



JAMDA

journal homepage: www.jamda.com

Original Study

Progressive Resistance and Balance Training for Falls Prevention in Long-Term Residential Aged Care: A Cluster Randomized Trial of the Sunbeam Program

Jennifer Hewitt BAppSc, MHealthSc^{a,*}, Stephen Goodall PhD^b, Lindy Clemson PhD^a, Timothy Henwood PhD^c, Kathryn Refshauge PhD^a

^aHealth Sciences, University of Sydney, East Street, Lidcombe, New South Wales, Australia

^bCentre for Health Economic Research and Evaluation, University of Technology, Sydney, New South Wales, Australia

^cUniversity of Queensland, Brisbane Street, St Lucia, Queensland, Australia

A B S T R A C T

Keywords:

Nursing care facility
exercise
falls prevention
quality of life
training

Background: Falls prevention is an international priority, and residents of long-term aged care fall approximately 3 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 high level balance and moderate intensity progressive resistance 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 at 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 (number of falls and days followed up). Secondary outcomes included physical performance (Short Physical Performance Battery), quality of life (36-item Short-Form Health Survey), 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 (incidence rate ratio = 0.45, 95% confidence interval 0.17–0.74); an improvement was also seen in physical performance ($P = .02$). 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.

© 2017 AMDA – The Society for Post-Acute and Long-Term Care Medicine.

HUR Health and Fitness equipment provided in kind support with the use of the resistance training equipment for this trial and contributed funds toward some travel expenses for research assistants. Feros Care and Domain Principal Group donated funds to support masked assessors. It was agreed a priori that none of these supporters would have any influence over the study design, the decision to submit the results of the research for publication, or the preparation of this manuscript.

<https://doi.org/10.1016/j.jamda.2017.12.014>

1525-8610/© 2017 AMDA – The Society for Post-Acute and Long-Term Care Medicine.

The authors declare no conflicts of interest.

* Address correspondence to Jennifer Hewitt, BAppSc, MHealthSc, Faculty of Health Sciences, University of Sydney, 75 East Street, Lidcombe, NSW 2141, Australia.

E-mail address: jhew4562@uni.sydney.edu.au (J. Hewitt).

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 to the needs of the aging population, and has highlighted falls prevention among older adults as an international priority.¹ Falls are the most common cause of injury-related death and fracture³ 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 adults 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 3 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 intervention⁸ 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 data from trials in this setting: 2 trials demonstrated a reduction in fall rates, 2 showed no change in falls, and data from 4 studies returned an increase in fall rates. Authors were therefore unable to determine the value of exercise for falls prevention in residential care⁵, and such programs were reported to be 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 (PRT) 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 all 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 protocol¹⁴ can be found at <https://doi.org/10.2147/CIA.S539311> 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; or 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 gym program), or insufficient cognition (defined as $\leq 15/30$ using the Mini-Mental State Exam).¹⁵ Written consent was provided by facility management, and 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 (S.G.) 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 on to a research team member (J.H.) 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, because of 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 2 trained staff [either a physiotherapist and activities officer from the facility, or 2 activities officer]. 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 PRT plus balance exercise performed for 1 hour twice per week for 50 hours^{9,10,16,17} (Figure 1). Progressive resistance training targeted large muscle groups using pneumatic resistance equipment that resisted both concentric and eccentric contractions throughout the 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 she or he moved on to 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 physiotherapist 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 to 3 sets of 10 to 15 repetitions for each exercise at a self-determined “moderate” intensity, defined as 12 to 14 of 20 using the Borg Scale of Perceived Exertion.^{9,10,18} Dosage was reviewed fortnightly and gradually adjusted by the physiotherapist as participants’ abilities changed throughout the course of the program. The ratio of leaders to 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 because of physical, cognitive, or behavioral 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 maximize safety (Figure 2). 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. 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 1-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).

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).

Usual Care

Participants in clusters allocated to “usual care” continued with their regular activity schedule without the introduction of 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 recorded⁸ (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 36-item Short-Form Health Survey)²⁰ and the EuroQol–5 Dimensions–5 Levels),²¹ physical performance (Short Physical Performance Battery),²² functional mobility (The University of Alabama–Life Space Assessment),²³ fear of falling (Falls Efficacy Scale–International),²⁴ and cognition (Addenbrooke’s Cognitive Examination–Revised).²⁵

Statistical Analysis

Analyses were carried out using a predefined analysis plan¹⁴ on an intention-to-treat basis whereby participants were analyzed according to the group they were assigned, irrespective of whether they participated in the intervention (intervention group). All statistical tests were 2-sided, and *P* values were considered significant when less than .05. Analyses were conducted using Stata Software, version 13 (StataCorp LP, College Station, TX). 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 to 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 ($\beta = 0.20$, $\alpha = 0.05$). To allow a conservative 25% dropout, 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 2 groups. Length of follow-up was included as an exposure term in the models. Baseline characteristics were compared between the 2 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 2 groups (using modified Poisson regression models), and to compare group rates of the number of falls during the intervention period, falls during

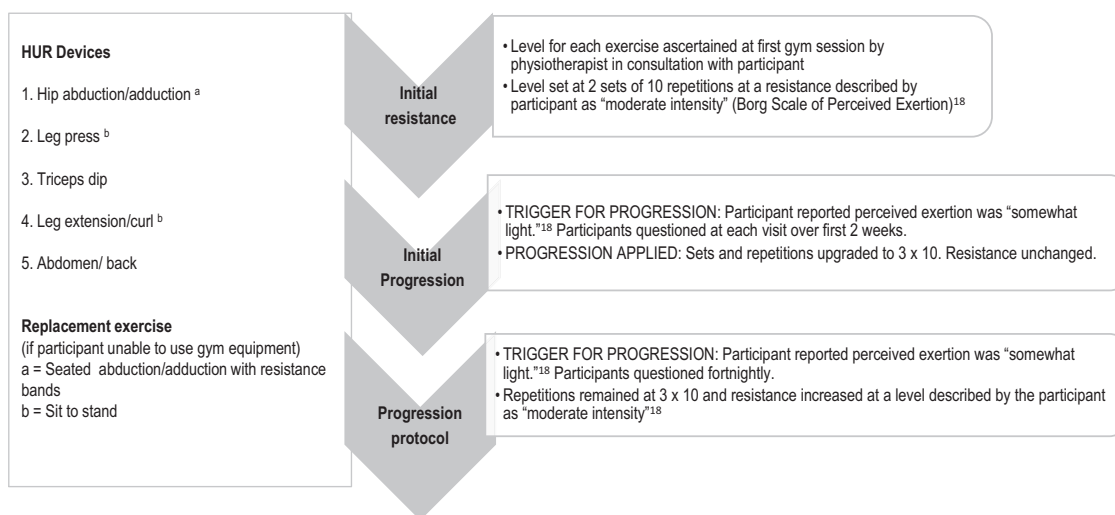


Fig. 1. Resistance exercises and progression schedule used in stage 1.

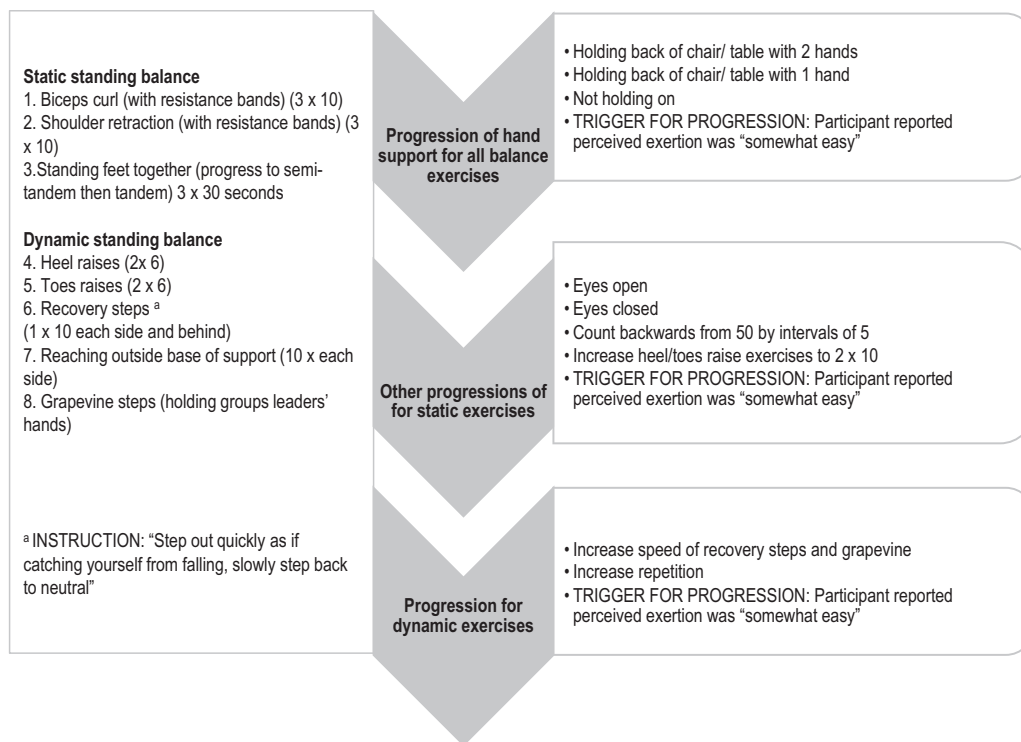


Fig. 2. Balance exercises and progression schedule used in stage 1.

the follow-up period, injurious, and noninjurious falls. Clustering was adjusted for using a random effect for cluster.

For the physical performance measure (ie, Short Physical Performance Battery) 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 because of physical impairment. Prespecified 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' postestimation of Cohen *d*.

Results

Facilities were recruited between June 30, 2012, and February 17, 2015. Participants were recruited between July 31, 2012, and March 18, 2015. Figure 4 shows the flow of participants through the study. Sixteen clusters with 221 participants were randomized to one of the 2 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

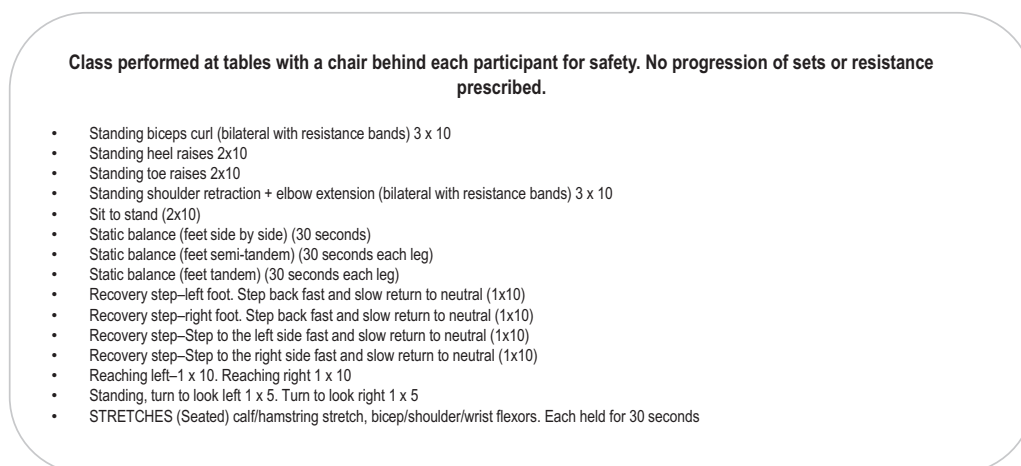


Fig. 3. Maintenance exercises used in stage 2.

Table 1
Participant Characteristics at Baseline

Characteristic	Intervention Group (n = 113)	Usual Care Group (n = 108)
Age, mean (range)	86 (65-100)	86 (65-99)
Female	71 (62.8)	73 (68.2)
Male	42 (37.2)	34 (31.8)
Months in RACF, mean (SD)	22.9 (7.6)	26.9 (24.6)
Falls in prior 12 months, n	189	114
Fallers	69 (61.0)	54 (50.5)
Uses mobility aid	86 (76.1)	86 (80.3)
High care status	61 (54)	54 (50)
Diagnosed comorbid 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 multifocal 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)

SD, standard deviation.

Values are n (%) unless otherwise noted.

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 randomized 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 ($n = 8$), having 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 and 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 (14.8%). 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%).

Baseline Characteristics

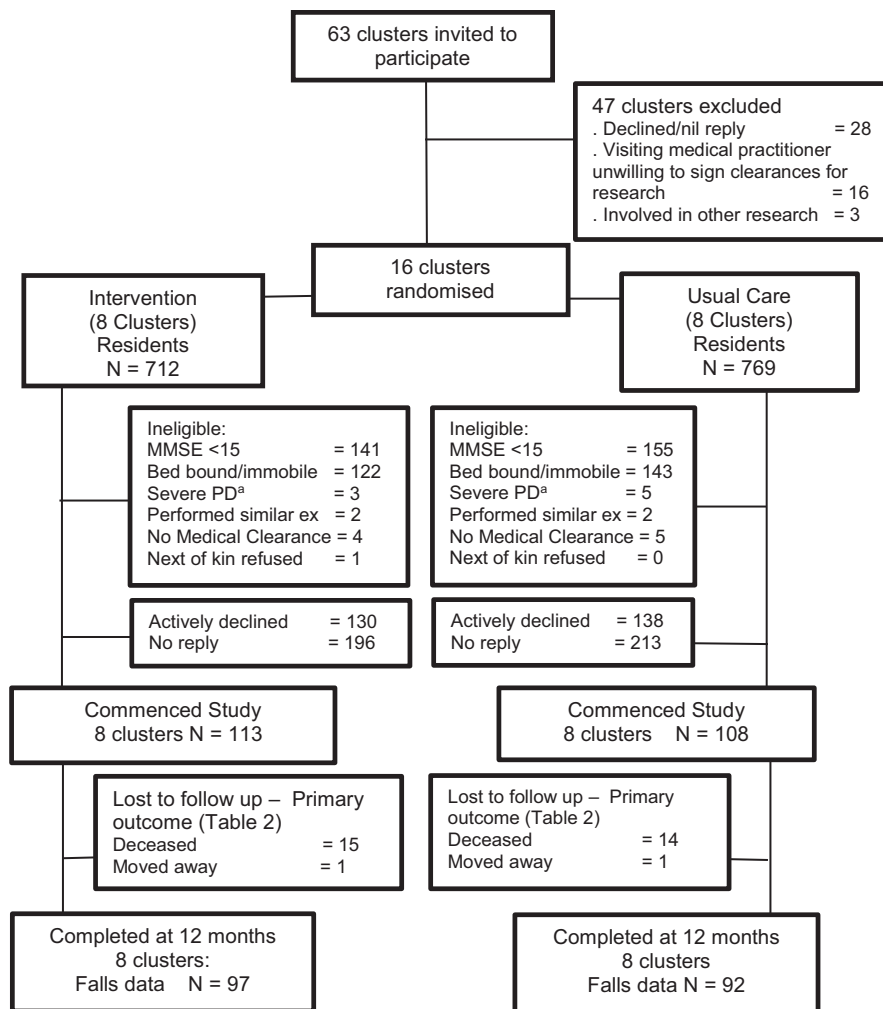
Both the exercise and usual care groups were found to be similar in terms of demographic descriptors and comorbidities at baseline (Table 1). Mean age was 86 years (SD = 7.0); 65% of participants were female and 77% relied on a mobility aid for walking (walking stick 7%, wheeled walker 70%). Fall history 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 ($P = .08$).

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 of 0.45 [95% confidence interval, 0.17-0.74]. 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% reduction 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 (incidence rate ratio = 0.46). There were similar numbers of fractures in each group (5:6, intervention: usual care).

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 as a result of the extended time required to complete the assessments (ACE-R and SF-36; each took >20 minutes), or a deterioration in sight or hearing or dysphasia rendering them unable to complete the assessments. A significantly greater improvement was found in physical performance (ie, Short Physical Performance Battery) in the intervention group than in the usual care group at 12 months ($P = .02$).



^a PD= Parkinson's Disease

Fig. 4. Trial profile.

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 musculoskeletal aches and pains that settled quickly and did not interfere with continuing the program.

Table 2
Falls Outcomes

	Intervention Group 8 Clusters, 113 Participants	Usual Care Group 8 Clusters, 108 Participants
Falls rate, falls per person-year*	1.31	2.91
Total number of falls	142	277
Number of fallers (≥ 1 falls)	50	73
Number that fell ≥ 5 times	9	20
Number of injurious falls [†]	72	157
Number of ambulance attendances	17	41
Number transported to hospital	9	19
Number of fall-related fractures	5	6

*Negative binomial regression, analyzed at participant level and adjusted for clustering.

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

One participant incurred a noninjurious 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 nonattendance were declining to attend (13.8% of available sessions), comorbid 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, and 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% to 31% of available sessions.

Discussion

This study found that 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

Table 3
Secondary Outcomes

	Sunbeam Program		Control Group		Comparison of Groups	Effect Size*
	n	Mean Score (SD)	n	Mean Score (SD)		
Physical functioning						
SPPB [†]						
Baseline	112	5.16 (2.57)	105	4.30 (2.90)	$F(2, 168) = 23.25$ $P = .019$	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 [‡]						
Baseline	113	34.56 (18.56)	105	30.06 (15.94)	$P = .667$	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 (FES-I)						
Baseline	112	27.75 (10.08)	103	31.28 (13.03)	$P = .443$	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 [§]						
Baseline	100	71.45 (14.46)	95	72.11 (15.36)	$P = .765$	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)	$P = .765$	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)	$P = .770$	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)	$P = .433$	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						
Baseline	113	0.70 (0.27)	105	0.68 (0.30)	$P = .576$	-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)		

FES-I, Falls Efficacy Scale—International; SD, standard deviation.

SF-36, points range: 0-100. Higher score = improvement; fear of falling = 16-64; lower score = improvement.

*Hedges' postestimation of Cohen *d* in Stata.

†Short Physical Performance Battery, points range: 0-12.

‡University of Alabama Birmingham—Life Space Assessment, points range: 0-120.

§Addenbrooke's Cognitive Evaluation—Revised, points range: 0-100.

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 ($P = .02$). 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 to 3 sets of 10 to 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 PRT and balance exercise (stage 1) were provided and followed by 6 months of maintenance exercise (stage 2); however, few participants achieved the 50 hours goal 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 ($P < .002$). A dose of 30 or more hours of this type of exercise over a 25-week time frame may therefore produce outcomes similar to those with the higher doses previously recommended.

Attendance was variable during the first 25 weeks of the program but ranged from 81% to 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 was relatively poor, ranging from 51% to 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.

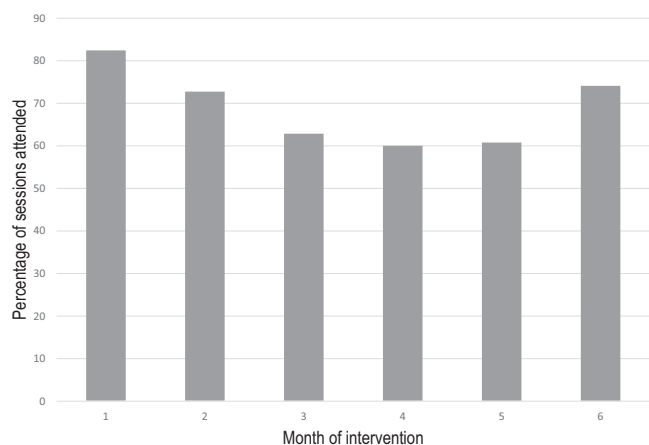


Fig. 5. Attendance during Sunbeam Program, stage 1.

Other recommendations for future research include incorporating the Sunbeam program into multifaceted 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 of 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%) of 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 because of 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 to 20

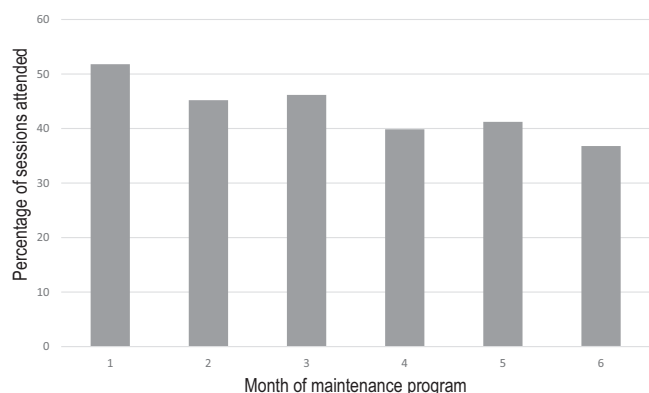


Fig. 6. Attendance during Sunbeam Program, stage 2: Maintenance program.

clusters, which was scaled up to 300 participants to allow for a 25% loss to follow-up because of 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 noninjurious falls.²⁸ This method of capturing falls data has been widely used in prior research,^{29–33} 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 using a gymnasium and physiotherapy input, and this protocol is scalable, although there may be barriers to the provision of these resources.

Conclusion

The key discovery from this research is that moderate-intensity PRT 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 comorbid health conditions, adverse events while 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 and cost savings, and a contributes to the health policy debate.

Acknowledgments

The authors gratefully acknowledge Dr Claire Hiller and Dr Jean Nightingale for their support and expertise throughout each stage of this trial. We are grateful also to the residents, management, and staff from Feros Village Wommin Bay, Feros Village Byron Bay, St Hedwig Village, De Paul Villa, 501 Care, Ozcare Keith Turnbull Place, Sundale Rod Voller Care Centre, Sundale Palmwoods Care Centre, RSL Care Darlington, RSL Care Galleon Gardens, Opal Ashmore, Opal Varsity Rise, Superior Care Merrimac, Superior Care Redlands, Masonic Care, and James Milson Village. Finally, we thank Chris Turner from Allied Connect for his contribution to the concept and commencement of the trial and Manjinder Gaba from Blisscare for coordinating with the Sydney-based facilities.

References

1. World Health Organization. Global Health and Ageing. Available at: http://www.who.int/ageing/publications/global_health.pdf. Accessed June 10, 2016.
2. World Health Organization. World report on ageing and health. Available at: <http://www.who.int/ageing/publications/world-report-2015/en/>. Accessed June 6, 2016.

3. Ibrahim J, Willoughy M, Bevan M, et al. Premature deaths in nursing home residents: An epidemiological analysis. *Med J Aust* 2017;206:1–6.
4. Bradley C. Hospitalisations due to falls by older people, Australia 2009–10. Injury Research and Statistics Series No. 70. Cat. no. INJCAT 146. Canberra: AIHW. Available at: <http://www.aihw.gov.au/WorkArea/DownloadAsset.aspx?id=60129542822>. Accessed July 8, 2016.
5. Cameron ID, Gillespie LD, Robertson MC, et al. Interventions for preventing falls in older people in care facilities and hospitals. *Cochrane Database Syst Rev* 2012;12:CD005465.
6. Cumming R, Kelsey J, Nevitt M. Methodologic issues in the study of frequent and recurrent health problems. Falls in the elderly. *Ann Epidemiol* 1990;1:49–56.
7. Gillespie L, Roberston C, Gillespie W, et al. Interventions for preventing falls in older people living in the community. *Cochrane Database Syst Rev* 2012;9:CD007146.
8. Lamb SE, Becker C, Gillespie LD, et al. Reporting of complex interventions in clinical trials: Development of a taxonomy to classify and describe fall-prevention interventions. *Trials* 2011;12:125.
9. Sherrington C, Tiedemann A, Fairhall N, et al. Exercise to prevent falls in older adults: An updated meta-analysis and best practice recommendations. *NSW Public Health Bull* 2011;22:78–83.
10. Tiedemann A, Sherrington C, Close JC, et al. Exercise and Sports Science Australia position statement on exercise and falls prevention in older people. *J Sci Med Sport* 2011;14:489–495.
11. Sherrington C, Michaleff Z, Fairhall N, et al. Exercise to prevent falls in older adults: An updated systematic review and meta-analysis. *Br J Sports Med* 2017;51:1750–1758.
12. Panel on Prevention of Falls in Older Persons, American Geriatrics Society, and British Geriatrics Society. Summary of the updated American Geriatrics Society/British Geriatrics Society clinical practice guideline for prevention of falls in older persons. *J Am Geriatr Soc* 2011;59:148–157.
13. Silva R, Eslick G, Duque G. Exercise for falls and fracture prevention in long term care facilities: A systematic review and meta-analysis. *J Am Med Dir Assoc* 2013;14:685–689.
14. Hewitt J, Refshauge K, Goodall S, et al. Does progressive resistance and balance exercise reduce falls in residential aged care? Randomized controlled trial protocol for the SUNBEAM Program. *Clin Interv Aging* 2014;9:369–376.
15. Folstein M, Folstein S, McHugh P. “Mini-Mental State.” A practical method for grading the cognitive state of patients for the clinician. *J Psychiatr Res* 1975;12:189–198.
16. Sherrington C, Whitney J, Lord S, et al. Effective exercise for the prevention of falls: A systematic review and meta-analysis. *J Am Geriatr Soc* 2008;56:2234–2243.
17. Liu C, Latham N. Progressive resistance training for improving physical function in older adults. *Cochrane Database Syst Rev* 2009;3:CD0022759.
18. Borg GA. Psychophysical bases of perceived exertion. *Med Sci Sports Exerc* 1982;14:377–381.
19. Lamb SE, Jorstad-Stein EC, Hauer K, et al. Development of a common outcome data set for fall injury prevention trials: The prevention of falls network Europe consensus. *J Am Geriatr Soc* 2005;53:1618–1622.
20. Ware JE Jr, Sherbourne CD. The MOS 36-item short-form health survey (SF-36). I. Conceptual framework and item selection. *Med Care* 1992;30:473–483.
21. Herdman M, Gudex C, Lloyd A, et al. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Qual Life Res* 2011;20:1727–1736.
22. Guralnik JM, Simonsick EM, Ferrucci L, et al. A short physical performance battery assessing lower extremity function: Association with self-reported disability and prediction of mortality and nursing home admission. *J Gerontol* 1994;49:M85–M94.
23. Peel C, Sawyer Baker P, Roth DL, et al. Assessing mobility in older adults: The UAB study of aging life-space assessment. *Phys Ther* 2005;85:1008–1119.
24. Yardley L, Beyer N, Hauer K, et al. Development and initial validation of the falls efficacy scale-international (FES-I). *Age Ageing* 2005;34:614–619.
25. Mioshi E, Dawson K, Mitchell J, et al. The Addenbrooke’s cognitive examination revised (ACE-R): A brief cognitive test battery for dementia screening. *Int J Geriatr Psychiatry* 2006;21:1078–1085.
26. Fiatarone M, O’Neill E, Ryan N, et al. Exercise training and nutritional supplementation for physical frailty in very elderly people. *N Engl J Med* 1994;33:1769–1775.
27. de Ruijter SC, de Jonghe JFM, Gormans T, et al. Cognitive impairment is very common in elderly patients with syncope and unexplained falls. *J Am Med Dir Assoc* 2017;18:409–413.
28. Haines T, Cornwell P, Fleming J, et al. Documentation of in-hospital falls on incident reports: Qualitative investigation of an imperfect process. *BMC Health Serv Res* 2008;8:254.
29. Rosendahl E, Gustafson Y, Nordin E, et al. A randomized controlled trial of fall prevention by a high-intensity functional exercise program for older people living in residential care facilities. *Aging Clin Exp Res* 2008;20:67–75.
30. Shimada H, Obuchi S, Furuta T, Suzuki T. New intervention program for preventing falls among frail elderly people: The effects of perturbed walking exercise using a bilateral separated treadmill. *Am J Phys Med Rehabil* 2004;83:493–499.
31. DeSure AR, Peterson K, Gianan FV, Pang L. An exercise program to prevent falls in institutionalized elderly with cognitive deficits: A crossover pilot study. *Hawaii J Med Public Health* 2013;72:391–395.
32. Sitjà-Rabert M, Martínez-Zapata MJ, Fort Vanmeerhaeghe A, et al. Effects of a whole body vibration (WBV) exercise intervention for institutionalized older people: A randomized, multicentre, parallel, clinical trial. *J Am Med Dir Assoc* 2015;16:125–131.
33. Resnick B, Gruber-Baldini AL, Zimmerman S, et al. Nursing home resident outcomes from the Res-Care intervention. *J Am Geriatr Soc* 2009;57:1156–1165.
34. Senior HE, Henwood TR, Beller EM, et al. Prevalence and risk factors of sarcopenia among adults living in nursing homes. *Maturitas* 2015;82:418–423.