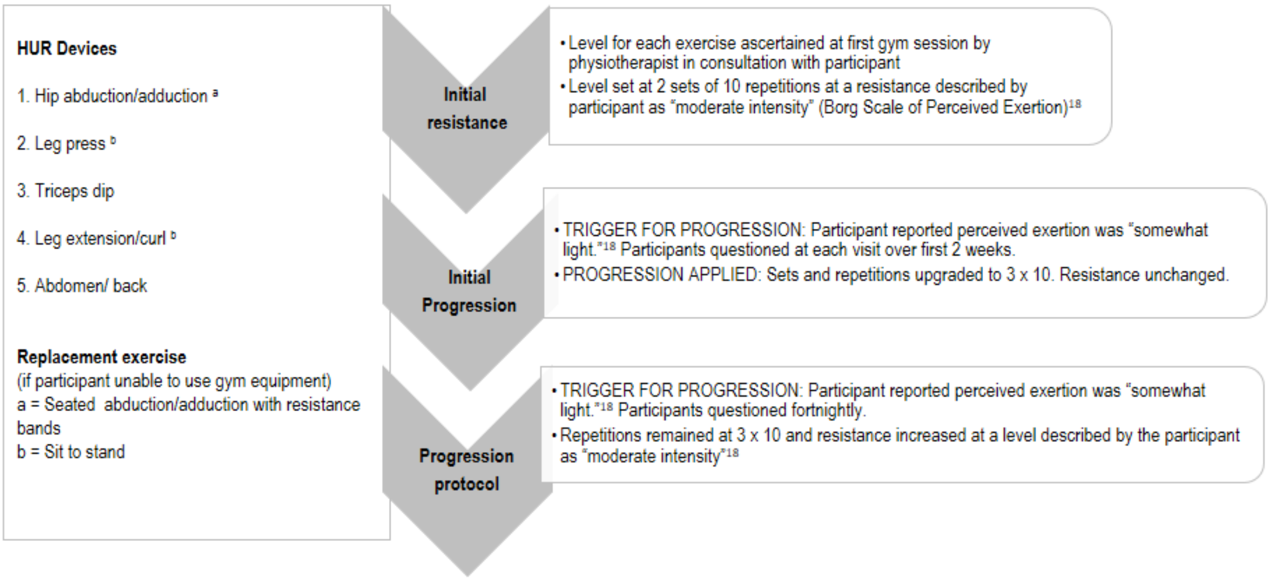
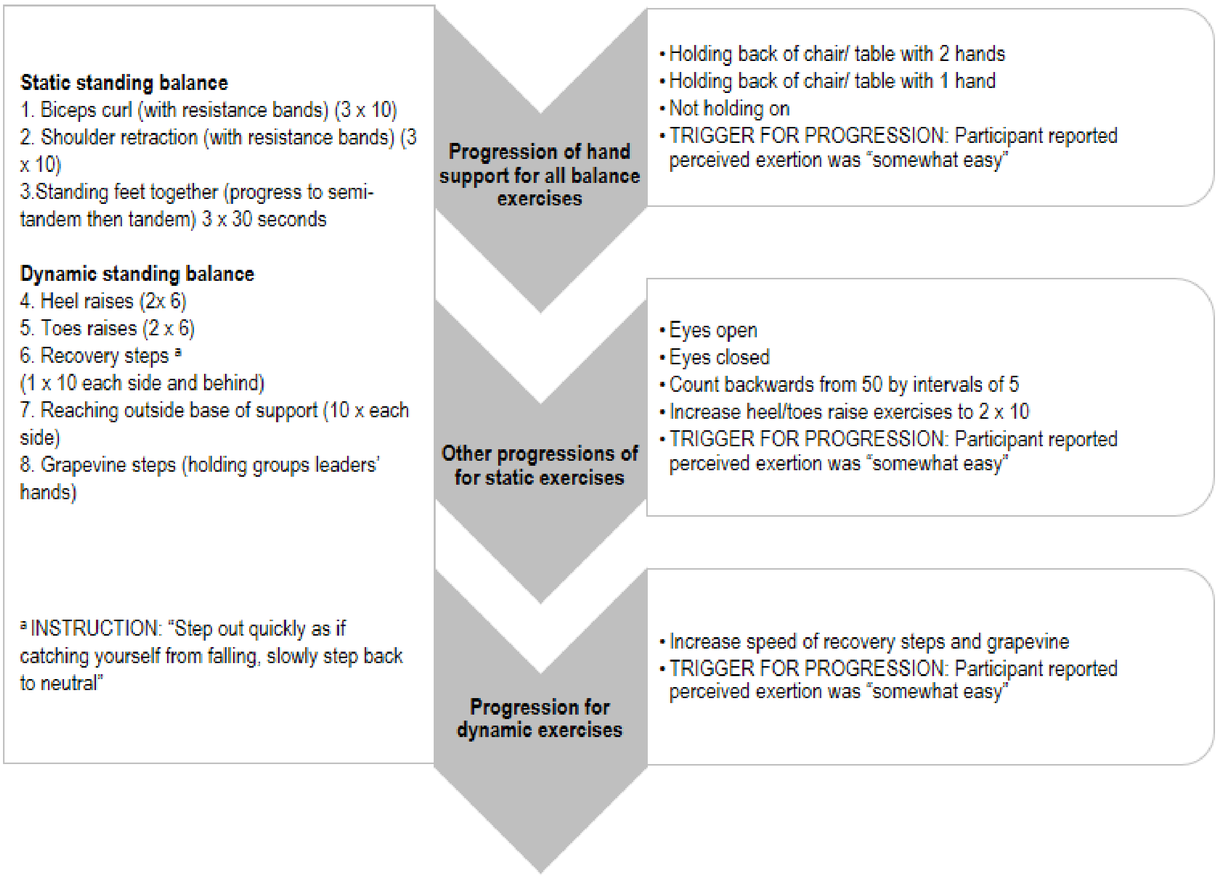


Figure 2. Balance exercises and progression schedule used in Stage 1.



Stage 2 The Maintenance Program (7-12 months)

The maintenance program included resistance, weight bearing balance and functional group exercise sessions.[9,10,16,17] These were conducted twice weekly for 30 minutes by trained facility staff or volunteers. Dosage was not progressed during the maintenance period (Figure 3).

Figure 3: Maintenance exercises used in Stage 2.

Class performed at tables with a chair behind each participant for safety. No progression of sets or resistance prescribed.

- Standing biceps curl (bilateral with resistance bands) 3 x 10
- Standing heel raises 2x10
- Standing toe raises 2x10
- Standing shoulder retraction + elbow extension (bilateral with resistance bands) 3 x 10
- Sit to stand (2x10)
- Static balance (feet side by side) (30 seconds)
- Static balance (feet semi-tandem) (30 seconds each leg)
- Static balance (feet tandem) (30 seconds each leg)
- Recovery step [a] – left foot. Step back fast and slow return to neutral (1x10)
- Recovery step [a] – right foot. Step back fast and slow return to neutral (1x10)
- Recovery step [a] – Step to the left side fast and slow return to neutral (1x10)
- Recovery step [a] – Step to the right side fast and slow return to neutral (1x10)
- Reaching left – 1 x 10. Reaching right 1 x 10
- Standing, turn to look left 1 x 5. Turn to look right 1 x 5
- STRETCHES (Seated) calf/hamstring stretch, bicep/shoulder/wrist flexors. Each held for 30 seconds

Usual Care

Participants in clusters allocated to "usual care" continued with their regular activity schedule without the introduction the program described above.

Data were collected for both groups at baseline, 6 months and 12 months by blinded assessors. In addition to falls data, a range of demographic variables and known risk factors for falls were recorded[8] (Table 1). The primary outcome was the rate of falls captured by the number of falls for each participant during the 12-month trial period and the (days) they were followed up. The definition of a fall was "an unexpected event in which the participant comes to rest on the ground, floor, or lower level.[19] Prior to the study, staff at all facilities had routinely kept records of all falls experienced by residents, these records were audited monthly throughout the trial period. A faller was defined as a person who fell at least once during the follow-up period.[19]

Secondary outcomes included: quality of life (measured using the Short Form-36,[20] SF-36, and the EuroQuol-5 Dimensions-5 Levels, EQ-5D-5L);[21] physical performance (Short Physical Performance Battery -SPPB);[22] functional mobility (The University of Alabama – Life Space Assessment UAB-LSA);[23] fear of falling (Falls Efficacy Scale – international - FES-I);[24] and cognition (Addenbrooke's Cognitive Examination-Revised).[25]

Statistical Analysis

Analyses were carried out using a pre-defined analysis plan[14] on an intention-to-treat basis whereby participants were analysed according to the group they were assigned, irrespective of whether they participated in the intervention (intervention group). All statistical tests were two-sided and p values were considered significant when less than 0.05. Analyses were conducted using Stata Software (StataCorp LP. College Station, Texas versions 13). An *a priori* sample size calculation was based on a demonstrated reduction in fall rates of 38% with exercise intervention, in a mixed community and residential aged care setting.[9] We therefore calculated that we needed to recruit 16-20 clusters and 194 residents to allow us to detect a 20% absolute difference with 80% power if the intra-cluster correlation coefficient was 0.01 (β=0.20, α=0.05). To allow a conservative 25% drop-out, given the participants' age and presence of comorbid conditions we planned to recruit 300 residents. A lower drop-out rate would require lower participant numbers to maintain 80% power. The primary outcome was fall rate and was analyzed using negative binomial regression to estimate the difference between the two groups. Length of follow up was included as an exposure term in the models. Baseline characteristics were compared between the two groups; any potential confounding factors found to be imbalanced between groups were included as covariates in the regression models. Model assumptions were tested and appropriately adjusted in the analysis. Secondary analyses were also conducted to compare the proportion of fallers in the two groups (using modified Poisson regression models), and to compare group rates of the number of: falls during the intervention period; falls during the follow up period; injurious; and non-injurious falls. Clustering was adjusted for using a random effect for cluster.

For the physical performance measure (SPPB) linear regression models were used to compare the groups. This approach was also used for continuously scored secondary outcome measures. A score of 0 was given if participants were unable to carry out a test due to physical impairment. Pre-specified subgroup analyses were performed on the following variables: level of care, previous faller, number of falls in the 12 months prior to inclusion, adherence and dosage of exercise completed, age, and presence of other known falls risk factors including; gait disturbance, psychotropic medication prescription, diagnosis of syncope and/or visual impairment. All models included the experimental group as a covariate in the model, with clustering adjusted for using mixed models, with a random effect for cluster. Effect size was calculated using Hedges' Cohen's d post estimating.

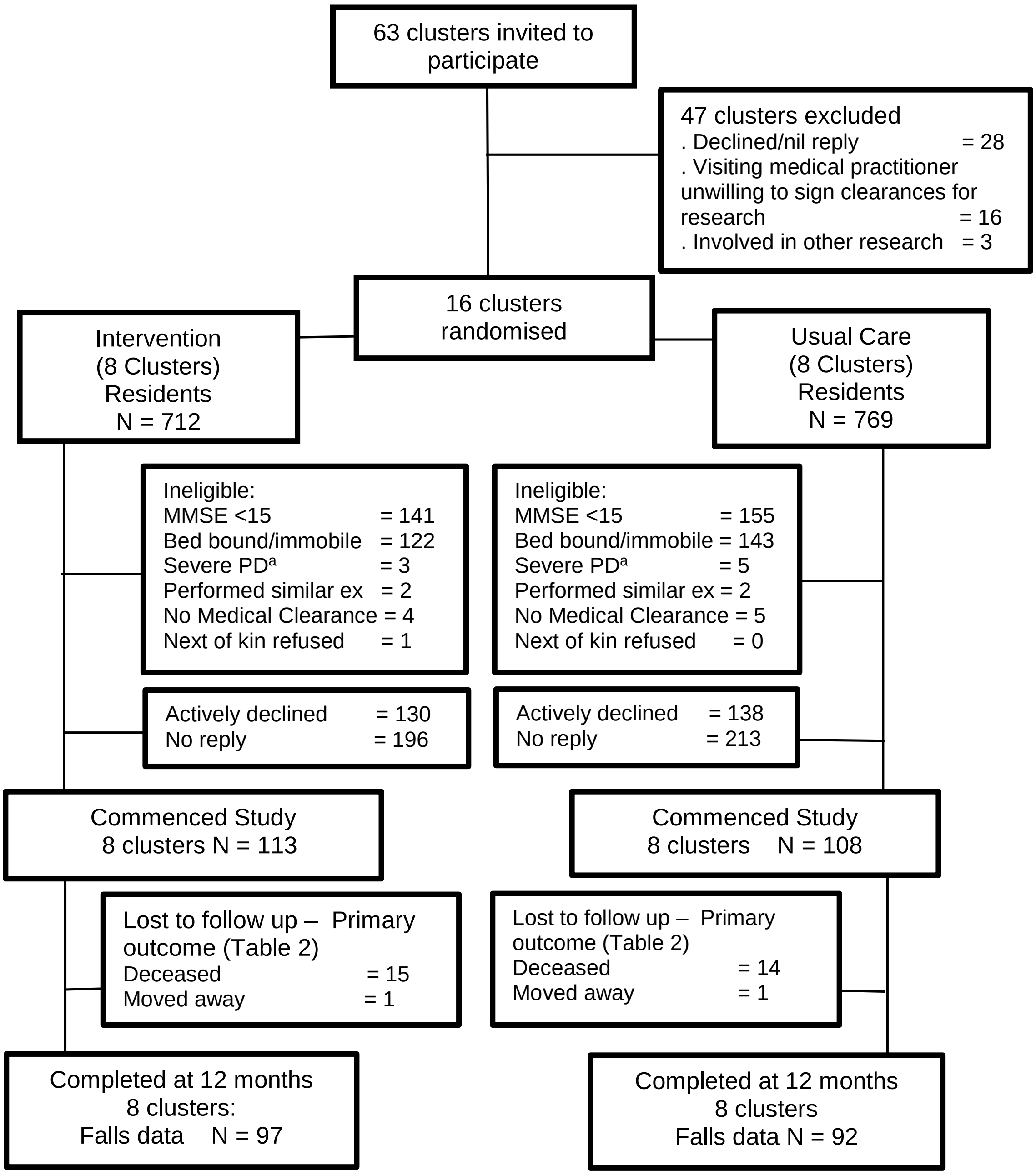
Results

Facilities were recruited between 30th June 2012 and 17th February 2015. Participants were recruited between 31st July 2012 and 18th March 2015. Figure 4 shows the flow of participants through the study. Sixteen clusters with 221 participants were randomized to one of the two groups: 8 clusters (113 participants) to the intervention group and 8 clusters (108) participants to the usual care group.

Clusters were recruited in pairs (1:1), baseline data were collected on participants from both clusters prior to randomization. Of 63 residential aged care facilities contacted, 28 declined or did not respond, the medical practitioner attending 16 facilities in the study location was unwilling to sign clearance for research, and 3 facilities were involved in other research. Sixteen facilities met the eligibility criteria and were randomised to the intervention (8 clusters) or usual care (8 clusters). In total this included 1481 residents. The major reasons for excluding residents were: cognitive ability (n=296); being permanently bed-bound/immobile (n= 265); severe Parkinsonian symptoms that rendered them unable to join group gymnasium sessions (n=8); had performed similar exercise in the previous 12 months (n=4); medical clearance declined (n=9); or Enduring Power of Attorney declined signing consent (n=1). Of the 898 eligible residents, 268 declined to participate in the trial, a further 409 did not respond to their invitations, leaving a total of 221 residents who volunteered to participate.

Loss to follow up for the primary outcome was 15 in the intervention group (13.3%) and 16 in the usual care group (1 4.8%). The predominant reason for loss to follow-up was death (n = 29) or moved to other aged care facilities (n=2). The loss to follow-up was similar in both groups (intervention n=16, usual care n=15) and the combined total loss to follow up for the falls outcome over the 12-month trial was 31 (14.0%).

Figure 4: Trial Profile



[a] PD= Parkinson's Disease

Baseline characteristics

Both the exercise and usual care groups were found to be similar in terms of demographic descriptors and co-morbidities at baseline (Table 1). Mean age was 86 years (SD = 7.0), 65% of participants were female and 77% relied on a mobility aide for walking (walking stick 7%, wheeled walker 70%). Previous fall history is one of the most important predictors of incident falls, there were more falls and fallers in the intervention group

(189 falls by 69 fallers) than in the usual care group (114 falls by 54 fallers) in the 12 months prior to baseline, which may have been clinically relevant however, these differences were not statistically significant (p = 0.08).

Characteristic	Intervention Group (n= 113)	Usual Care Group (n= 108)
Age	Mean 86 (65-100[a])	Mean 86 (65-99[a])
Female	71 (62·8%)	73 (68.2%)
Male	42 (37·2%)	34 (31.8%)
Months in RACF	22.9 (7·6 [b])	26.9 (24.6[b])
Falls in prior 12 months	189	114
Fallers	69 (61.0%)	54 (50.5%)
Uses mobility aide	86 (76.1%)	86 (80.3%)
High Care Status	61 (54%)	54 (50%)
Diagnosed co-morbid conditions associated with increased falls risk:		
Anxiety and depression	56 (49.6%)	31 (28.7%)
Cardiac disease	54 (47.8%)	47 (43.5%)
Cerebrovascular Disease/Stroke	21 (18.6%)	21 (19.4%)
Cognitive Impairment	63 (55.8%)	45 (41.7%)
Foot pain	35 (31.0%)	33 (31.0%)
Hypertension	69 (61.1%)	60 (55.6%)
Incontinence	30 (26.6%)	17 (15.9%)
Parkinson's Disease	3 (2.7%)	0 (0.0%)
Visual Impairment	38 (33.6%)	29 (27.1%)
Wears multi-focal glasses	11 (9.8%)	13 (12.2%)
Psychotropic medication use	10 (8.8%)	15 (14.0%)
Regular exercise:		
Walking	53 (46.9%)	41(38.3%)
Seated range of motion or aerobic exercise	28 (24.8%)	28 (26.1%)
Standing exercise	5 (4.4%)	10 (9.3%)
Other (eg. swimming)	2 (1.8%)	1 (0.9%)
NIL	25 (23.4%)	27 (25.2%)

Falls

Table 2 presents a summary of falls-related outcomes. There was a significant reduction of 55% in the rate of falls for those in the Sunbeam Program, with an incidence rate ratio (IRR) of 0.45 (95% confidence interval (CI), 0.17 to 0.74). This is equal to an overall incidence of falls in the Sunbeam program of 1.31 per person-years, compared with 2.91 in the usual care group. Throughout the 12-month follow up period 142 falls were recorded in the intervention group and 277 in the usual care group. There was a 60% reducing in falls during the intervention period and a 40% reduction in falls during the maintenance period. Median length of follow up for all participants was 365 days (range 29 – 365, interquartile range 365-395). There were fewer fallers in the intervention group (n=52, 46%) than in the usual care group (n=74, 69%). Participants in the usual care group were more likely to have multiple falls. There were 72 injurious falls (fracture, laceration, pain, bruising) in the intervention group and 157 injurious falls in the usual care group. This represents a significant reduction of

54% in the rate of injurious falls in the intervention group (IRR = 0.46). There were similar numbers of fractures in each group (5:6, intervention: usual care).

Table 2: Falls Outcomes

	Intervention Group 8 clusters, 113 participants	Usual Care Group 8 clusters, 108 participants
Falls rate [a]	1.31 falls per-person-year	2.91 falls per-person-year
Total number of falls	142	277
Number of Fallers (one or more falls)	50	73
Number that fell ≥5 times	9	20
Number of Injurious falls [b]	72	157
Number of ambulance attendances	17	41
Number transported to hospital	9	19
Number of fall related fractures	5	6

a Negative binomial regression, analysed at participant level and adjusted for clustering.

[b] Falls resulting in documented pain, bruising, laceration or fracture

Secondary outcomes

A summary of secondary outcome measures can be found in Table 3. The loss to follow up for secondary outcomes was higher than for the falls outcome and was attributed to participants refusing repeated measures due to: the extended time required to complete the assessments (ACE-R and SF-36, each took > 20 minutes); or a deterioration in sight, hearing or dysphasia rendering them unable to complete the assessments. A significantly greater improvement was found in physical performance (SPPB) in the intervention group than the usual care group at 12 months ($p = 0{\cdot}02$).

Table 3: Secondary Outcomes

	SUNBEAM program		Control group		Comparison of groups	Effect size[a]
	N	Mean score (SD)	N	Mean score (SD)		
Physical functioning						
SPPB[b]						
Baseline	112	5.16 (2.57)	105	4.30 (2.90)	F(2,168) =23. 25 P=0.019	0.56
6 months	100	5.89 (2.86)	93	3.76 (2.74)		
12 months	93	5.81 (3.02)	86	4.13 (2.92)		
UAB_LSA[c]						
Baseline	113	34.56 (18.56)	105	30.06 (15.94)	P=0.667	0.22
6 months	99	44.07 (19.81)	89	39.51 (20.06)		
12 months	94	41.72 (22.37)	85	36.91 (21.18)		
Mental Functioning						
Fear of Falling (FESi)						
Baseline	112	27.75 (10.08)	103	31.28 (13.03)	P=0.443	0.06
6 months	97	27.09 (8.65)	85	30.67 (10.76)		
12 months	91	30.01 (9.67)	79	30.57 (9. 69)		
ACE-R[d]						
Baseline	100	71.45 (14.46)	95	72.11 (15.36)	P=0.765	0.11
6 months	83	73.34 (15.54)	77	74.61 (15.69)		
12 months	72	73.78 (16.66)	70	75.41 (13.56)		
Quality of Life						
SF-36 – Physical						
Baseline	108	58.50 (20.83)	102	56.99 (19.46)	P=0.765	0.13
6 months	94	69.56 (18.27)	85	65.62 (21.23)		
12 months	88	68.39 (20.25)	80	65.88 (18.69)		
SF-36 Mental						
Baseline	108	70.14 (18.38)	102	71.16 (15.74)	t P=0.770	0. 01
6 months	94	76.34 (17.88)	85	73.75 (18.06)		
12 months	88	74.19 (20.82)	80	74.48 (17.38)		
SF-36 Total						
Baseline	108	65.72 (18.30)	102	64.96 (16.98)	P=0.433	0.13
6 months	94	74.52 (17.13)	85	71.64 (19.09)		
12 months	88	74.66 (18.51)	80	72.43 (16.60)		
EQ 5D 5L Baseline	113	0.70 (0.27)	105	0.68 (0.30)	P= 0.576	-0.07
6 months	99	0.83 (0.22)	86	0.84 (0.19)		
12 months	94	0.85 (0.18)	82	0.83 (0.23)		

Points rage for each outcome measure: a. Hedges' Cohen's d post estimating in Stata b. Short Physical Performance Battery 0-12; c. University of Alabama Birmingham -Life Space Assessment 0-120; d. Addenbrooke's Cognitive Evaluation-Revised 0-100; SF-36 0-100. Higher score = improvement. Fear of falling 16-64. Lower score = improvement.

Adverse events

Group leaders were trained to record any adverse events that occurred during exercise. Three participants in the clusters assigned to the intervention reported short-term musculo-skeletal aches and pains that settled quickly and did not interfere with continuing the program. One participant incurred a non-injurious fall during a session. No serious adverse events occurred (cardiac incidents, stroke, injurious falls during exercise, soft tissue injuries).

Attendance

During Stage 1, 54% of participants attended at least 30 hours (60%) of exercise with the mean dosage being 31.6 hours (SD 14.3). The main reasons for non- attendance were: declining to attend (13.8% of available sessions), co-morbid condition (10%), and acute illness (8.1%). Figure 5 displays the proportion of sessions attended for each month of Stage 1. Approximately 80% of sessions were attended in the first month of the program. Attendance declined to approximately 60% during months 4 and 5 then rose again in the last month of Stage 1. Figure 6 displays attendance during the Maintenance Program. Attendance rates were poor during this period, ranging from 51%-31% of available sessions.

Figure 5. Attendance during Sunbeam Program - Stage 1

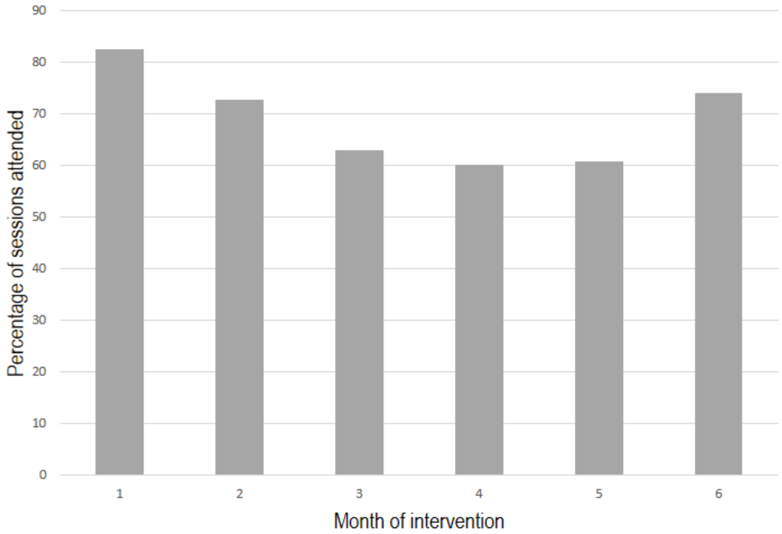
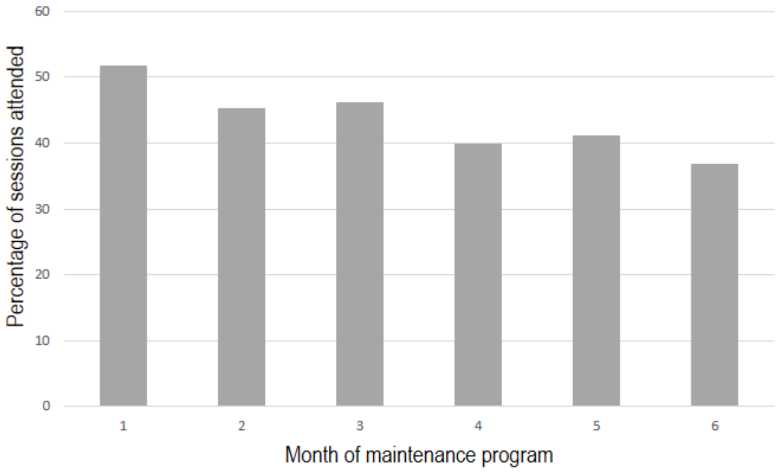


Figure 6. Attendance during Stage 2 - Maintenance program



Discussion

This study found the exercise program reduced both falls and fall rates in residential aged care. A 31% fall rate reduction has been previously described as clinically important.[13,26] The exercise program in this trial achieved a 55% fall rate reduction, a greater reduction than for any previous intervention in a residential aged care setting, potentially because it is the first to implement the published key components and dosage of successful falls prevention exercise programs.[9,10] Physical performance also improved significantly ($p = 0{\cdot}02$). Outcomes differ from previous research that employed the use of seated, range of motion, light resistance or simple walking programs. The intensity of the PRT in this trial, that is, 2-3 sets of 10-15 repetitions for each exercise at a perceived intensity of "moderate" using the Borg Scale of Perceived Exertion,[18] also differs from prior research that advocated more intense training.[26] In accordance with the dosage recommended in best practice guidelines,[10] 50 hours of progressive resistance training and balance exercise (Stage 1) were provided and followed by 6 months of maintenance exercise (Stage 2), however, few participants achieved the 50 hours in Stage 1 (median 36 hours). To test adherence, hours of exercise was entered into the negative binomial regression model as a covariate, finding that ≥30 hours of exercise during this stage was associated with improved falls outcomes ($p < 0{\cdot}002$). A dose of 30 or more hours of this type of exercise over a 25-week timeframe may therefore produce similar outcomes to the higher doses previously recommended.

Attendance was variable during the first 25 weeks of the program but ranged from 81%-56% of available sessions. The last month of Stage 1 saw an increase in attendance that may have been related to participants choosing to spend time attending the classes in their known format using both gym equipment and physiotherapy involvement. Attendance during the Maintenance Program were relatively poor, ranging from 51%-31% of available sessions. Apart from the initial guidelines given to participants and the facilities about the ongoing maintenance exercise program, there was no further guidance from the research team or physiotherapists during this stage. Given that this was a pragmatic trial, we expected there to be differences in how each facility embraced the continuation of the program. During the intervention period there were 58 falls in the intervention group and 139 falls in the control group, a 60% reduction. During the maintenance period there were 85 falls in the intervention group and 142 falls in the control group, a 40% reduction. There appears to be a maintained benefit of the intervention provided in Stage 1 despite low attendance during the maintenance period. It is possible that greater benefit may be achieved by continuing the exercise program used in Stage 1 for longer than the 25-week protocol, this may be a meaningful direction for further research.

Other recommendations for future research include; incorporating the Sunbeam program into multi-faceted interventions that also target other risk factors for falls, testing the program on those excluded from this trial and further investigating secondary outcomes. Future research investigating the effects the Sunbeam Program with Vitamin D prescription may result in further reduced fall rates as there is evidence supporting the prescription of Vitamin D for falls prevention in this setting.[5] Measurement of serum Vitamin D levels was beyond the resources available to this trial, however, less than one third of our participants had been prescribed this medication at baseline (27% and 30% in the intervention and usual care groups, respectively) suggesting a divide between research and clinical practice. Approximately half (48.9%) the included participants had a diagnosis of mild to moderate cognitive impairment, however fall rates are reported to be higher for those with advanced cognitive decline.[27] It is recommended that future trials be conducted for those with higher levels of cognitive impairment, replicating this protocol but using additional support for supervision of the exercises. Finally, this trial returned no statistically significant improvements in quality of life or cognition, although there was a positive trend (Table 3). The lack of change may be explained by incomplete data with consequent reduced sample size for these outcomes, predominantly due to participants declining these repeated measures. Future research that includes fewer or shorter questionnaires may assist in clarifying the effects of the Sunbeam Program on these outcomes.

Careful consideration was applied to minimize sources of potential bias in this study however there were limitations. We calculated *a priori* that we needed to recruit 194 participants from 16-20 clusters, which was scaled up to 300 participants to allow for a 25% loss to follow up due to the advanced age of participants. At the end of the study we had recruited 221 participants in 16 clusters. The loss to follow-up was lower than anticipated (14%), therefore we retained 80% power and remain confident in the results. Falls incidents were recorded by care staff or registered nurses as standard practice for all residents (regardless of whether they were involved in the trial) at all included facilities. This process was a routine already existing within the facilities prior to their involvement in the study however, this method has been previously shown to underestimate falls, particularly non-injurious falls.[27] This method of capturing falls data has been widely used in prior research,[29,30,31,32,33] and incorporating multiple approaches to collecting falls data was beyond the resources available to this study. Future research incorporating wearable technology may assist in improving accuracy.

Of the 63 facilities and 898 eligible residents for this trial, 16 residential care facilities (25%) and 221 participants (24%) agreed to join the trial, potentially limiting the generalizability of outcomes. Similar participation rates have been reported previously in this setting.[34] The outcomes reported also relate to implementation of an exercise program utilising a gymnasium and physiotherapy input, this protocol is scalable however there may be barriers to the provision of these resources.

Conclusion

The key discovery from this research is that moderate intensity progressive resistance training and high- level balance exercise can significantly reduce falls and improve physical performance in residents of long term aged care facilities. When prescribed and upgraded by a suitably qualified allied health professional with consideration for co-morbid health conditions, adverse events performing the exercises can be avoided. This is the first trial in this setting to demonstrate a strongly significant finding of benefit compared to usual care. This finding is important as prior work has been relatively scarce and has returned poor and inconsistent outcomes[5] resulting in current best practice guidelines being cautious about recommending exercise in this setting[9-12] and some aged care facilities abandoning exercise as a falls prevention measure.[13] The work has important implications for the residential aged care sector as the intervention is relatively simple to roll out widely and provides an opportunity for improved resident outcomes, cost savings and a contribution to the health policy debate.

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Chapter 5

Analysis of secondary outcome results

5.1 Background and context

The efficacy of the Sunbeam Program was assessed by performing between group comparisons on the primary outcome of fall rates and secondary outcomes of physical performance, mobility, fear of falling (confidence), cognition and quality of life (QOL). Cost effectiveness was also assessed and forms the content of Chapter 6. The aim was to develop an understanding of the wholistic effects of exercise in residential aged care and its concurrent effect on several outcomes. The concept of a "trade off" has been documented previously.[1] An example of this is prioritising falls risk reduction by limiting mobility (walking less), which may in turn negatively impact physical performance and quality of life.[1] In this chapter, data collected on the secondary outcomes in the Sunbeam trial are compared to other randomised controlled trials (RCT) that have implemented falls prevention exercise programs in the residential aged care setting and measured at least one of the secondary outcomes from the Sunbeam Trial. The relevance of the interplay between these outcomes and recommendations for future research are also presented.

5.2 Secondary outcomes selected for the Sunbeam trial.

A battery of tests was selected that captured major known risk factors for falls in residential care and that may have an impact on an exercise intervention. These factors are also issues observed in clinical practice and include physical performance, mobility, confidence (fear of falling), cognition and QOL.[2-4] There is a paucity of outcome measures that had been validated in a residential aged care setting so the research team discussed measures a priori and decided by consensus on tools that were either validated in a number of diverse populations or were widely used in the literature on interventions for older people and deemed suitable for this population. Outcomes were measured at baseline, six months and 12 months by assessors blinded to group allocation.

1) *Physical performance and mobility*

Physical performance and mobility were measured as they have been identified as potential risk factors for falls[2] that may be remediable with exercise.[5, 6] The short physical performance battery (SPPB, Appendix 3)[7] was used as it has been widely used in research and has evidence of high validity and reliability in diverse populations.[8] The SPPB assesses gait speed, balance and repeated chair stands, each scored between zero and four points and summed to give a total score out of 12.

Mobility was assessed using the University of Alabama Life-Space Assessment (UAB-LSA, Appendix 4).[9] This tool records the extent of mobility and frequency of movement along with any assistance needed so this measure provides a practical context to the mobility outcome. Questions include, "how often did you travel: out of your room, out of the building, off the facility grounds, into the nearest town and beyond the nearest town"? Scores range from 0-120 with highest scores representing greatest independence (meaning the participant had mobilised daily over the past 4 weeks, without an aid or personal assistance, beyond the nearest town).

2) *Fear of falling (confidence)*

Fear of falling was measured as data suggest that older people tend to limit their mobility if they have higher levels of fear of falling.[3] The Falls Efficacy Scale–international (FES-I, Appendix 5)[10] evaluates confidence in avoiding falls when performing basic activities of daily living and has been shown to maintain good measurement properties in persons with or without moderate cognitive impairment and when administered in an interview format with frail older persons living in the community.[11] Score range from 16-64 with lower scores representing less fear of falling.

3) Cognition

Cognitive impairment has been identified as an independent risk factor for falls[12] and there is evidence for exercise training leading to improvements in health-related physical fitness and cognitive function in older people with Dementia.[4] Cognitive status was measured using the Addenbrooke's Cognitive Examination-Revised (ACE-R,[13] Appendix 6). This tool tests five cognitive domains: attention, memory, verbal fluency, language and visuo-spatial abilities. Absolute scores are presented with 100 being the maximum possible score .

4) Quality of life (QOL)

QOL has been shown to be reduced in a residential aged care setting.[14] The aim was therefore to investigate what aspects of QOL were affected, and to what extent, if any, QOL was improved in the intervention group. QOL was measured using the SF-36 (Appendix 7)[15] and the EQ-5D-5L (Appendix 8).[16] The SF-36 is the most widely used measure of general health.[15] The questionnaire is designed for self- reporting and scores range from 0-100 with higher scores representing greater QOL. The presence of either a visual or cognitive impairment may impede participants from completing the questionnaire which takes approximately 20 minutes so the EQ-5D-5L was also used as it is cognitively undemanding and takes only a few minutes to complete. The EQ-5D-5L is widely used as a multi-attribute utility index[17] but is yet to be validated in a residential care setting, scores range from 0 - 1.0 with higher scores indicating higher QOL. Both the SF-36 and EQ-5D-5 have been used to estimate quality of life adjusted years (QALYs) in cost effectiveness studies.[17,18] Information regarding the implementation and outcomes collected from both measures will be compared and discussed.

5.3 Results of secondary outcomes from the Sunbeam Trial (Table 1)

At the 12 months follow-up a significant between group difference was demonstrated in physical performance (SPPB), favouring the Sunbeam Program group (p = 0·02). Some improvements can be seen from other secondary outcome scores in the intervention group, except fear of falling, however none of these reached statistical significance. Details of these outcomes are presented in Table 1.

TABLE 1 – Secondary outcome measures from the Sunbeam Trial (this table has also been presented in Chapter 4).

	SUNBEAM program		Control group		Comparison of groups	Effect size[a]
	N	Mean score (SD)	N	Mean score (SD)		
Physical functioning						
SPPB[b]						
Baseline	112	5.16 (2.57)	105	4.30 (2.90)	F(2,168)	0.56
6 months	100	5.89 (2.86)	93	3.76 (2.74)	=23.25	
12 months	93	5.81 (3.02)	86	4.13 (2.92)	P=0.02	
UAB_LSA[c]						
Baseline	113	34.56 (18.56)	105	30.06 (15.94)	P=0.67	0.22
6 months	99	44.07 (19.81)	89	39.51 (20.06)		
12 months	94	41.72 (22.37)	85	36.91 (21.18)		
Mental Functioning						
Fear of Falling (FESi)						
Baseline	112	27.75 (10.08)	103	31.28 (13.03)	P=0.44	0.06
6 months	97	27.09 (8.65)	85	30.67 (10.76)		
12 months	91	30.01 (9.67)	79	30.57 (9.69)		
ACE-R[d]						
Baseline	100	71.45 (14.46)	95	72.11 (15.36)	P=0.77	0.11
6 months	83	73.34 (15.54)	77	74.61 (15.69)		
12 months	72	73.78 (16.66)	70	75.41 (13.56)		
Quality of Life						
SF-36 – Physical						
Baseline	108	58.50 (20.83)	102	56.99 (19.46)	P=0.77	0.13
6 months	94	69.56 (18.27)	85	65.62 (21.23)		
12 months	88	68.39 (20.25)	80	65.88 (18.69)		
SF-36 Mental						
Baseline	108	70.14 (18.38)	102	71.16 (15.74)	P=0.77	0.01
6 months	94	76.34 (17.88)	85	73.75 (18.06)		
12 months	88	74.19 (20.82)	80	74.48 (17.38)		
SF-36 Total						
Baseline	108	65.72 (18.30)	102	64.96 (16.98)	P=0.43	0.13
6 months	94	74.52 (17.13)	85	71.64 (19.09)		
12 months	88	74.66 (18.51)	80	72.43 (16.60)		
EQ Baseline	113	0.70 (0.27)	105	0.68 (0.30)	P= 0.58	-0.07
5D 6 months	99	0.83 (0.22)	86	0.84 (0.19)		
5L 12 months	94	0.85 (0.18)	82	0.83 (0.23)		

Points rage for each outcome measure: a. Short Physical Performance Battery 0-12; b. University of Alabama Birmingham -Life Space Assessment 0-120; c. Addenbrooke's Cognitive Evaluation-Revised 0-100; SF-36 0-100. Higher score = improvement. Fear of falling 16-64. Lower score = improvement.

5.4 Limitations

The Sunbeam trial was powered to detect between group differences in falls rate and the loss to follow up for secondary outcomes was higher than for the falls outcome, these factors may have limited the validity of the findings. Loss to follow up ranged from 19% for the SPPB physical activity/balance measure to 36% for the ACE-R. The primary reason for loss to follow up was death (14%). Attrition for other reasons is not uncommon in this population and was attributed to participants moving from the facility or refusing repeated measures due to the following reasons: the time required to complete the assessments (approximately one hour); hospitalisation at the time of the assessment; or a deterioration in sight, hearing or dysphasia that rendered the participant unable to complete the assessments by self- report or interview.

It is possible that the SF-36, EQ-5D-5L and UAB-LSA were not sensitive enough to pick up nuances in residents of aged care facilities. These tools have not been tested in this setting, so it is possible that their validity and reliability are equivocal. The presence of comorbid conditions that impeded implementation of the tools should also be acknowledged. Visual, auditory and cognitive impairments resulted in the tools being delivered in an interview format which may have affected their validity. A decline in these comorbid conditions over the trial period may also result in a deterioration in scores suggesting a reduction in quality of life or mobility when the issue may instead be an inability to complete the questionnaires. Acknowledging these limitations, results obtained from the Sunbeam trial will be related to previous research in this setting.

5.5 Comparison of results to prior research

Medline, CINAHL, Web of Science and PEDro were searched for RCT that used exercise as a single intervention for falls prevention in residential aged care, and measured at least one of the following secondary outcomes: physical performance, mobility, confidence (fear of falling) or cognition. A total of 18 trials were identified, nine were RCT of exercise versus usual care alone, seven trials compared two or more types of exercise and/or usual care, and two compared exercise to friendly visits or an enhanced calendar of activities for residents to attend. Studies were found to be heterogenous in terms of risk of bias in design, sample sizes, types of exercise tested, and co-morbid conditions included. Tables 2-4 display the data collected from these trials alongside the results obtained from the Sunbeam Trial.

1) RCT that implemented exercise for falls prevention in residential aged care and measured physical performance.

The Sunbeam Trial returned a significant between group improvement in physical performance measures using the SPPB (p=0.02) and a moderate effect size (0.56).[19] The usual care group demonstrated a reduction in scores (indicating a deterioration in physical condition) but the exercise groups' scores increased. This is an important finding that may demonstrate the mechanism by which the intervention was able to mediate a falls outcome. There was however no significant between group difference for the UAB-LSA measure and both groups demonstrated an increase in scores indicating that participants were mobilising further afield at the 12- month follow up than at baseline.

There are 15 other studies that have used exercise as a single intervention in residential aged care and examined both falls rates and physical performance or mobility (Table 6). Comparisons are hindered by a large variation in the type of exercise implemented including:

strength and balance;[20-25] functional exercise;[26, 27] walking;[22,25,29] seated coordination and proprioception;[29 30] standing or walking using mechanical perturbation;[31,32] Tai Chi[33,34] and Yoga.[35] The duration of the intervention period was also variable, ranging from 6 weeks[32] to 2 years[34] and follow up ranged from 12 weeks[21, 29, 33] to 12 months.[22, 24, 26, 30, 34, 36] Between group comparisons were provided and in most cases the comparator was usual care, or social visits however in 6 of the papers it was an alternative exercise program.[20,22,32, 34,36, 37]

Despite these differences, most trials reported a statistically significant improvement in both physical performance and mobility with exercise.[19, 22, 27-31, 33, 37] Trials that found a reduction or no change in mobility tended to exclude progressive resistance training (PRT) except one trial by Serra-Rexach that incorporated PRT but for a relatively short duration of 8 weeks.[21] Only three of the trials reported an improvement in both falls and mobility.[30,36,37] All of these implemented the exercise program for a minimum of six months, the two that used progressive resistance and balance exercise[36,37] returned better falls rate reduction than the one performed in sitting.[30] Both trials that returned increased falls in the intervention group utilised walking as a major component of the intervention.[28,21]

Best practice guidelines state that key components of successful falls prevention exercise for community dwelling older adults include PRT for those who are deconditioned, high level balance carried out over a period of at least 6 months.[6] Data from the Sunbeam trial and the RCT included in Table 6 support this recommendation in a residential aged care setting.

Table 2. RCT that used exercise for falls prevention in residential aged care and measured physical performance.

First Author	Year	Sample	Exercise	Intervention duration	Comparator	Follow up	Physical performance measure	Falls/ Falls rate outcome	Physical performance measure
Hewitt[19]	2017	221	Sunbeam Program	6 months	Usual care	12 months	SPPB[7]	Reduced by 55% IRR 0.45 (95% CI 0.17-0.74)	Improved (p=0.02)
Choi[33]	2005	68	Tai Chi	12 weeks	Usual care	12 Weeks	6 -minute walk test (6MWT)[38]	No between group difference	Improved (p<0.001)
Faber[21]	2006	278	Walking	20 weeks	Balance or Usual Care	12 months	SPPB[7]	Increased in walking group. (3.3 fall/ y) No change in balance group (2.4 falls/y)	Improved 1.3 (95% CI 0.6-2.0)
Lord[36]	2003	121	Aerobic, strength, balance and flexibility	12 months	Flexibility class	12 months	6 MWT[38]	Reduced by 22%. IRR 0.78 (95% CI 0.62-0.99) Improved outcome for prior fallers - 31% reduction in falls.	Improved (p< 0.05)
Kerse[26]	2008	682	Functional ADL repetition	6 months	Social visits	12 months	Timed up and go (TUG)[39]	No between group difference	No between group difference
Kovacs[37]	2011	41 with visual impairment	Progressive, tailored multimodal exercise + standard osteoporosis exercise program	6 months	Standard OP program alone	6 months	TUG[39]	Time to first falls between groups difference, favours intervention p= 0.049	Improved (p= 0.001)

First Author	Year	Sample	Exercise	Intervention duration	Comparator	Follow up	Physical performance measure	Falls/ Falls rate outcome	Physical performance measure
Mulrow[27]	1994	194	1:1 strength, functional, and range of movement with physiotherapist	4 months	Friendly visits	4 months	Mobility subscale of Physical Disability Index[40]	No between group difference	Improved - 15.5% (95% CI 6.4%-24.7%)
Nitz[29]	2011	47	Mostly seated exercise reactive steps, some standing	12 weeks	Usual care	12 weeks	TUG[39]	No between group difference	No between group difference
Nowalk[34]	2001	110	Tai Chi, counselling to reduce fear of falls, enhanced activity calendar of group events	24 months	1. Strength, balance and endurance exercise and enhanced activity calendar of group events 2. Enhanced activity calendar of group events		20 ft walk test[41]	No between group difference	No between group difference
Rolland[24]	2007	134 with Alzhei-mer's Disease	Walk, strength, balance and flexibility exercise	12 months	Usual care	12 months	6 MWT[38]	No between group difference	Improved (p= 0.002)
Schoen-Felder[28]	2000	16	Heel raises and walking	12 weeks	Usual care	6 months	6 MWT[38]	Falls increased	Mobility reduced

First Author	Year	Sample	Exercise	Intervention duration	Comparator	Follow up	Physical performance measure	Falls/ Falls rate outcome	Physical performance measure
Serra-Rexach[21]	2011	40 ≥90 years old	Resistance training legs	8 weeks	Range of movement exercise	12 weeks	8 MWT[42]	1.2 fewer falls per person (95% CI 0.0-3.0, p= 0.3)	No between group difference
Shimada[31]	2004	32	Split treadmill walking	6 months	Usual care	6 months	10 MWT[42]	No between group difference	No between group difference
Sitja-Rabert[32]	2015	159	Strength and balance on Whole Body Vibration (WBV) platform	6 weeks	Strength and balance without WBV	6 months	TUG[39]	No between group difference	No between group difference
Toulotte[20]	2003	20	Strength, balance, stretches	16 weeks	Usual care	6 months	TUG[39]	Reduced during intervention period. No change after.	Improved (p= 0.0015)
Yokoi[30]	2015	108	Seated short stick throwing	6 months	Usual care	12 months	TUG[39]	Number of fallers reduced (HRR 0.15 (95% CI 0.03-0.74, p-= 0.02)	Improved (p< 0.01)

2) RCT that used exercise for falls prevention in residential aged care and measured fear of falling (confidence) (Table 3)

The Sunbeam trial failed to detect any between group difference in fear of falling. There have been 3 other trials in the residential aged care setting that investigated the effects of exercise on falls rate and fear of falling,[28,33,43] each recruited small samples and utilized short exercise interventions ranging from 4-12 weeks and each returned a different outcome for this measure. Fear of falling decreased with Tai Chi but there was no between groups difference in falls.[33] The study that tested balance exercise returned no between group difference in falls or fear of falling[43] and the protocol that incorporated heel raise and walking exercise[28] returned an increase in falls and in fear of falling.

It can be seen therefore that neither previous literature nor the findings from the Sunbeam trial clearly establish the role of exercise in confidence or fear of falling in residential aged care. A possible cause for the finding of slightly elevated fear of falling within the Sunbeam trial exercise group is that the intervention incorporated high level balance exercise which may have alerted participants to the risk of falls. It is also possible that the FESi (Appendix 5)[10] is not sensitive enough to detect change in a residential aged care setting as some of the questions may be difficult for residents to answer, for example, "do you think you would be concerned about falling if you: sweep/vacuum/dust the house; prepare a simple meal; take a bath or shower." In a residential care setting these activities are either performed by staff or performed with assistance. Further research into a valid and reliable tool to measure fear of falling in the residential aged care space is therefore warranted.

3) *RCT that used exercise for falls prevention in residential aged care and measured cognition. (Table 3)*

The Sunbeam trial returned little variation in ACE-R scores[13] (Appendix 6) for both groups which suggests cognitive ability was maintained over the 12-month period and there was no between group difference at follow-up. This is the first trial in this setting to utilise a validated tool that assesses five cognitive domains: attention, memory, verbal fluency, language and visuo-spatial abilities[13] and an exercise intervention. We found the utility of the questionnaire to be difficult for participants with visual impairment as 25% of the questions which contribute to the overall score required some degree of visual acuity (reading, copying diagrams or recognising patterns). Visual acuity may contribute to some reduction in scores over a 12- month period rather than reduced cognition and should be examined in future trials. A literature review revealed only one other trial that measured cognition and falls in response to an exercise program in residential aged care.[30] This trial used the Mini-mental Score Evaluation (MMSE)[44] to measure cognition and also returned no between group difference (compared to usual care). The MMSE however is a screening tool that has not been validated as an outcome measure. More research is therefore recommended into the use of exercise for enhancing cognition using different primary outcome measures in the residential care setting.

Table 3. RCT that used exercise for falls prevention in residential aged care and measured: fear of falling and/or cognition

First Author	Year	Sample	Exercise	Intervention duration	Comparison	Length of follow up	Falls/ Falls rate outcome	Fear of falling outcome	Fear of falling measure	Cognition outcome	Cognition measure
Hewitt[19]	2017	221	Sunbeam Program	6 months	Usual care	12 months	Reduced by 55% IRR 0.45 (95% CI 0.17-0.74)	No between group difference	FESi[10]	No between group difference	ACE-R[13]
Choi[33]	2005	68	Tai Chi	12 weeks	Usual care	12 weeks	No between group difference	Improved ($p < 0.001$)	FESi[10]	NA	NA
Sihvonen[43]	2004	27	Individual feedback balance exercise	4 weeks	Usual care	12 months	No between group difference	No between group difference	3 point question: no fear, some fear, high fear.	NA	NA
Schoenfelder[28]	2000	16	Heel raises and walking	12 weeks	Usual care	6 months	Falls increased	Fear of falling increased	FESi[10]	NA	NA
Yokoi[30]	2015	108	Seated short stick throwing	6 months	Usual care	12 months	Number of fallers reduced (HRR 0.15 (95% CI 0.03-0.74, p-= 0.02)	NA	NA	No between group difference	Mini Mental Score Evaluation[44]

4) RCT that implemented exercise for falls prevention in residential aged care and measured quality of life (QOL) (Table 4)

Results from the Sunbeam Trial demonstrated improved QOL scores in both groups over the 12-month period in both physical and mental domains of the SF-36, resulting in no significant between group differences. Similarly, there were no between group differences identified on the EQ-5D-5L. The scores on the SF-36 were found to be higher in both groups at the time of the follow up and these may be clinically important as a 3-5% increase in SF-36 scores has previously been described as clinically significant.[45] Table 3 displays 4 other randomised controlled trials that investigated both falls prevention and QOL in response to exercise as a single intervention in residential aged care. A variety of exercise programs were investigated, including: functional strength,[26] Tai Chi and Yoga,[35] seated short stick throwing (reactive exercise)[30] and resistance training with or without a balance component.[46] The short stick throwing program[30] and Tai Chi program[35] resulted in a between group difference in quality of life outcomes favouring the intervention. The Tai Chi program was the only trial to result in improvement in both fall rates and QOL outcomes, some caution should be applied however as the Tai Chi study used a short follow up period of 14 weeks, and a small sample size of 33. The short stick throwing study was the only trial to report both a reduction in falls rate and an improvement in QOL.[30]

Interpretation of these results is difficult due to the heterogeneity of findings however it is possible that QOL in residents of aged care is not related to falls or physical performance. Qualitative research supports this supposition and has indicated that QOL in the residential aged care setting is related to issues about autonomy, control and staff-resident interaction,[14] and these factors are not directly addressed with exercise. More detailed analysis of co-morbid conditions such as pain, depression and anxiety may also deepen our understanding of factors affecting QOL in this setting and assist future researchers to target interventions appropriately.

Table 4. RCT that implemented exercise for falls prevention in residential aged care and measured quality of life (QOL)

First Author	Year	Sample	Exercise	Intervention duration	Comparison	Length of follow up	Falls/ Falls rate	QOL Outcome	QOL measure
Hewitt[19]	2017	221	Sunbeam Program	6 months	Usual care	12 months	Reduced by 55% IRR 0.45 (95% CI 0.17-0.74)	No between group difference	SF-36[15] EQ-5D-5L[16]
Kerse[26]	2008	682	Functional ADL repetition	6 months	Social visits	12 months	No between group difference	No between group difference	EQ-5D[47]
Saravanakumar[35]	2014	33	Tai Chi and Yoga	14 weeks	1. Tai Chi 2. Yoga 3. Usual Care	6 months	No between group difference	Improved with Tai Chi	DQoL[48]
Tuuainen[49]	2013	55	Strength	3 months	With or without balance	3 years	No between group difference	No between group difference	HRQoL 15D[50]
Yokoi[30]	2015	108	Seated short stick throwing	6 months	Usual care	12 months	Number of fallers reduced (HRR 0.15 (95% CI 0.03-0.74, p-= 0.02)	Improved p< 0.01	SF 8[51]

5.6 Summary of findings and discussion

The key finding from the secondary outcomes was a significant between group improvement in physical performance measures using the SPPB (p=0.02) and a moderate effect size (0.56). This is an important finding that may demonstrate the mechanism by which the intervention was able to mediate a falls outcome. Despite limited evidence of between group differences for other secondary outcomes in the Sunbeam trial, results may be used to inform future research. Identifying interplay between outcomes may also enrich our understanding of the role of exercise in a residential care environment. The only statistically significant improvement between group finding was in physical performance and both groups demonstrated a trend towards improvement in UAB-LSA scores (indicating that participants were walking further afield at 12 months than at baseline). It is possible that increased walking contributed to the increase in falls rate identified in the usual care group as doing so with poorer balance and gait ability increases falls risk.[52,53] Fear of falling outcomes were also not significantly different between groups, but there was a slight increase in scores over the 12-month period with the intervention group. Participants in the intervention group did not appear to limit their activity or mobility despite this finding (according to the UAB-LSA measure) and it is possible that they were more cautious when mobilising which may have been beneficial for falls prevention.

The Sunbeam trial is the first to use a validated cognitive outcome measure in a group of residents of aged care that participated in exercise. Results showed maintenance of cognitive ability however there were no between group differences. Further research that focusses on cognition as the primary outcome is warranted. Also participants with advanced cognitive decline, categorised by a MMSE score of <15/30,[44] were excluded from this trial, their inclusion in future research is also recommended to provide a more comprehensive understanding of the role of exercise in this cohort.

QOL measures proved problematic using the SF-36 in this setting due to both application issues and low responsiveness, this has also been documented in other settings.[45] It is possible that QOL outcome measures were affected by some questions in the SF-36, for example; "Answer true or false: I expect my health to get worse," a 100 year old residential aged care trial participant would truthfully answer this differently to a 25 year old in another setting, but the same question is used. Respondent bias may have also been an issue. For example, participants are asked whether they have recently had "difficulty performing their usual tasks," in this cohort many tasks are eliminated or performed with assistance to reduce difficulty rendering this question less relevant than in another setting where daily tasks are an inherent part of life. The EQ-5D-5L however was shorter and easier for participants to complete as and contained questions that applied readily to the residential care setting, it also returned similar findings to the SF-36. Future research may therefore benefit from using the EQ-5D-5L to assess QOL assessment tool in the residential aged care setting.

Neither the SF-36 nor EQ-5D-5L returned between group differences in QOL after 12 months follow up. It is possible that QOL is not affected by changes in falls and physical performance measures, qualitative research has indicated that factors related to autonomy, control and relationships may be more important.[14] Future research that targets these issues and addresses QOL as the primary measure is warranted to assist in understanding and impacting on this outcome.

5.7 Concluding remarks

This chapter has presented the secondary outcomes measured in the Sunbeam trial and compared them to previous research however loss to follow up in the Sunbeam trial may have limited the validity of the findings. The selection of five questionnaires and two physical assessments resulted in each assessment taking approximately one hour to complete and this may have been detrimental to this process. It is recommended that future research in this setting may benefit from taking fewer or less time- consuming measures.

In summary, findings from the Sunbeam Trial and other research in the residential aged care setting show that:

- Physical performance improves with exercise programs that include both resistance and balance training over a six- month period.
- More research which is adequately powered to assess QOL, fear of falling and cognition is required in the residential aged care setting.
- The validity and reliability of tools to measure these outcomes also requires further investigation.

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Chapter 6

Cost-effectiveness of the Sunbeam strength and balance program for falls prevention in residential aged care.

Preamble

This chapter presents a cost effectiveness analysis of the intervention provided in the cluster randomised controlled trial (Sunbeam Trial). The work presented here has been submitted to the Journal of the American Medical Directors Association for publication and is therefore presented in the format required in their author guidelines (Appendix 2)

Cost effectiveness of The Sunbeam strength and balance program for falls prevention in residential aged care.

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Cost effectiveness of The Sunbeam strength and balance program for falls prevention in residential aged care.

ABSTRACT

Objective: Falls are the leading cause of preventable deaths in residential aged care, and occur three more often in this setting than in the community-dwelling aged sector. A cluster randomized controlled trial of the Sunbeam Exercise Program returned a significant reduction in the rate of falls in the exercise group relative to usual care (IRR = 0.45 (95% CI 0.17 to 0.74), an improvement was also demonstrated in physical performance (p = 0.02). The aim of this study was to determine the cost-effectiveness analysis of the Sunbeam Program.

Methods: A stepped cost-effectiveness analysis was undertaken examining the costs of providing the exercise program and any acute cost-offsets due to reduced health service use arising from falls.

Incremental cost-effectiveness ratios (ICER) were calculated relative to the usual care group for the incremental cost per fall avoided per person and for the incremental cost per person avoiding mobility decline. Bootstrapping of the costs and outcomes was performed to obtain adjusted confidence intervals and the ICER for cost per fall per person. Sensitivity and scenario analyses explored the robustness and validity of cost-effectiveness data.

Results: The Sunbeam Program cost $463 per-person to deliver, including the upfront capital cost of the gym equipment. The ICER was $22 per fall avoided with the mean bootstrapped ICER $19 per fall avoided (95% CI: -$380.34 to $417.85). Scenario analysis that accounted for program implementation after the equipment had been purchased demonstrated that program was the dominant strategy compared to usual care (cost benefit of $333 per fall avoided). Using a model that accounts for both acute and long-term costs of falls returned a between group difference of $670 per fall avoided.

Conclusion: The Sunbeam Program appears to be cost- effective compared to usual care, it also significantly reduces falls and improves physical performance in residents of long term aged care facilities. For older people living in aged care the direct benefits of the program are a reduced probability of falling and the sequelae of a fall, such as; injury, reduced mobility, and hospitalization. The work also has important implications for the residential aged care sector as the intervention is relatively simple to roll out widely and provides evidence to contribute to the health care policy debate.

INTRODUCTION

The population aged over 85 years is projected to increase by 351% by 2050.[1] The World Health Organization has highlighted the prevention of falls as an international priority as they are the leading cause of both fatal and non-fatal unintentional injuries for those aged over 65 years.[1-3] The majority of falls prevention research has focused on community dwelling older adults however the number of falls in residents of aged care facilities is reported to be three times higher.[2] Consequences of falls are often traumatic, including reduced independence, injury or death.[2,3] The burden of falls to society is also substantial, Australian data show that while representing 6% of the older population, residents of aged care account for >20% of fall-related hospital in-patient costs.[4] Health care costs are projected to increase 60% by 2050 and urgent action to prevent falls is essential.[5]

There is evidence from randomized controlled trials (RCT) that exercise programs can prevent falls in older community dwellers.[6-11] Key components of these programs include; high challenge balance training, moderate to high intensity progressive resistance training; and at least 50 total hours of exercise over a six month period.[8] A cluster RCT performed by our group tested the effectiveness of this approach in residential aged care and included 16 clusters (residential aged care facilities) and 221 participants over a 12 month follow up period. Residents in clusters randomized to the intervention group participated in an exercise program incorporating the key components listed above (Sunbeam Program), while those residing in facilities randomized to the control group continued with their usual care.[12] Results from the trial favoured the intervention; the rate of falls in the intervention group was 1.31 per person years, compared to 2.91 in the usual care group which equates to a significant reduction of 55% (95% confidence interval 16.7%-74.1%).[13] This paper presents the results of the cost-effectiveness analysis conducted alongside the Sunbeam Trial.

METHODS

Randomized controlled trial: A two-group cluster randomized controlled trial was conducted, the protocol and outcomes of this trial have been described elsewhere.[12, 13] Ethics approval was granted by The University of Sydney Human Research Ethics Committee (Approved protocol 14995).

Intervention: Participants in clusters allocated to the intervention group performed the Sunbeam program[12] in two stages over a 12-month trial period. The first 6 months comprised of progressive resistance training using pneumatic resistance training equipment (HUR Health and Fitness), and high- level balance exercise. Sessions were one hour in duration and conducted in small group settings (up to 10 participants), two days per week for 25-weeks. The second stage (7-12 months) was a maintenance program of weight-bearing, balance, and functional exercise conducted two days per week for 30 minutes. Participants in clusters allocated to the "usual care" group continued with their usual activities without the maintenance program.

Outcome measures: The primary outcome was falls rate (falls per person year). A fall was defined as "an unexpected event in which the participant comes to rest on the ground, floor, or lower level" in accordance with the consensus statement.[14] A faller was defined as a person who fell one or more times during the trial. Falls data and demographic information and known risk factors for falls were collected at baseline. Secondary outcomes included: quality of life measured using the Short Form-36 (SF-36)[15] and EuroQuol-5 Dimensions–5 Levels (EQ-5D-5L)[16]; and "functional mobility" measures using the short physical performance battery (SPPB).[17]

Cost-effectiveness analysis: A stepped cost effectiveness analysis was undertaken examining the costs of providing the exercise program and any cost-offsets due to reduced health service use arising from falls. Program costs include the upfront capital cost of the exercise equipment, the cost of staff training, plus the physiotherapist and facility staff time required to deliver the intervention. Health service use was determined from audits of each clusters' records to extract data specific to fall incidents sustained throughout the trial period. This included medical services received; such as registered nurse assessment and follow-up; medical practitioner visits; physiotherapist reviews; ambulance assessment and/or transfers to hospital; hospital admissions; and injuries sustained. The total health service costs were estimated by multiplying the resource used by the relevant Medicare Schedule Benefit (MBS) item fee, Pharmaceutical Benefits Schedule (PBS) price or Australian-Related Diagnosis Resource Group schedule (AR-DRG). The analysis adapted a health service perspective and all costs were based on 2015 Australian prices ($AUD).

Sunbeam Program delivery: The costs of the capital equipment was estimated at $60,000 (acquisition cost) with a projected life of 10 years, servicing of $600 per annum (p.a.) and capital loss at 3% p.a. Hence, the equipment cost for the 6-month intervention was $3,729 per cluster or $264, on average, per participant for the intervention. Staff training costs (Table 1) consisted of a two-hour session where the physiotherapist (PT) trained two activity officers (AO) per cluster in the use of the gym equipment, balance exercises, techniques to maximise safety and record keeping. Ongoing staff costs were for two staff for every 60-minute gym session. During the trial this comprised of one researcher or facility-based PT and one AO from the facility. The configuration recommended for clinical application is for PT attendance once per fortnight and two trained AO for all other sessions. One AO would be running the gym session as part of usual duties, therefore, only one additional AO is costed (Table 1).

Registered nurse: Time taken for the registered nurse (RN) at each cluster to assess, treat, refer and record fall incidents was attained from one of the research team (JH) interviewing the RN at three included clusters. A non- injurious fall was allocated 30 minutes for the initial consultation and 15 minutes for a follow up visit. Injurious falls (defined as laceration, bruising, pain or fracture) were allocated 50 minutes for the initial fall, and 20 minutes for follow up visits (3.59 additional visits were allocated for lacerations, 3.26 additional visits for bruising and 3.08 additional visits for pain). For falls with multiple injuries, for instance, laceration and bruising, the maximum of 3.59 additional visits was used. The number of additional registered nurse visits by injury sustained was calculated using mean data from a detailed analysis of participant records for a subset from the first 4 clusters included in the trial. Costs attributed to RN time were derived from the NSW State award for a middle grade registered nurse with additional 40% on-costs.

Medical Practitioner and Physiotherapist Reviews: Falls incurring two or more injuries were assumed to be referred for a PT and medical practitioner (MP) review. It was assumed that this would occur at the visiting health professional’s next scheduled visit, not as a new individual consultation. MP costs were derived from the Medical Benefit Scheme, item code 35 for RACF. Physiotherapy costs were calculated for a 20-minute consultation using the NSW State award for a Level 2, Year 1 therapist plus 40% on costs.

Ambulance: A fixed fee for an ambulance attending a cluster[18] after a fall were derived by adding the published call out fee to the per kilometre fee at a distance of 5.4km (mean distance from each cluster to its local ambulance station). If the participant was transported to hospital, an additional per km fee for 6.33km was added (the mean distance from each cluster to its local public hospital). Return from hospital to the aged care facility was calculated using the same data and applied to all incidents when the participant was transported to hospital.[18]

Hospital Costs: Hospital costs were derived from the AR-DRG for same day discharge and fracture type sustained. An acute admission cost was applied for falls that required hospital admission but were not related to a fracture.[19]

Incremental cost-effectiveness ratio (ICER) and sensitivity analysis: The ICERs were calculated relative to the usual care group. ICERs were calculated for the incremental cost per fall avoided per person. Additionally, ICERs were calculated for the incremental cost per person avoiding mobility decline (defined as an unaltered or improved SPPB score), this method has been used previously when calculating the ICER for falls prevention exercise in community dwelling older adults[,25,26]. A within-trial time horizon forms the base case analysis. The confidence intervals for the estimate for the mean total cost per fall per person (intervention and usual care group) were adjusted for clustering using STATA® 13 (StataCorp, Texas USA). Bootstrapping (1,000 repetitions, adjusted for clustering) of the costs and outcomes was performed to obtain adjusted confidence intervals and the ICER for cost per fall per person. Sensitivity analyses explored the robustness and validity of cost-effectiveness data and tested any assumptions in the economic model.[27] A scenario analysis excluding the upfront capital equipment from the cost of the intervention was conducted to test the cost-effectiveness of the program assuming the gym equipment had already been purchased and the program implemented. Scenario analyses assuming the average cost of attending to, or treating, a fall regardless of group allocation, and the cost of attending to or treating an injurious fall or non-injurious fall (regardless of group) were also performed.

Our data collection extended only to the acute costs of falls, long term costs are an important reality but collecting such records was beyond the resources available to this study. However, a model formulated by Haines and colleagues[28] examined the combined acute and long- term costs of falls in residential aged care, so we have performed a scenario analysis that incorporates our outcomes into the model.

Table 1: Unit costs for attending to or treating a fall

	Cost	Unit	Source
PT - with on costs	$53.93	per hour	Level 2, Year 1[20]
AO - with on costs	$28.52	per hour	Aged Care Employee Level 3; Paid as equivalent to a Personal Care Worker Grade 2[21]
RN - with on costs	$37.23	per hour	Residential Care Nurse 02RCN03[22]
MP	$40.35	per 20-minute session	Item 35 for RACF, 20 minutes, assume 7 patients[23]
Ambulance	$287	per attendance	By road[18]
Ambulance travel	$1.77	per kilometre	By road[18]
Acute Admitted patient without fracture	$4,294	per visit	Acute admitted patient per night[19]
Hospitalizations fractures	$2,672 to $9,096		Weighted average of I178A and I78B [neck of femur]; I175A and I75B [neck of humerus and upper limb fracture]; B79A and B79B [skull fracture and assumed same for spinal fracture]; I77A and I77B [pelvis fracture]; I74Z [lower limb fracture]; I76A and I76B [rib fracture][24]
Hospitalization for same-day visit	$1,271		Z61B[24]

Abbreviations: PT, physiotherapist; AO, activities officer; RN, registered nurse; MP, medical practitioner. Note: Base year 2015, $AUD

RESULTS

Participant Characteristics: The mean age of the participants was 86.0 (SD=6.8: exercise group) and 86.6 (SD=7.1: usual care) respectively. The majority (65.2%) of participants were female and 77.8% relied on a mobility aide for walking. There was a non-significant difference in number of falls and fallers between the exercise group (189 falls and 69 fallers) and the usual care group (114 falls and 54 fallers) in the 12 months prior to baseline.[13]

Health outcome results: After 12 months of follow up, 142 falls were recorded in the exercise group and 277 in the usual care group. This equated to an incidence of 1.31 falls per person years in the exercise group, compared to 2.91 in the usual care group: IRR =0.45 (95% CI 0.17- 0.74). Participants were more likely to have multiple falls (>5) in the usual care group than the exercise group (19% of participants versus 8% respectively). There were 72 injurious falls in the intervention group and 157 injurious falls in the usual care group, 11 fractures were sustained during the study period, 5 in the intervention group and 6 in the usual care group. This equated to a mean number of injurious falls per person of 0.64 in the Exercise Group and 1.45 in the usual care group, with an incremental difference of 0.81 fewer injurious falls per person in the exercise group.[13] Table 2 displays the resource use per fall, by group.

Table 2: Amount of resource use regarding the treatment of falls over the study period comparing the exercise and usual care groups

	Exercise Group				Usual Care Group			
	No.	Units	Mean No. per fall	Mean No. of units per participant	No.	Units	Mean No. per fall	Mean No. of units per participant
Overview of falls data								
Falls rate [a]	1.31				2.91			
Falls	142				277			
Injurious falls	72				157			
Participants	113				108			
Participants that had a fall	50				73			
Personnel								
RN								
Non-injurious fall visits	102	204	1.44	1.81	211	422	1.52	3.91
Injurious fall visits	40	80	0.56	0.71	66	132	0.48	1.22
Injurious fall - multiple injuries	45	162	1.14	1.43	131	470	1.70	4.35
Injurious fall – Laceration	6	22	0.15	0.19	3	11	0.04	0.10
Injurious fall - Bruising	1	3	0.02	0.03	4	13	0.05	0.12
Injurious fall - Pain	20	62	0.43	0.55	19	59	0.21	0.54
PT								
Injurious fall – Laceration	35	35	0.25	0.31	62	62	0.22	0.57
Injurious fall – Pain (w/o laceration)	36	36	0.25	0.32	91	91	0.33	0.84
MP								
Injurious fall – Laceration	35	35	0.25	0.31	62	62	0.22	0.57
Injurious fall - Pain (w/o laceration)	36	36	0.25	0.32	91	91	0.33	0.84
Ambulance and hospital								
Ambulance attendance at RACF	8	8	0.06	0.07	22	22	0.08	0.20
Ambulance transport to ER	9	9	0.06	0.08	19	19	0.07	0.18
Ambulance and ER Visit	3	3	0.02	0.03	14	14	0.05	0.13
Admitted patient - no fracture	3	3	0.02	0.03	6	6	0.02	0.06
Admitted patient – fracture	5	5	0.04	0.04	6	6	0.02	0.06

[a] Negative binomial regression, analyzed at participant level and adjusted for clustering. Falls per-person-year

Abbreviations: RN, registered nurse; PT, physiotherapist; MP, general practitioner.

Note: multiple injuries defined as at least 2 of the following – laceration, bruising, and pain.

With respect to physical performance measures (SPPB[17]) outcomes from baseline to 12 months, in the exercise group 67 (59%) participants had the same or improved scores compared to baseline (94 response, 113 participants). The usual care group had 47 (44%) participants with the same or improved scores compared to baseline (22 responses, 108 participants). A statistically significant between-group difference (p=0.02) was found for functional mobility at 12 months.[13] Previous studies in community-dwellers reported a 49% improvement in this measure for the exercise group versus 38% for usual care (difference in proportions 0.11, 95% CI 0,01-0,22).[25] No significant between groups difference in quality of life measures were demonstrated in the Sunbeam trial.

Cost results: The mean costs per fall per 25- week intervention are presented in Table 3. The additional cost of delivering the intervention (capital, gym sessions run by physiotherapist and activities officer/s, and training of staff) was $463 per participant in the exercise group compared to usual care. The capital cost was applied per person in the exercise group. The health care cost of treating falls (non-injurious falls and treating injurious falls) was an additional $52 in the exercise group compared to usual care. The key drivers for the cost of falls were visits to hospital and treatment of fractures. Specifically, treatment of a pelvic fracture for one of the exercise group participants (the most expensive fracture on the AR-DRG) reflected a higher admitted hospital cost.

Table 3: Mean total costs of falls in AUD$ per fall per 25- week exercise intervention by cost category [a]

	Exercise Group (n= 113)	UC (n= 108)	Difference
Number of falls	142	277	-135
Intervention costs			
Capital	$264.00	NA	$264.00
Gym session – PT	$70.87	NA	$70.87
Gym session – AO	$112.43	NA	$112.43
Training – PT	$7.64	NA	$7.64
Training – AO	$8.08	NA	$8.08
Total intervention costs	$463.01	0	$463.01
Cost of attending to or treating a fall			
Personnel - RN (non-injurious and injurious)	$53.96	$56.38	-$2.42
Personnel – PT	$12.53	$13.76	-$1.23
Personnel – MP	$28.13	$30.88	-$2.75
Ambulance and ER costs	$39.65	$88.05	-$48.29
Admitted hospital cost	$300.30	$193.35	$193.35
Total cost of fall per fall	$434.57(±$1,422.81)	$382.41 (±1,157.42)	$52.16 (95%CI:-$-202.14, 306.46)
Total cost of fall per fall			
Total cost of fall – intervention or UC same (n=419)		$400.09 (±$1,228.17)	
Total cost of fall – non-injurious (n=190)		$28.66 (±$3.02)	
Total cost of fall – injurious (n=229)		$708.27 (±$1,391.56)	

[a] Values are the mean ± SD costs per patient in 2015 AUD. Mean costs have been adjusted for clustering. Calculations based on personnel recommended for clinical application of Sunbeam Trial. Abbreviations: AO, activities officer; CI, confidence interval; Ex, exercise group; MP, medical practitioner; PT, physiotherapist; RN, registered nurse; UC, usual care group

Cost effectiveness results: The total cost of treating falls per person in the Exercise group was $1,009 and the usual care group was $981, with an incremental cost of $28 (Table 4). The ICER was estimated based on the incremental number of falls avoided per person over the intervention period between the exercise group and usual care. The ICER was $22 per fall avoided ($28/1.31 fewer falls). The bootstrapped ICER of 1000 repetitions provided a point estimate of $18 per fall avoided (95% CI: -$380 to $417 per fall avoided). With respect to injurious falls the ICER was $35 ($28/0.82 per injurious fall avoided. The ICER based on the SPPB outcomes (with score same or improved at 12 months) was $179 per avoided mobility deterioration ($28/0.16 same or improved SPPB score).

Scenario Analyses: (Table 4) A scenario excluding the upfront cost of gym equipment return a cost benefit resulting in an ICER of -$333 per fall avoided. The exercise group is the dominant strategy as it provides greater benefit (fewer falls) at a lower cost compared to usual care. A second scenario analysis assumed that the type of fall would be the same in either exercise or usual care group. This led to an ICER that indicated the Exercise Group was the dominant strategy (cost saving and improved outcomes). The third scenario analysis accounts for both acute and long-term costs of falls[28] and returned a cost benefit of $670 per fall avoided with the Sunbeam program.

Table 4: Incremental cost-effectiveness ratio

Exercise Group	Usual Care Group	Incremental	Exercise Group	Usual Care Group	Incremental	ICER
Mean cost	Mean cost	Mean cost (95% CI)			Mean No. of falls (95% CI)	
Base Case						
$1,009.11	$980.82	$28.29 (-$573.77, $630.35)	1.26	2.56	-1.31 (-2.28, -0.34)	$22 per fall avoided Bootstrapped ICER ($19, 95% CI: -$380.34, $417.85) per fall avoided
Scenario analysis						
Total cost after gym cost paid						
$546.10	$980.82	-$434.72 (-$1,036.78, $167.34)	1.26	2.56	-1.31 (-2.28, -0.34)	-$333 per fall avoided Exercise Dominant
Injurious falls						
$1,009.11	$980.82	$28.29 (-$573.77, $630.35)	0.64	1.45	-0.82 (0.01, -1.63)	$35 per injurious fall avoided
Injurious falls and injurious falls cost						
$914.30	$1,029.61	-$115.32 (-$565.53, $334.90)	0.64	1.45	-0.82 (-1.45, -0.18)	-$141 per injurious fall avoided Exercise Dominant
Cost of falls from Haines et al. [17]						
$1,749.81	$2,626.37	-$876.56 (-$1,868.31, $115.19)	1.26	2.56	-1.31 (-2.28, -0.34)	-$670 per fall avoided Exercise Dominant
Cost of falls same in Exercise Group and Usual Care group						
$965.78	$1,026.16	-$60.38 (-$447.87, $327.11)	1.26	2.56	-1.31 (-2.28, -0.34)	-$46 per fall avoided Exercise Dominant
SPPB						
$1,009.11	$980.82	$28.29 (-$573.77, $630.35)	0.59	0.44	0.16	$179 per avoided mobility deterioration

Incremental defined as exercise group minus usual care group.

DISCUSSION

Studies have reported on the cost effectiveness of a range of falls prevention interventions in residential aged care.[5] This is the first, to our knowledge, to investigate the cost per fall avoided alongside a RCT that used exercise as a single intervention and returned significant evidence of fall reduction. The Sunbeam program is cost effective, the program costing $463 per participant to implement including the cost of the gym equipment. The ICER was $22 per fall avoided with the mean bootstrapped ICER $18 per fall avoided (95% CI: -$380.34 to $417.85). Results indicate that the Sunbeam trial was the dominant strategy (cost-saving and benefit producing) compared to usual care when the gymnasium equipment had been purchased upfront ($333 per fall avoided). When both the acute costs (immediate care, transportation and hospitalization) and long- term costs (ongoing changed care needs due to the sequelae of falls) are modelled there is also a cost benefit of $670 per fall avoided.

No significant between-groups differences in quality of life measures were demonstrated in the Sunbeam trial, hence, a cost per quality of life year (QALY) gained was not estimated. Similar outcomes for quality of life have been identified in other falls prevention exercise trials.[29] Prior cost effectiveness evaluations alongside RCTs have however used functional mobility measures (using the SPPB) to calculate ICERs.[25, 26] Farag and colleagues[25] investigated fall interventions in community- dwelling Parkinson's Disease patients and found that the average cost of the intervention for their exercise program was $1010 per participant and the ICER relative to usual care was $574 per fall avoided and $9570 per person avoiding mobility deterioration.[26] Another study explored the cost effectiveness of home exercise versus usual care post hospitalisation for community-dwellers.[25] The average cost of the program was $751 per participant and the ICER of the program compared to usual care for mobility improvement was $22, 958 per person. The study reported a QALY difference favouring the intervention group that did not reach statistical significance, however the authors were unable to report on the costs of falls avoided as falls increased in the intervention group.[25] The strongly significant reduction in falls-rate found in the Sunbeam trial has driven the ICER calculations and resulted in the program being more cost effective than these programs, with a cost of $463, an ICER of $22 per fall avoided and the ICER compared to usual care per mobility deterioration avoided was $179.

Despite care being taken to ensure the accuracy and robustness of this study, it is not without limitations. It is recognised that caution must be applied when using data from RCTs to calculate cost effectiveness when the study was powered for falls.[28] Secondly, we refer only to financial costs, but there are also likely to be psychological and emotional costs of falls. This may be a meaningful direction for future research. Also, the absence of a significant between group difference in quality of life scores rendered us unable to calculate QALYs which limits the opportunity to compare policy makers' established thresholds for willingness to pay for the Sunbeam Program.

The key discovery from this research however is that the Sunbeam Program is cost effective, it also significantly reduces falls and improves physical performance in residents of long-term aged care facilities. The work has important implications for the residential aged care sector as the intervention is relatively simple to roll out widely and provides evidence to contribute to the health care policy debate. For older people living in aged care the direct benefits of this exercise program are likely to be a reduced probability of falling and therefore reduced sequelae of a fall, such as; injury, reduced mobility and independence, and hospitalisation. For the healthcare system benefits include fewer fall-related injuries, reduced load on ambulance and hospital systems and reduced costs to society. Benefits for the health economy will be realised if the exercise program is funded and accepted by policy makers and implemented by staff at residential aged care facilities and residents.

ROLE OF THE FUNDING SOURCES

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DISCLOSURE STATEMENT

None of the authors have any actual or potential conflict of interest to disclose, including any financial, personal or other relationships with other people or organizations that could inappropriately influence this work.

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Supplementary Data

Table 5: Scenario analysis applying cost effectiveness data to a 70-bed Residential Aged Care Facility

Residents living in aged care facility	70
COSTS OF FALLS	
Acute cost per fall[13] Combined acute and long- term costs[17]	$400.09 $1734.30
USUAL CARE for 70 residents	
Falls rate (per person year) Falls per person year Acute costs Combined acute and long- term costs	2.91 204 $81, 498.33 $353,797.20
Proportion of residents eligible and likely to participate in the Sunbeam Program	24% [13] n=17
USUAL CARE FOR 17 residents	
Falls rate Falls per person year Acute costs of falls Combined acute and long-term costs	2.91 49 $19,604.41 $84,980.70
SUNBEAM PROGRAM for 17 residents	
Falls rate with program Falls per person year with program Acute costs of falls Combined acute and long-term costs	1.31 22 $8,801.98 $38,154.60
Potential acute cost saving	$10,802.43
Potential combined acute and long-term saving	$46,826.10

Chapter 7

Discussion

The aims of this thesis were to determine whether an exercise program designed using best practice guidelines reduced falls rate in residential aged care, improved physical performance, quality of life, fear of falling and/or cognition and was cost effective. This chapter summarises and synthesises the information gained from a literature review on the epidemiology of falls, a cluster randomised controlled trial and cost-effectiveness analysis. Data presented in each chapter will be combined to help inform clinical practice and make recommendations for policy reform. Limitations and recommendations for further research will also be presented.

A review of the literature[1,2] identified that successful fall prevention interventions for community dwellers did not successfully translate to those living in residential aged care. Meta-analysis of data from exercise trials[1] returned inconsistent results with more trials favouring usual care than the exercise interventions being tested. Closer examination revealed that none of the trials performed had tested exercise programs that implemented the key components of best practice fall prevention exercise from a community setting. Therefore, a protocol for a cluster randomised controlled trial was developed to test the efficacy of such a program in residential care compared to usual care with a follow up over a 12- month period. The exercises included both balance and progressive resistance training (PRT), individually prescribed and progressed by a physiotherapist, at a moderate intensity for 50 hours over 25-weeks and a maintenance program followed the intervention for a further six months. The hypothesis tested was that the falls rate would be reduced in the group allocated to receive the exercise program compared to usual care. Secondary outcomes (physical performance, mobility, quality of life, fear of falling, cognition) were also hypothesised to improve.

Equipment based exercise (HUR Health and Fitness Equipment) was selected for the resistance training component of the program for several reasons to do with dosage and safety. Dosage was able to be increased in small increments (100g) permitting regular progression and increased precision of individualised exercise. The exercises targeted the large muscles of the lower limbs, trunk and triceps and were all performed seated, increasing safety and reducing the amount of supervision needed for this component of the sessions. Integrity of the program was maintained and monitored utilising the "smart card" system so that when each participant inserted the card into a device, their individually prescribed resistance, sets, repetitions and rest periods automatically loaded onto the machine. The device counted the repetitions of each exercise and displayed it, providing feedback to the participants. The amount of exercise performed for every session was also automatically saved onto the card. By using these features for the resistance training component of the program, group leaders were able to concentrate on closely supervising the high challenge balance exercises being performed by other group participants in the same room simultaneously.

The trial was conducted with sixteen residential aged care facilities and 221 participants were recruited. A gymnasium was delivered to each facility randomized to the intervention and participants were provided with 50 hours of progressive resistance and balance training.[3, 4] The maintenance period (6-12 months) was conducted by trained facility staff or volunteers. At 12 months follow up, 142 falls were recorded in the intervention group and 277 in the usual care group. Participants were more likely to have had multiple falls in the usual care group, 20 participants (19%) in the usual care group fell >5 times compared to nine (8%) in the intervention group. There was also a higher proportion who did not fall at all (n=63, 56%) in the intervention group compared to the usual care group (n=35, 32%). There were 72 injurious falls in the intervention group compared to 157 with usual care. Overall, there was a significant reduction of 55% in the rate of falls for those in the Sunbeam Program (incidence rate ratio = 0.45. 95% confidence interval 0·17- 0·74). This finding is important as it is the first randomised controlled trial in a residential aged care setting to provide clear evidence for an exercise program in the prevention of falls. It is possible that findings differed from previous research because of the type and dosage of exercise that was tested. This is the first trial to implement the published key components of successful falls prevention exercise programs for community dwelling older adults into residential aged care,[3,4] using additional support for safety. The focus on progressive resistance training is also hypothesised to have been an important factor to address the high level of sarcopenia in people who live in residential care.[5] The intensity of the PRT prescribed was 2-3 sets of 10-15 repetitions for each exercise at a perceived intensity of "moderate" using the Borg Scale of Perceived Exertion.[6] This is a further difference from prior research that has advocated more intense training[7] and may have accounted for the avoidance of any serious adverse events. It is recognised however that the use of the Borg Scale for participants with cognitive impairment may be limited.

One quarter of the total number of residents living in included aged care facilities were eligible and volunteered to participate in the trial. This was due to a combination of factors including residents declining involvement in clinical research and staff and residents' beliefs about exercise in the oldest-old. Educating staff and residents on the potential benefits of PRT and balance training may have resulted in higher participation rates. Improved training of research assistants may have also altered recruitment. Several residents declined trial participation but later requested joining the program once they saw the equipment and received feedback from their peers, staff also commented on being surprised at residents' abilities when participating in the program. Beliefs about exercise participation in this setting may be a meaningful direction for further study and improve recruitment in future studies. Further research is also recommended to determine if the reach of the program could be expanded by including residents with greater cognitive impairment (MMSE<15) utilising smaller groups and extra supervision.

Few participants in our trial achieved the recommended dosage of 50 hours of exercise over 6 months[3 4] (median attendance was 36 hours). Hours of exercise was therefore entered into the negative binomial regression model as a covariate and ≥30 hours of exercise were found to be associated with improved falls outcomes ($p < 0{\cdot}002$). A dose of ≥30 hours of this type of exercise over a 25-week timeframe is therefore recommended as more feasible for future practice. The practical application of this recommendation is that participants attend 2 sessions per week for the first 5 weeks then a minimum of one per week thereafter. This pattern of attendance reflects the pattern observed in the trial, where the highest attendance occurred in the first month.

Our protocol aimed to collect both self-report and recorded falls. Collecting self- report data proved to be inconsistent and problematic. In a pre-trial feasibility study (unpublished) we provided 20 residents with falls diaries and returned one month later to collect them. Only one diary was located, the other 19 residents reported losing the document or not recalling having been given them. Assessments were carried out at 6 monthly intervals (baseline, 6 months and 12 months). When questioned about falls since the previous assessment, some residents recalled having fallen but others did not. Injurious falls tended to be more likely to be recalled but the timing of these falls often did not match documented incidents. The decision was made therefore to use facility records to measure the falls outcome. This is a limitation of the trial that is presented in the discussion section of the published paper. A recommendation to potentially improve accuracy in future research is wearable technology (also presented and referenced in the published article in Chapter 4).

A significant between-group improvement in physical performance was also recorded (p=0.02) however, none of the other secondary outcomes measured returned statistically significant between-group differences. These findings are consistent with previous studies that found improvements in physical performance with exercise, particularly exercise programs that include both progressive resistance and balance training.[8,9] More research is required to adequately assess the outcomes of quality of life, fear of falling, and cognition in response to exercise programs in the residential aged care setting. The validity and reliability of tools to measure these outcomes in this setting also require further investigation. A meaningful direction for research may involve removing or rewording some of the questions used in the questionnaires to adapt them for the oldest- old. The question "I expect my health to get worse, true or false" in the Short-Form 36[10] for example may indicate negative affect in a younger person or one with no comorbid health conditions. For a 100 year- old person or someone dwelling in residential care because of multiple health conditions, this statement may carry some truth. Similarly, 6 of the 16 items (37.5%) in the Fall Efficacy Scale (international)[11] are activities that are not generally in the performed by residents of aged care, or are performed with assistance. The instruction to imagine performing these activities without assistance may affect the validity of the results found.

Finally, a stepped cost effectiveness analysis was performed alongside the RCT to examine the costs of providing the exercise program and cost-offsets due to reduced health service use arising from falls. Incremental cost effectiveness ratios (ICER) were calculated relative to the usual care group for the incremental cost per fall avoided per person and for the incremental cost per person avoiding mobility decline. Bootstrapping of the costs and outcomes was performed to obtain adjusted confidence intervals and the ICER for cost per fall per person. Sensitivity and scenario analyses explored the robustness and validity of cost-effectiveness data.

The Sunbeam Program cost $463 per person to deliver, including the upfront capital cost of the gym equipment, the ICER was $22 per fall avoided with the mean bootstrapped ICER $19 per fall avoided (95% CI: -$380.34 to $417.85). The program was more cost effective than other falls prevention programs delivered in community settings.[12,13] This finding is important as the Australian Aged Care sector is currently undergoing policy review and the Australian Government has commissioned research to identify effective and cost- saving health care delivery methods.[14] The World Health Organisation has also recommended that comprehensive public health action on population ageing is urgently needed and will require fundamental shifts in service delivery.[15]

A scenario projecting cost savings for the Australian health economy can be estimated by implementing the data obtained from the cost effectiveness study conducted alongside the Sunbeam Trial. In 2016 there were 172 000 people living permanently in residential aged care nationally.[16] Data from the Sunbeam trial suggests that 25% are likely to be eligible and to volunteer for the program (43, 000 residents). The falls per person year for participants continuing with usual care was 2.91 and for participants engaged in the Sunbeam Program was 1.31. Therefore, the number of falls under usual care conditions would be estimated at 125, 130 and for Sunbeam participants, 56, 330. The acute cost of falls was calculated to be $400.09. Modelled acute and long-term costs of falls are estimated at $1734.30.[17] Using these figures, acute cost savings of $28M are projected with the implementation of the Sunbeam

Program. This figure reflects savings in the first year of implementation of the program. It is projected that savings would improve further in subsequent years when the upfront costs of the gymnasium equipment has been accounted for. This cost benefit would be incurred predominantly by State Governments as ambulance and hospital services are funded at a State level in Australia. When modelling the combined acute and long- term costs of falls, continuing with current usual care is projected to cost $217M compared to a cost $97M if the Sunbeam program was implemented. This represents a cost saving of $120M. This cost benefit would be shared by State governments and residential aged care facilities (as they pay for the cost of residents' care needs). An example of the projected cost effectiveness of the program when implemented in a 70 bed Australian aged care facility is also provided in Chapter 6 (Table 5).

This information demonstrates the potential cost benefits of implementing the program, the programs' clinical efficacy also provides evidence to challenge current funding models for the provision of allied health services in residential aged care. At present care services in this setting are governed by The Australian Aged Care Quality Agency and funded by the Aged Care Funding Instrument (ACFI).[18] The ACFI currently consists of a number of categories that determine the level of funding an aged care facility receives for each resident, based on their individual level of disability and care needs. There is no provision within the current ACFI for funding of any form of exercise program delivery. There is instead a perverse incentive. If an exercise program is implemented that improves a resident's mobility, the funding provided to the aged care facility for that resident's care is reduced. A further barrier is that current physiotherapy service funding is limited to the application of transcutaneous electrical nerve stimulation and therapeutic massage,[18] neither of which have evidence of efficacy for the outcomes of pain management, falls prevention, physical performance or mobility.[19,20,21] The studies presented in this thesis provide evidence to challenge the clinical and economic implications of the ACFI funding mechanism and advocate for policy reform.

The data obtained from the studies within this thesis should serve to encourage clinicians to implement resistance and balance exercise with confidence, despite the presence of co-morbid conditions. There were no serious adverse events, and physical performance measures improved along with fall rates. This information serves to challenge prior warnings that "improving the mobility of residents with severe mobility impairment may enhance their independence but paradoxically increase their risk of falls."[22]

Concluding remarks

The key discoveries are that the Sunbeam Program significantly reduces falls and improves physical performance in residents of aged care facilities, and the program is cost effective. The work has important implications for the residential aged care sector as the intervention is relatively simple to roll out widely and provides evidence to contribute to the health care policy debate. For older people living in aged care the direct benefits of this exercise program are likely to be a reduced probability of falling and therefore reduced sequelae of a fall, such as; injury, reduced mobility and independence, and hospitalisation. For the healthcare system benefits include fewer fall-related injuries, reduced load on ambulance and hospital systems and reduced costs to society.

In closing, it is recommended that the Sunbeam program be considered as an evidence based alternative to current physiotherapy services in Australian Residential Aged Care. Benefits should be realised if the exercise program is funded and accepted by policy makers and applied by residential aged care facilities and their residents.

Closing thoughts

“A person’s most beautiful asset is not a head full of knowledge, but a heart full of love, an ear ready to listen and a hand willing to help others.” (*anonymous)*

May this work be applied to help improve services for a generation that have endured The Great Depression, the World Wars, outliving their loved ones including their life partners, friends and often their own children. It is their collective stoicism, wisdom and good humour that has continued to inspire me and push me to strive for change.

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Appendices

Appendix 1

Manuscript preparation

- While the editors fully understand the extra challenges posed to authors whose native language is not English, we must ask that all manuscripts be reviewed and edited by a native speaker of English with expertise in that area prior to submission
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Appendix 2

Introduction

JAMDA is the premiere Journal for issues in post-acute and long-term care. Therefore, primary priority is given to submissions in these focus areas.

Types of articles

ORIGINAL STUDIES

Please provide a structured abstract using the following headings: Objectives, Design, Setting, Participants, Intervention (if any), Measurements, Results, and Conclusion. The text portion should be approximately 7-8 double-spaced pages in length, using the following format:
Introduction - should describe the question posed that the research was designed to answer.
Methods - should describe the design, how it was carried out, selection and assignment of subjects, treatment, outcome measurements, and statistical methods.
Results - should be listed in order of importance and include any adverse effects.
Discussion - should provide a brief synopsis of the findings, limitations of the study, and a comparison with relevant findings from other studies.
Conclusion - should provide a brief summary of the implications of the study findings.

Meta-analyses will be considered original research.

Brief Reports are a condensed version of Original Studies, limited to 6-8 double-spaced pages including title page, abstract, text, references, tables, and figures. This category is ideal for reporting preliminary results of a study or reporting a small study.

REVIEW ARTICLES

A review article is a systematic, critical assessment of the literature and data sources relevant to clinical topics (including treatment) that are commonly encountered in long-term care settings. Authors should emphasize factors such as cause, diagnosis, prognosis, prevention, or therapeutic intervention(s). All articles and date sources reviewed should include information about a specific type of study (eg, case study, double-blind, randomized trial), population, intervention, and outcomes. Articles or data sources should be selected systematically for inclusion in the review and critically evaluated. The selection process should be described in the paper. The typical length is 10-12 double-spaced pages, not including tables, figures, and references. Submission of a textbook replication is discouraged. The review section also includes **Brief Reviews**. These articles are narrow in scope, answering a single clinical question, such as: What is an effective intervention for prevention of injurious falls? All review articles should be formatted using the following headings: Objectives/Introduction; Methods (data sources, type of study); Results; Discussion; Conclusion. Review articles should have a brief abstract with or without subheadings.

CONTROVERSIES IN LONG TERM CARE

These articles will deal with behaviors or practices in long term care settings that lack an evidence base, but rather are guided by opinions of local leaders and/or regulations without a clearly tested process that leads to a beneficial outcome. The following structure should be used: Problem, Significance of the Problem, Discussion, Conclusion. These articles should include a brief abstract without subheadings. These should be no longer than 6-8 double-spaced pages.

CLINICAL EXPERIENCE

These articles should address the use of assessment and/or intervention methods in the long-term care setting (home, assisted living, and nursing facilities), which have the potential to improve quality of care or quality of life. Examples: Algorithms, clinical practice guidelines, the impact of regulatory requirements on practice or policy, and procedure implementation. These reports may describe a clinical experience or an investigation that is preliminary but that may be of clinical or scientific interest. The manuscript should include a short Introduction and Rationale, a Methods section to include subjects and approach, and an Outcomes or Results section. In the case results are not available, some mention should be made of methods to be employed to measure outcome of the work process. The reports are limited to 10 double-spaced narrative manuscript pages with 1-2 tables and/or figures, plus a brief, structured abstract using the headings above. Forms and checklists are welcome as tables or appendices.

CASE REPORTS should be approximately 3-5 double-spaced, typewritten pages and contain instructional value, such as those of successful interventions in managing uncommon syndromes or unsuccessful ones where a diagnosis was made after the fact. These articles should include a brief abstract without subheadings.

QUALITY IMPROVEMENT IN LONG-TERM CARE

These articles are case-based presentations of nursing home behavior/practice that led to an adverse regulatory or legal outcome. The discussant should review state-of-the-art practice/clinical guidelines that, if applied, would have resulted in a satisfactory conclusion. The format to use is: Case presentation, comments, recommendations. These articles should include a brief abstract without subheadings.

LONG-TERM CARE AROUND THE GLOBE

This section reports on long-term care services in different countries and health systems aimed to educate and exchange information. When feasible, these articles should include a brief structured abstract stating objectives, design, methods, results and conclusion.

SPECIAL ARTICLES

Special articles are usually solicited by the editor. Topics of interest to the readers, which do not easily fit into any of the regular categories, will appear in this section. These articles should include a brief abstract without subheadings.

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Topics for Updates articles come from lectures or workshops presented at the annual AMDA meeting. Examples of Updates articles are the Clinical Updates in Nursing Home Medicine by Messinger-Rapport et al published each fall beginning in the September 2008 issue. These should be discussed with and topics approved by the editor prior to submission.

IN TOUCH

This section affords authors the opportunity to share personal experiences with the readers. They are generally 3-5 double-spaced pages, non-clinical in nature, and should pertain, in some way, to long term care issues. Appropriate topics include: compassion, quality of life, human value, dignity of death and the sanctity of life. A short story format, fact or fiction, is acceptable.

IN THE TRENCHES

Debuted in the June 2008 issue, page 291 (T.R. Cote), this provides an opportunity for authors to share with other long-term care providers tools they have developed to advance better care for their patients. It can be a one-page "how-to" illustration or a two- to three-page description followed by a figure that illustrates the procedure or instrument.

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Letters should be double-spaced and approximately 1-3 pages in length. Those referring to an article published in the journal should be submitted within 1 month of the article's appearance. The editor may send it to the author of the paper for a response. References and a small illustration are acceptable.

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Appendix 3

Short Physical Performance Battery

1. Balance Testing

Side-by-Side stand

Instructions: I want you to try to stand with your feet together, side by side, for about 10 sec. Please watch while I demonstrate. You may use your arms, bend your knees, or move your body to maintain your balance, but try not to move your feet. Try to hold this position until I tell you to stop.

Grading: Stand next to the participant to help him or her into the side-by-side position. Allow participant to hold onto your arms to get balance. Begin timing when participant has feet together and lets go.

Grading

1. Held of 10 sec   0. Held for less than 10 sec

Semi-tandem Stand

Instructions: Now I want you to try to stand with the side of the heel of one foot touching the big toe of the other foot for about 10 seconds. You may put either foot in front, whichever is more comfortable for you. Please watch while I demonstrate.

Grading: Stand next to the participant to help him or her into semi-tandem position. Allow participant to hold onto your arms to get balance. Begin timing when participant has the feet in position and lets go.

Circle one number

1. Held for 10 sec   0. Held for less than 10 sec

Tandem Stand

Only perform this is the participant was able to perform the semi-tandem test for 10 seconds.

Instructions: Now I want you to try to stand with the heel of one foot in front of and touching the toes of the other foot for 10 sec. You may put either foot in front, whichever is more comfortable for you. Please watch while I demonstrate.

Grading: Stand next to the participant to help him or her into the tandem position. Allow participant to hold onto your arms to get balance. Begin timing when participant has feet together and lets go.

Grading

2. Held for 10 sec   1. Held for less than 10 sec   0. Not attempted

BALANCE COMPONENT [   ] / 4

2. Gait speed test (3 meters)

Instructions: This is our walking course. If you use a cane or other walking aid when walking outside your home, please use it for this test. I want you to walk at your usual pace to the other end of this course (a distance of 3m'). Walk all the way past the other end of the tape before you stop. I will walk with you. Are you ready?

Grading: Press the start button to start the stopwatch as the participant begins walking. Measure the time take to walk 3m. Then complete ordinal scoring.

0 = Unable   1 = >6.52 sec   2 = 4.66 – 6.52 sec   3 = 3.62-4.65 sec

4 = <3.62 sec

GAIT COMPONENT [ ]/4

3. Chair Stands

Instructions: Do you think it is safe for you to try and stand up from a chair without using your arms? Please stand up straight as quickly as you can so we can see if you are safe.

Repeated chair stand test.

Only perform this test if the participant safely achieved 1 x rep sit to stand without using arms. Instruction: Please try to stand up from your chair five times, without stopping in between or using your arms. After standing up each time, sit down and then stand up again. Keep your arms folded across your chest. Please watch while I demonstrate. I'll be timing you with a stopwatch. Are you ready? Begin

Grading: Begin stop watch when subject begins to stand up. Count aloud each time subject arises. Stop the stopwatch when subject has sat down after the last repetition. Also stop if the subject uses arms, or after 1 minute, if subject has not completed rises, and if concerned about the subject's safety. Record the number of seconds then complete ordinal scoring.

0 = unable   1 = ≥ 16.7 sec   2 = 16.69-13.70 sec   3 = 13.69-11.20 sec

4 = < 11.19 sec

CHAIR STAND COMPONENT [ ]/4

Total SPPB Score = Balance score + Gait score + Chair stand score / 12

Guralnik JM, Simonsick EM, Ferrucci L, Glynn RJ, Berkman LF, Blazer DG, Scherr PA, Wallace RB. A short physical performance battery assessing lower extremity function: association with self-reported disability and prediction of mortality and nursing home admission. J Gerontol Med Sci 1994; 49(2):M85-M94

Appendix 4

UAB_LSA:

These questions are related to your activities within the past month.

Life-space level			**Frequency**				**Independence**	**Score**
During the past 4 weeks have you been to….			*How often did you get there?*				*Did you use equipment or have help from someone?*	
Level 1 Other rooms of your home besides the room where you sleep?	Yes **1**	No **0**	< 1 x per week **1**	1-3 x per week **2**	4-6 x per week **3**	Daily **4**	**1**= personal assistance **1.5**= equipment only **2**= none of above	**Level 1 Score**
Score	___		X	______		X	______ =	
Level 2 An area outside your home such as a porch, deck, patio, driveway?	Yes **2**	No **0**	< 1 x per week **1**	1-3 x per week **2**	4-6 x per week **3**	Daily **4**	**1**= personal assistance **1.5**= equipment only **2**= none of above	**Level 2 Score**
Score	___		X	______		X	______ =	
Level 3 Places in your neighbourhood other than your own yard or building?	Yes **3**	No **0**	< 1 x per week **1**	1-3 x per week **2**	4-6 x per week **3**	Daily **4**	**1**= personal assistance **1.5**= equipment only **2**= none of above	**Level 3 Score**
Score	___		X	______		X	______ =	
Level 4 Places outside your neighbourhood but within your town?	Yes **4**	No **0**	< 1 x per week **1**	1-3 x per week **2**	4-6 x per week **3**	Daily **4**	**1**= personal assistance **1.5**= equipment only **2**= none of above	**Level 4 Score**
Score	___		X	______		X	______ =	
Level 5 Places outside your town?	Yes **5**	No **0**	< 1 x per week **1**	1-3 x per week **2**	4-6 x per week **3**	Daily **4**	**1**= personal assistance **1.5**= equipment only **2**= none of above	**Level 5 Score**
Score	___		X	______		X	______ =	
TOTAL SCORE							ADD ALL	

Appendix 5

ProFaNE
Prevention of Falls Network Europe

MANCHESTER 1824
The University of Manchester

In association with:

BRITISH GERIATRICS SOCIETY

HELP THE AGED WE WILL

ProFaNE
School of Nursing, Midwifery and Social Work,
University of Manchester
University Place,
Oxford Road,
Manchester
M13 9PL
Great Britain

Key Action 6.4:
Ageing Population and Disabilities
EC contract QLK6-CT-2002-02705

Falls Efficacy Scale International (FES-I)

Introduction

Members of ProFaNE carried out a systematic review of the literature on measures of fear of falling [1] and had two extended workshops on this topic, with invited experts from across Europe. After intensive review of all the fear of falling, self effiacy and balance confidence questionnaires that had been developed and validated showed that all had some limitations, especially for use in different languages and cultures. Members of ProFaNE's Workpackage 4, led by Chris Todd and Lucy Yardley, then developed the Falls Efficacy Scale - International (FES-I)[2], which has been proven to be just as reliable and a little more sensitive to between group differences than the original FES, developed by Tinetti [3,4]. FES-I has been validated in four European Countries [5] and is feasible in clinical practice [6].

The Short-FES-I was developed to allow the tool to be more feasibly used in clinical practice [7] as it comprises 7 questions rather than 16 questions. The Short-FES-I is reliable and useful in clinical practice [6] and has also been validated for use in older adults with cognitive impairment [8]. For other references that have used or cited FES-I, download the Reference Manager file "NAME".

See below for a full list of all available translations and their current status. For information regarding translation of the FES-I or Short FES-I, contact Chris Todd. There is a section below on how to translate the FES-I into your language, the scoring of the FES-I and how to handle missing data. If you need to contact the authors of translations, please click the names of the authors of the particular translation and this will prepare an email. ProFaNE members are now carrying out studies to assess FES-I and Short FES_I's sensitivity to change following an intervention.

References:

[1] Jørstad EC, Hauer K, Becker C, Lamb SE on behalf of the ProFaNE group. Measuring the psychological outcomes of falling: a systematic review. J Am Geriat Soc. 2004;5:501-510.

[2] Yardley L, Beyer N, Hauer K, Kempen G, Piot-Ziegler C, Todd C. Development and initial validation of the Falls Efficacy Scale-International (FES-I). Age Ageing. 2005;34(6):614-9.

[3] Tinetti ME, Mendes de Leon CF, Doucette JT, Baker DI. Fear of falling and fall-related efficacy in relationship to functioning among community-living elders. J Gerontol. 1994;49(3):M140-7.

[4] Hauer K, Yardley L, Beyer N, Kempen G, Dias N, Campbell M, Becker C, Todd C. Validation of the Falls Efficacy Scale and Falls Efficacy Scale International in geriatric patients with and without cognitive impairment: results of self-report and interview-based questionnaires. Gerontology. 2010;56(2):190-9.

[5] Kempen GI, Todd CJ, Van Haastregt JC, Zijlstra GA, Beyer N, Freiberger E, Hauer KA, Piot-Ziegler C, Yardley L. Cross-cultural validation of the Falls Efficacy Scale International (FES-I) in older people: results from Germany, the Netherlands and the UK were satisfactory. Disabil Rehabil. 2007;29(2):155-62.

[6] Helbostad JL, Taraldsen K, Granbo R, Yardley L, Todd CJ, Sletvold O. Validation of the Falls Efficacy Scale-International in fall-prone older persons. Age Ageing (Letter). 2010;39(2):259.

[7] Kempen GI, Yardley L, van Haastregt JC, Zijlstra GA, Beyer N, Hauer K, Todd C. The Short FES-I: a shortened version of the falls efficacy scale-international to assess fear of falling. Age Ageing. 2008;37(1):45-50.

[8] Hauer KA, Kempen GI, Schwenk M, Yardley L, Beyer N, Todd C, Oster P, Zijlstra GA. Validity and Sensitivity to Change of the Falls Efficacy Scales International to Assess Fear of Falling in Older Adults with and without Cognitive Impairment. Gerontology. 2010 Oct 22. [Epub ahead of print].

FES-I Translations

Complete list of all the available translations of the FES-I:

Language In alphabetical order	FES-I Status Click to Download	Short FES-I Status Click to Download	Contacts Click to Email
Brazilian-Portugese	Translated	Not Available	Rosangela Correa Dias
Chinese	Translated	Not Available	Jacqui Close
Danish	Translated	Translated	Nina Beyer
Dutch	Validated	Validated	Ruud Kempen
English	Validated	Translated	Lucy Yardley Chris Todd
French	Translated	Not Available	Chantal Piot-Ziegler
German	Validated	Translated	Klaus Hauer
Greek	Translated	Translated	Evdokia (Vicky) Billis Ismene Dontas
Hindi	Translated	Not Available	Lucy Yardley Chris Todd
Norwegian	Translated	Translated	Jorunn L. Helbostad
Punjabi	Translated	Not Available	Lucy Yardley Chris Todd
Spanish	Translated	Not Available	Antoni Salva
Swedish	Validated	Translated	Eva Nordell
Swiss_French	Translated	Translated	Chantal Piot-Ziegler
Urdu	Translated	Not Available	Lucy Yardley Chris Todd

Translating the FES-I into your language

You can translate the FES-I into your own language. We ask that you read the original documentation on the development of the FES-I, and the Translation/Interviewer notes and Translation Manual before proceeding. We also ask that you contact Chris Todd first to check if someone else is already doing this translation and so that he can keep an up to date record of the current translations.

Handling FES-I Sumscores

To obtain a total score for the FES -I simply add the scores on all the items together, to give a total that will range from 16 (no concern about falling) to 64 (severe concern about falling).

Missing data

If data is missing on more than four items then that questionnaire cannot be used. If data is missing on no more than four of the 16 items then calculate the sumscore of the items that have been completed (i.e. add together the responses to each item on the scale), divide by the number of items completed, and multiply by 16. The new sumscore should be rounded up to the nearest whole number to give the score for an individual.

FES-I: Now we would like to ask you some questions about how concerned you are about the possibility of falling. Please reply thinking about how you usually do the activity. If you currently do not do the activity, please answer to show **whether you think you would be concerned about falling IF you did the activity**.

	ACTIVITY	*Not concerned at all* **[1]**	*Somewhat concerned* **[2]**	*Fairly concerned* **[3]**	*Very concerned* **[4]**
1	Cleaning the house Eg, sweep, vacuum, dust				
2	Getting dressed or undressed				
3	Preparing simple meals				
4	Taking a bath or shower				
5	Going to the shop				
6	Getting in or out of a chair				
7	Going up or down stairs				
8	Walking around in the neighbourhood				
9	Reaching for something above your head or on the ground				
10	Going to answer the telephone before it stops ringing				
11	Walking on a slippery surface				
12	Visiting a friend or relative				
13	Walking in a place with crowds				
14	Walking on an uneven surface				
15	Walking up or down a slope				
16	Going out to a social event				

Appendix 6

ADDENBROOKE'S COGNITIVE EXAMINATION - ACE-R

Final Revised Version A (May 2004) - Australian Version

Name :
Date of birth :
Hospital no. :

Addressograph

Date of testing: .... /........ /.......
Tester's name: ....
Age at leaving full-time education: ....
Occupation: ....
Handedness: ....

ORIENTATION

						Score
➢ Ask: What is the	Day	Date	Month	Year	Season	[Score 0-5]
➢ Ask: Which	Building	Floor	Town	State	Country	[Score 0-5]

REGISTRATION

➢ Tell: 'I'm going to give you three words and I'd like you to repeat after me: lemon, key and ball'. After subject repeats, say 'Try to remember them because I'm going to ask you later'. Score only the first trial (repeat 3 times if necessary).

Register number of trials ....

[Score 0-3]

ATTENTION & CONCENTRATION

➢ Ask the subject: ' could you take 7 away from a 100? After the subject responds, ask him or her to take away another 7 to a total of 5 subtractions. If subject make a mistake, carry on and check the subsequent answer (i.e. 93, 84, 77, 70, 63 -score 4)

Stop after five subtractions (93, 86, 79, 72, 65). ....

➢ Ask: 'could you please spell **WORLD** for me? Then ask him/her to spell it backwards:

....

[Score 0-5]
(for the best performed task)

ATTENTION & ORIENTATION

MEMORY - Recall

➢ Ask: 'Which 3 words did I ask you to repeat and remember?'

....

[Score 0-3]

MEMORY - Anterograde Memory

➢ Tell: ' I'm going to give you a name and address and I'd like you to repeat after me. We'll be doing that 3 times, so you have a chance to learn it. I'll be asking you later'

Score only the third trial

[Score 0-7]

	1st Trial	2nd Trial	**3rd Trial**
Harry Barnes	....	....	....
73 Market Street	....	....	....
Rockhampton	....	....	....
Queensland	....	....	....

MEMORY - Retrograde Memory

➢ Name of current Prime Minister ....
➢ Name of the Premier of New South Wales ....
➢ Name of the USA president ....
➢ Name of the USA president who was assassinated in the 1960s ....

[Score 0 -4]

MEMORY

VERBAL FLUENCY - Letter 'P' and animals

➢ **Letters**

Say: 'I'm going to give you a letter of the alphabet and I'd like you to generate as many words as you can beginning with that letter, but not names of people or places. Are you ready? You've got a minute and the letter is P'

[Score 0 - 7]

total	correct
>17	7
14-17	6
11-13	5
8-10	4
6-7	3
4-5	2
3-4	1
<3	0

➢ **Animals**

Say: 'Now can you name as many animals as possible, beginning with any letter?

[Score 0 - 7]

total	correct
>21	7
17-21	6
14-16	5
11-13	4
9-10	3
7-8	2
5-6	1
<5	0

FLUENCY

LANGUAGE - Comprehension

➢ Show written instruction:

[Score 0-1]

Close your eyes

➢ 3 stage command:
'Take the paper in your right hand. Fold the paper in half. Put the paper on the floor'

[Score 0-3]

LANGUAGE - Writing

➢ Ask the subject to make up a sentence and write it in the space below:
Score 1 if sentence contains a subject and a verb (see guide for examples)

[Score 0-1]

LANGUAGE

LANGUAGE - Repetition

➢ Ask the subject to repeat: **'hippopotamus'; 'eccentricity; 'unintelligible'; 'statistician'**
Score 2 if all correct; 1 if 3 correct; 0 if 2 or less.

[Score 0-2]

➢ Ask the subject to repeat: **'Above, beyond and below'**

[Score 0-1]

➢ Ask the subject to repeat: **'No ifs, ands or buts'**

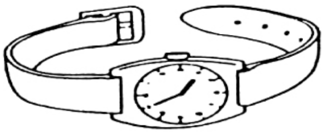
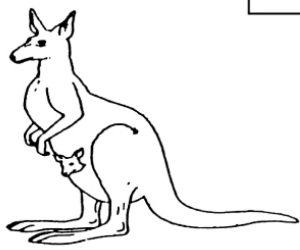
[Score 0-1]

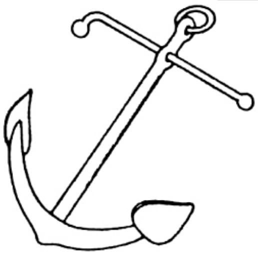
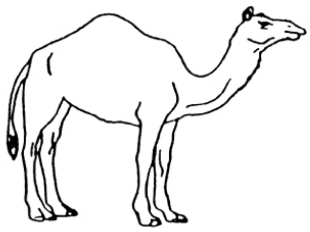
LANGUAGE - Naming

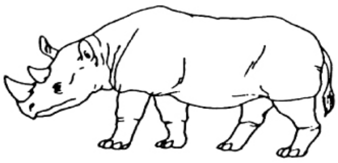
➢ Ask the subject to name the following pictures:

[Score 0-2] pencil + watch

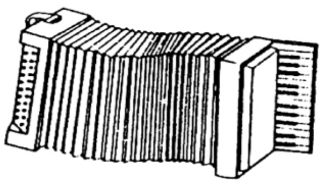
[Score 0-10]







LANGUAGE - Comprehension

➢ Using the pictures above, ask the subject to:

- Point to the one which is associated with the monarchy ____________
- Point to the one which is a marsupial ____________
- Point to the one which is found in the Antarctic ____________
- Point to the one which has a nautical connection ____________

[Score 0-4]

LANGUAGE

LANGUAGE - Reading

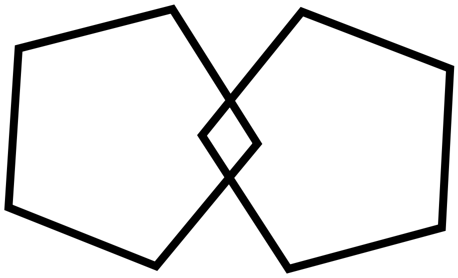
- Ask the subject to read the following words: [Score 1 only if all correct] [Score 0-1]

sew
pint
soot
dough
height

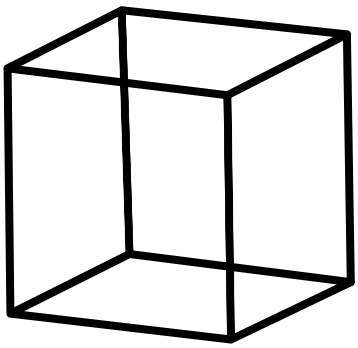
LANGUAGE

VISUOSPATIAL ABILITIES

- Overlapping pentagons: Ask the subject to copy this diagram: [Score 0-1]



- Wire cube : Ask the subject to copy this drawing (for scoring, see instructions guide) [Score 0-2]



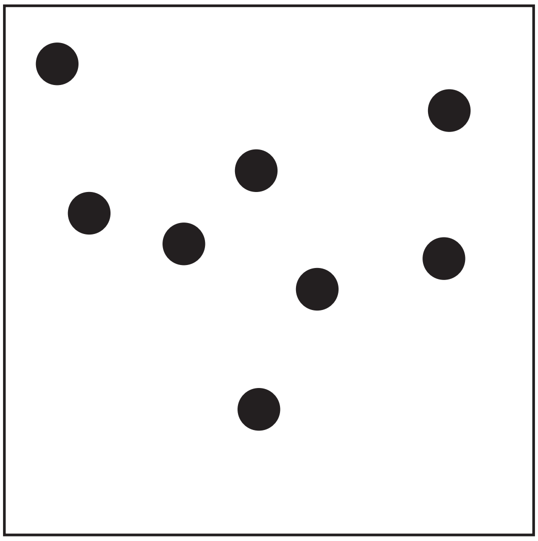
- Clock: Ask the subject to draw a clock face with numbers and the hands at ten past five. (for scoring see instruction guide: circle = 1, numbers = 2, hands = 2 if all correct) [Score 0-5]

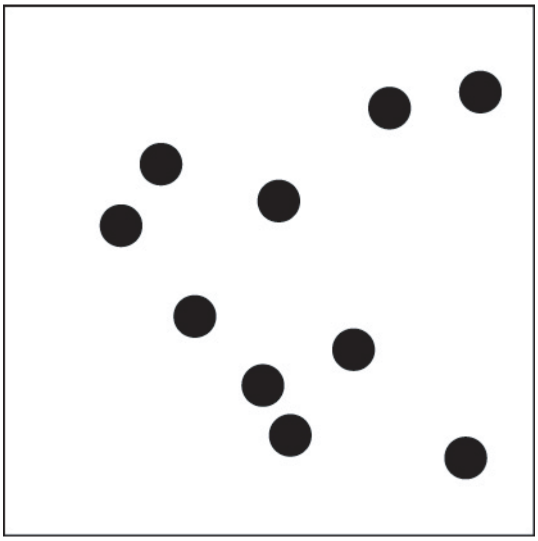
VISUOSPATIAL

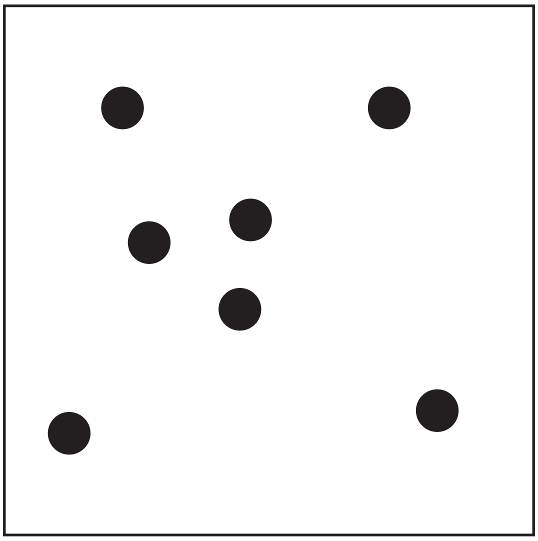
PERCEPTUAL ABILITIES

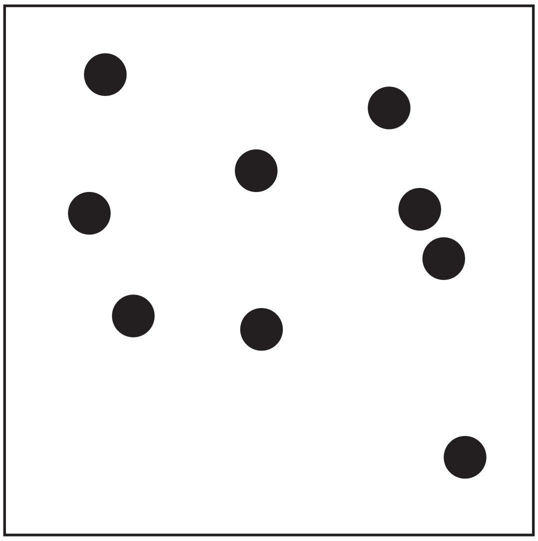
➢ Ask the subject to count the dots without pointing them

[Score 0-4]







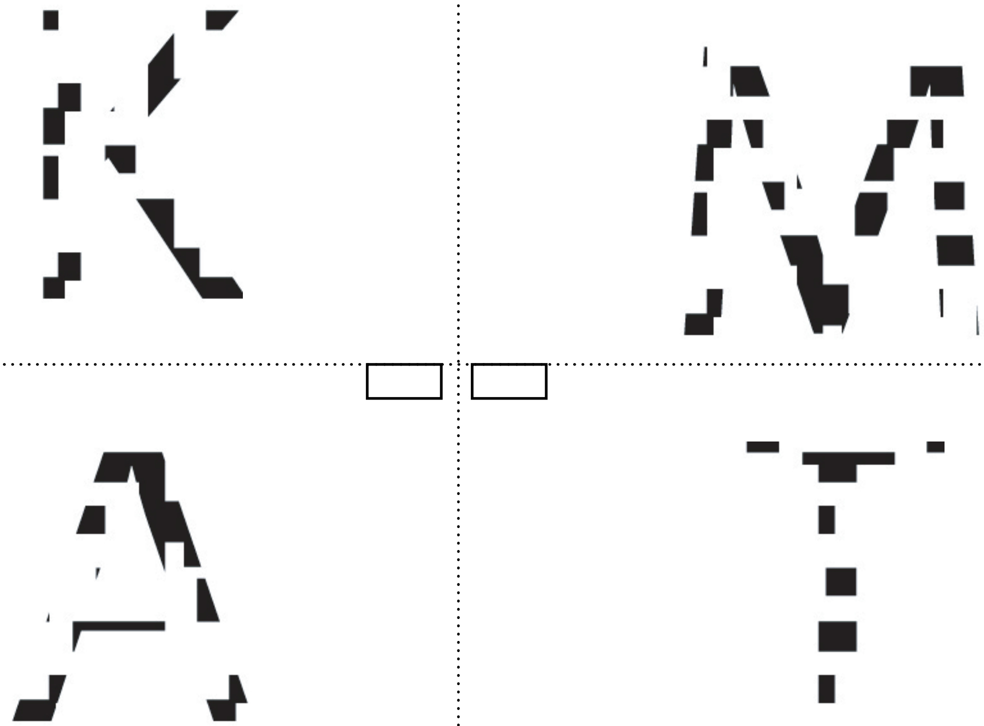


VISUOSPATIAL

PERCEPTUAL ABILITIES

➢ Ask the subject to identify the letters

[Score 0-4]



VISUOSPATIAL

RECALL

➢ Ask "Now tell me what you remember of that name and address we were repeating at the beginning'"

Harry Barnes 73 **Market** **Street** Rockhampton Queensland	………… ………… ……. ………… ………… ………… …………	[Score 0-7]

RECOGNITION

➢ This test should be done if subject failed to recall one or more items. If all items were recalled, skip the test and score 5. If only part is recalled start by ticking items recalled in the shadowed column on the right hand side. Then test not recalled items by telling "ok, I'll give you some hints: was the name X, Y or Z?" and so on. Each recognised item scores one point which is added to the point gained by recalling.

[Score 0-5]

Jerry Barne		Harry Barnes		Harry Bradford		recalled	
37		73		76		recalled	
Market Road		Martin Street		Market		recalled	
Margate		Rockhampton		Cairns		recalled	
Queensland		New South Wales		Victoria		recalled	

MEMORY

General Scores

MMSE	/30
ACE-R	/100

Subscores

Attention and Orientation	/18
Memory	/26
Fluency	/14
Language	/26
Visuospatial	/16

SCORE

Appendix 7

RAND CORPORATION HEALTH

36-Item Short Form Survey (SF-36) Scoring Instructions

Introduction

The RAND 36-Item Health Survey (Version 1.0) taps eight health concepts: physical functioning, bodily pain, role limitations due to physical health problems, role limitations due to personal or emotional problems, emotional well-being, social functioning, energy/fatigue, and general health perceptions. It also includes a single item that provides an indication of perceived change in health. These 36 items, presented here, are identical to the MOS SF-36 described in Ware and Sherbourne (1992). They were adapted from longer instruments completed by patients participating in the Medical Outcomes Study (MOS), an observational study of variations in physician practice styles and patient outcomes in different systems of health care delivery (Hays & Shapiro, 1992; Stewart, Sherbourne, Hays, et al., 1992).

Scoring Rules for the RAND 36-Item Health Survey (Version 1.0)

We recommend that responses be scored as described below. A somewhat different scoring procedure for the MOS SF-36 has been distributed by the International Resource Center for Health Care Assessment (located in Boston, MA). Because the scoring method described here (a simpler and more straightforward procedure) differs from that of the MOS SF-36, persons using this scoring method should refer to the instrument as RAND 36-Item Health Survey 1.0.

Scoring the RAND 36-Item Health Survey is a two-step process. First, precoded numeric values are recoded per the scoring key given in Table 1. Note that all items are scored so that a high score defines a more favorable health state. In addition, each item is scored on a 0 to 100 range so that the lowest and highest possible scores are 0 and 100, respectively. Scores represent the percentage of total possible score achieved. In step 2, items in the same scale are averaged together to create the 8 scale scores. Table 2 lists the items averaged together to create each scale. Items that are left blank (missing data) are not taken into account when calculating the scale scores. Hence, scale scores represent the average for all items in the scale that the respondent answered.

Example: Items 20 and 32 are used to score the measure of social functioning. Each of the two items has 5 response choices. However, a high score (response choice 5) on item 20 indicates the presence of limitations in social functioning, while a high score (response choice 5) on item 32 indicates the absence of limitations in social functioning. To score both items in the same direction, Table 1 shows that responses 1 through 5 for item 20 should be recoded to values of 100, 75, 50, 25, and 0, respectively. Responses 1 through 5 for item 32 should be recoded to values of 0, 25, 50, 75, and 100, respectively. Table 2 shows that these two recoded items should be averaged together to form the social functioning scale. If the respondent is missing one of the two items, the person's score will be equal to that of the non-missing item.

Table 3 presents information on the reliability, central tendency, and variability of the scales scored using this method.

References

1. Ware, J.E., Jr., & Sherbourne, C.D. "The MOS 36-Item Short-Form Health Survey (SF-36): I. Conceptual Framework and Item Selection,". *Medical Care*, 30:473-483, 1992.
2. Hays, R.D., & Shapiro, M.F. "An Overview of Generic Health-Related Quality of Life Measures for HIV Research," *Quality of Life Research*. 1:91-97, 1992.
3. Steward, A.L., Sherbourne, C., Hayes, R.D., et al. "Summary and Discussion of MOS Measures," in A.L. Stewart & J.E. Ware (eds.), *Measuring Functioning and Well-Being: The Medical Outcome Study Approach* (pp. 345-371). Durham, NC: Duke University Press, 1992.

Table 1

Step 1: Recoding Items

Item numbers	Change original response category *	To recoded value of:
1, 2, 20, 22, 34, 36	1 →	100
	2 →	75
	3 →	50
	4 →	25
	5 →	0
3, 4, 5, 6, 7, 8, 9, 10, 11, 12	1 →	0
	2 →	50
	3 →	100
13, 14, 15, 16, 17, 18, 19	1 →	0
	2 →	100
21, 23, 26, 27, 30	1 →	100
	2 →	80
	3 →	60
	4 →	40
	5 →	20
	6 →	0
24, 25, 28, 29, 31	1 →	0
	2 →	20
	3 →	40
	4 →	60
	5 →	80
	6 →	100
32, 33, 35	1 →	0
	2 →	25
	3 →	50
	4 →	75
	5 →	100

* Precoded response choices as printed in the questionnaire.

Table 2

Step 2: Averaging Items to Form Scales

Scale	Number of items	After recoding per Table 1, average the following items
Physical functioning	10	3 4 5 6 7 8 9 10 11 12
Role limitations due to physical health	4	13 14 15 16
Role limitations due to emotional problems	3	17 18 19
Energy/fatigue	4	23 27 29 31
Emotional well-being	5	24 25 26 28 30
Social functioning	2	20 32
Pain	2	21 22
General health	5	1 33 34 35 36

Table 3

Reliability, Central Tendency, and Variability of Scales in the Medical Outcomes Study

Scale	Items	Alpha	Mean	SD
Physical functioning	10	0.93	70.61	27.42
Role functioning/physical	4	0.84	52.97	40.78
Role functioning/emotional	3	0.83	65.78	40.71
Energy/fatigue	4	0.86	52.15	22.39
Emotional well-being	5	0.90	70.38	21.97
Social functioning	2	0.85	78.77	25.43
Pain	2	0.78	70.77	25.46
General health	5	0.78	56.99	21.11
Health change	1	—	59.14	23.12

Note: Data is from baseline of the Medical Outcomes Study (N=2471), except for "Health change," which was obtained one year later.

ABOUT

The RAND Corporation is a research organization that develops solutions to public policy challenges to help make communities throughout the world safer and more secure, healthier and more prosperous. RAND is nonprofit, nonpartisan, and committed to the public interest.

1776 Main Street
Santa Monica, California 90401-3208

Your Health and Well-Being

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

For each of the following questions, please mark an ☒ in the one box that best describes your answer.

1. In general, would you say your health is:

Excellent	Very good	Good	Fair	Poor
▼	▼	▼	▼	▼
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

2. Compared to one year ago, how would you rate your health in general now?

Much better now than one year ago	Somewhat better now than one year ago	About the same as one year ago	Somewhat worse now than one year ago	Much worse now than one year ago
▼	▼	▼	▼	▼
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

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

	Yes, limited a lot	Yes, limited a little	No, not limited at all
a Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	☐ 1	☐ 2	☐ 3
b Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	☐ 1	☐ 2	☐ 3
c Lifting or carrying groceries	☐ 1	☐ 2	☐ 3
d Climbing several flights of stairs	☐ 1	☐ 2	☐ 3
e Climbing one flight of stairs	☐ 1	☐ 2	☐ 3
f Bending, kneeling, or stooping	☐ 1	☐ 2	☐ 3
g Walking more than a mile	☐ 1	☐ 2	☐ 3
h Walking several blocks	☐ 1	☐ 2	☐ 3
i Walking one block	☐ 1	☐ 2	☐ 3
j Bathing or dressing yourself	☐ 1	☐ 2	☐ 3

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

	Yes	No
a Cut down on the amount of time you spent on work or other activities	☐ 1	☐ 2
b Accomplished less than you would like	☐ 1	☐ 2
c Were limited in the kind of work or other activities	☐ 1	☐ 2
d Had difficulty performing the work or other activities (for example, it took extra effort)	☐ 1	☐ 2

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

	Yes	No
a Cut down on the amount of time you spent on work or other activities	☐ 1	☐ 2
b Accomplished less than you would like	☐ 1	☐ 2
c Did work or other activities less carefully than usual	☐ 1	☐ 2

6. **During the <u>past 4 weeks</u>, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?**

Not at all	Slightly	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

7. **How much <u>bodily</u> pain have you had during the <u>past 4 weeks</u>?**

None	Very mild	Mild	Moderate	Severe	Very Severe
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

8. **During the <u>past 4 weeks</u>, how much did <u>pain</u> interfere with your normal work (including both work outside the home and housework)?**

Not at all	A little bit	Moderately	Quite a bit	Extremely
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

9. **These questions are about how you feel and how things have been with you during the <u>past 4 weeks</u>. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the <u>past 4 weeks</u>...**

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time
a Did you feel full of pep?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
b Have you been a very nervous person?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
c Have you felt so down in the dumps that nothing could cheer you up?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
d Have you felt calm and peaceful?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
e Did you have a lot of energy?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
f Have you felt downhearted and blue?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
g Did you feel worn out?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
h Have you been a happy person?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6
i Did you feel tired?	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6

10. During the <u>past 4 weeks</u>, how much of the time has your <u>physical health or emotional problems</u> interfered with your social activities (like visiting friends, relatives, etc.)?

All of the time	Most of the time	Some of the time	A little of the time	None of the time
☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

11. How TRUE or FALSE is <u>each</u> of the following statements for you?

	Definitely true	Mostly true	Don't know	Mostly false	Definitely false
a I seem to get sick a little easier than other people	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
b I am as healthy as anybody I know	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
c I expect my health to get worse	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5
d My health is excellent	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5

Thank you for completing these questions!

Appendix 8

EQ_5D_5L

This questionnaire helps us understand how you manage your daily activities and your quality of life. Please tick the box that most truthfully describes your health **TODAY**.

MOBILITY

[ ] I have no problems in walking about
[ ] I have slight problems in walking about
[ ] I have moderate problems in walking about
[ ] I have severe problems in walking about
[ ] I am unable to walk about

SELF-CARE

[ ] I have no problems with washing or dressing myself
[ ] I have slight problems with washing or dressing myself
[ ] I have moderate problems with washing or dressing myself
[ ] I have severe problems with washing or dressing myself
[ ] I am unable to wash or dress myself

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

[ ] I have no problems doing my usual activities
[ ] I have slight problems doing my usual activities
[ ] I have moderate problems doing my usual activities
[ ] I have severe problems doing my usual activities
[ ] I am unable to do my usual activities

PAIN / DISCOMFORT

[ ] I have no pain or discomfort
[ ] I have slight pain or discomfort
[ ] I have moderate pain or discomfort
[ ] I have severe pain or discomfort
[ ] I have extreme pain or discomfort

ANXIETY / DEPRESSION

[ ] I am not anxious or depressed
[ ] I am slightly anxious or depressed
[ ] I am moderately anxious or depressed
[ ] I am severely anxious or depressed
[ ] I am extremely anxious or depressed

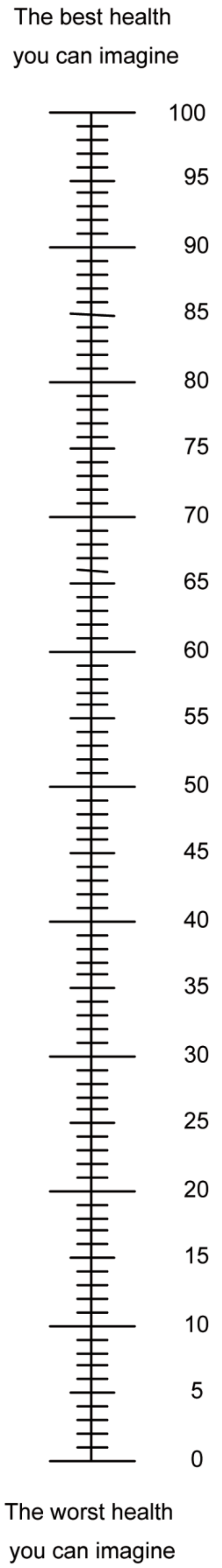
We would like to know how good or bad your health is **TODAY**.

This scale is numbered from **0** to **100**.

100 means the best health you can imagine.

0 means the worst health you can imagine.

Mark an **X** on the scale to indicate how your health is **TODAY**.



Now, please write the number you marked on the scale below.

YOUR HEALTH TODAY = ___________

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Appendix 9

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Letters to the Editor

Falls prevention research in residential aged care is itself tripped up by medical clearance issues

Dear Editor,

Australia's residential aged care (RAC) population is projected to more than treble by 2050 [1]. This increase will have significant implications for health-care expenditure [2]. Falls in older adults are common, and are a major cause of morbidity and mortality, in RAC, 60% of residents will fall each year, many will fall more than once [3]. There is compelling evidence that exercise, and specifically resistance and weight-bearing exercise programs can prevent falls in older adults [4–7]. While most trials have considered community-dwelling older people, research for exercise intervention in RAC has returned inconsistent data [5,8]. Current clinical practice guidelines suggest that there is insufficient evidence to recommend for or against the use of exercise programs in RAC and further research is recommended [6,8].

To address this, a randomised controlled trial is currently being undertaken to investigate the effect of strength and balance exercise versus usual care on falls and fear of falling, mobility, quality of life, cognition and cost-effectiveness, in RAC settings. To ensure participant safety, medical clearance is sought from treating general practitioners (GP) as part of the recruitment process. In general, GP consent to such programs is positive. However the inability to obtain medical clearance can have significant implications for both the individual and evidence-based knowledge development. In this case, a professional indemnity insurance provider recommended GPs not to take responsibility for participation in exercise research. This barrier to participation precludes residents from supervised exercise which may improve their functional capacity and quality of life. The implications for research include recruitment difficulty, population bias and potential bias estimation of the treatment effect. For GPs, a conflict of interest occurs between duty of care to their client, their clients' wishes and complying with the indemnity advice. Excluded residents argue that their right to decide to participate should be respected if their exclusion is not based on a medical condition, but on a blanket decision by the GP. A request to the Ethics Committee to alter the approved protocol and enable individuals to provide written requests concerning their personal wish to participate, and guarantee no indemnity claim, was unsuccessful.

Identification of effective interventions to reduce falls in residential aged care has the potential to significantly benefit older individuals and reduce the health-care burden. The problem is when the research process itself fails and medical clearance cannot be obtained, or be bypassed, then suitable participants are excluded.

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