

**J Am Med Dir Assoc. 2023 Nov 29:S1525-8610(23)00909-X.**

**doi: 10.1016/j.jamda.2023.10.022.**

**<https://pubmed.ncbi.nlm.nih.gov/38042173/>**

**Effects of an Exercise Program to Reduce Falls in Older People Living in Long-Term Care: A Randomized Controlled Trial**

Lynne Taylor<sup>1</sup>, John Parsons<sup>1</sup>, Simon A. Moyes<sup>1</sup>, Alana Cavadino<sup>1</sup>, Elizabeth Binns<sup>2</sup>, Denise Taylor<sup>2</sup>, Sue Lord<sup>2</sup>, Silvia Del Din<sup>3,4</sup>, Lynn Rochester<sup>3,4,5</sup> and Ngaire Kerse<sup>1</sup>

Author details

<sup>1</sup>The University of Auckland, Faculty of Medical and Health Sciences, Auckland, New Zealand.

<sup>2</sup>Auckland University of Technology, Health and Rehabilitation Research Institute, Auckland, New Zealand.

<sup>3</sup>Translational and Clinical Research Institute Clinical Ageing Research Unit, Newcastle University, Newcastle upon Tyne, UK.

<sup>4</sup>National Institute for Health and Care Research (NIHR) Newcastle Biomedical Research Centre (BRC), Newcastle University and The Newcastle upon Tyne Hospitals NHS Foundation Trust, Newcastle upon Tyne, UK

<sup>5</sup>The Newcastle upon Tyne Hospitals NHS Foundation Trust, Newcastle upon Tyne, UK

**Abstract**

**Objectives:** To investigate the effect of an exercise program on falls in intermediate and high-level long-term care (LTC) residents and to determine whether adherence, physical capacity, and cognition modified outcomes.

**Design:** Randomized controlled trial

**Setting and Participants:** Residents (n=520, aged 84±8 years) from 25 LTC facilities in New Zealand.

**Methods:** Individually randomized to *Staying UpRight*, a physical therapist-led, balance and strength group exercise program delivered for 1 hour, twice weekly over 12 months. The control arm was dose-matched and used seated activities with no resistance. Falls were collected using routinely collected incident reports.

**Results:** Baseline fall rates were 4.1 and 3.3 falls per person-year (ppy) for intervention and control groups. Fall rates over the trial period were 4.1 and 4.3 falls ppy respectively [P = 0.89, incidence rate ratio (IRR) 0.98 (95% CI: 0.76, 1.27)]. Over the 12-month trial period, 74% fell, with 63% of intervention and 61% of the control group falling more than once. Risk of falls, [P = 0.56, hazard ratio 1.08 (0.85, 1.36)], and repeat falling or fallers sustaining an injury at trial completion were similar between groups. Fall rates per 100 hours walked did not differ between groups [P = 0.42, IRR 1.15 (0.81, 1.63)].

Program delivery was suspended several times because of COVID-19, reducing average attendance to 26 hours over 12 months. Subgroup analyses of falls outcomes for those with the highest attendance ( $\geq 50\%$  of classes), better physical capacity (SPPB scores  $\geq 8/12$ ) or cognition (MoCA  $\geq 18/30$ ) showed no significant impact of the program.

**Conclusions/Implications:** In intermediate and high-level care residents, the *Staying UpRight* program did not reduce fall rates or risk compared with a control activity, independent of age, sex, or care level. Inadequate exercise dose because of COVID-19-related interruptions to intervention delivery likely contributed to the null result.

## Introduction

Falls are a significant concern for older people living in long-term care (LTC),<sup>1</sup> with 60% of residents falling at least once yearly;<sup>2, 3</sup> and fall-related hospitalizations three times higher in LTC residents than in community dwellers.<sup>4, 5</sup>

Balance and functional training exercises reduce falls in community-dwelling older people,<sup>6</sup> but the efficacy of exercise for fall prevention in LTC is less compelling.<sup>7, 8</sup> The Cochrane review concluded that exercise, based on low and very low-quality evidence, was of uncertain benefit in reducing falls or fallers in LTC.<sup>7</sup> World guidelines recommend supervised exercise, tailored by an exercise specialist (e.g. physical therapist) as part of a multi-domain approach, but note the recommendation is supported by low-quality evidence.<sup>8</sup>

LTC residents' high dependency and high falls risk makes falls prevention difficult. Physical frailty combined with cognitive impairment increases falls risk and may decrease exercise adherence and exercise dose.<sup>9</sup> Recent studies have addressed this issue by using individualized, higher intensity, longer duration exercise programs (i.e., 1-hour twice weekly) over 4 months or longer, but with mixed results.<sup>10-12</sup> Two of these studies, limited to residents without significant cognitive impairment, reduced falls,<sup>10, 11</sup> whereas the third, limited to residents with moderate to severe cognitive impairment, did not.<sup>12</sup> However, it remains unclear whether low adherence or participant fall risk attributes contributed to this null result. Unpicking the contributions that adherence, physical frailty, and cognitive impairment have on exercise interventions would help determine those most likely to benefit from exercise for fall prevention.

Additionally, some suggest that in physically frail residents, exercise that improves their ability to ambulate potentially increases their exposure to fall risk.<sup>13, 14</sup> The relationship

between fall risk and activity exposure (falls rates adjusted for ambulatory activity) has been evaluated in community-dwellers, but not in LTC.<sup>15, 16</sup>

Successfully piloted by researchers in our group,<sup>17</sup> *Staying UpRight* was developed as a physical therapist-led, progressive balance and strengthening exercise program for LTC residents that adheres to principles of appropriate tailoring of dose, intensity and progression.<sup>18</sup>

This trial evaluated the efficacy of the *Staying UpRight* program for reducing fall rate, fall risk, fall rate adjusted for ambulatory activity and fall-related injuries in LTC residential facilities for intermediate (24-hour health-related care) and high-level care residents (24-hour nursing care), including those with cognitive impairment. Secondly, we aimed to determine whether adherence, cognitive impairment, or physical capacity moderated outcomes.

## **Method**

### **Design and setting**

This was an investigator and assessor-blinded, parallel-group, individually randomized controlled trial set in 25 LTC facilities in Auckland and Hamilton, New Zealand. Ethical approval was granted by the national ethics board (NZHDEC 18/NTB/151), and the trial and all outcomes reported on were prospectively registered with the Australia and New Zealand Clinical Trial Registry (ACTRN12618001827224).

### *Participants*

LTC residents aged 65 years or over who were mobile i.e., able to walk and transfer with or without a walking aid, independently or with supervisory assistance, were eligible for inclusion. Residents were in high-level (requiring 24-hour nursing care or supervision), intermediate-level (requiring 24-hour health-related care but not nursing), or dementia-level care (intermediate-level care in a secure environment to manage dementia-related behaviors).

We excluded residents in psychogeriatric, respite or palliative care; or residents unable to participate in the exercise program because they were acutely unwell, or immobile i.e., unable to mobilize without 2-person assistance or bed bound.

Participants who were able gave informed written consent before enrolment. For participants with cognitive impairment without the capacity to consent, written consent was obtained from next of kin and the facility clinical lead, and verbal assent from the participant before enrolment.

### *Sample and Randomization*

We estimated a sample size of 264 in each group ( $n = 528$ ; two-tailed test,  $\alpha = 0.05$ , power = 90%) to detect a 25% reduction in falls, assuming a control rate of 2.6 falls per resident per year, based on pilot data<sup>17</sup> for the primary outcome, fall rate. We assumed attrition of 35%, given participants' age and health status, which was offset by recruiting new participants up to 12 weeks before the trial's end.

Participants were individually randomized after completion of the enrolment and baseline measures, stratified by facility and level of care to control for facility factors. The data manager, not involved in recruitment or assessment, used a computer-generated random sequence to randomize participants into intervention and control groups.

Group assignment knowledge was limited to the data manager, statistician, project, and intervention managers. The nature of the intervention precluded blinding of participants and staff delivering the intervention.

### *Intervention*

The intervention group undertook the *Staying UpRight* program in a group setting (maximum ratio 1:8). The protocol paper details the intervention.<sup>19</sup> Briefly, it is a progressive balance and strength exercise program, with exercise selection and progressions determined by the

participants' abilities. Strength exercises used body weight resistance only and low repetitions (2×10 repetitions at 5–7/10 effort) in standing whenever possible. Exercises were progressed by increasing the number of sets, changing the speed or amplitude of the movement or the complexity of the task. Balance exercises were progressed by reducing hand support, base of support, visual input or adding a cognitive task, or combining exercises and progressions.

*Staying UpRight* classes were delivered for 1-hour twice-weekly by a physical therapist trained in the program for the first 6 months. For the second 6-months, classes were delivered by the physical therapist or by a trained health-care staff member, depending on facility management preference.

The control group participated in a program comprising seated activities with no resistance or progressions, in a group setting e.g., seated swimming, seated marching, heel and toe tapping, seated stretches and seated activities such as balloon catch and throw. Classes were led by LTC staff trained in the program, and dose matched over the trial period.

Intervention and control group participants continued to participate in any usual activities provided by the facility.

*Class attendance, fidelity, and adverse events* Class instructors documented participant attendance and reasons for nonattendance.

On-site audits of exercise classes and electronic record checks of exercises and progressions were conducted by a study investigator to ensure fidelity. Participants were restricted to their allocated class to prevent contamination between groups. Adverse events i.e., death, falls, hospitalizations were reported to an independent Data Monitoring Committee throughout the trial.

## **Outcome measures**

The primary outcome was fall rate, measured during the 12-month trial period. We collected participants' fall data for the 6-month period prior to trial enrolment (to determine baseline fall rates) and for the 12-month trial period using incident records, routinely kept by the facilities.

Secondary outcomes were fall risk, fall-related hospitalizations, and fractures, fall rate per 100 hours walked, change in ambulatory and physical capacity measured at 6 and 12-months. Fall-related hospitalizations were collected from hospital records and causes of death from facility, hospital, and death records.

### *Descriptive assessments*

Trained assessors, blinded to group allocation measured physical capacity (Short Physical Performance Battery (SPPB)<sup>20</sup> and Timed Up and Go (TUG),<sup>21</sup> cognition (Montreal Cognitive Assessment (MoCA)),<sup>22</sup> and ambulatory activity at baseline, 6 months, and 12 months.

Time spent walking and step count were recorded using an accelerometer (Axivity AX3; Axivity, York, UK) worn on the low back for 7 days.<sup>23, 24</sup> Accelerometer data were uploaded for blinded processing using a validated algorithm.<sup>23, 25</sup> To ensure ambulatory activity was adequately captured, all ambulatory bouts of  $\geq 3$  steps were included in the analyses.<sup>25</sup>

Health status was described using interRAI™ (international Resident Assessment Instrument) records which are routinely completed for LTC residents on admission and thereafter 6-monthly.

### *Data Analyses*

Following intention to treat principles, we analyzed outcomes according to random treatment allocation of the trial participants. All models were controlled for confounding factors of

prior fall rate, age, sex, and level of care. Continuous data are presented using mean ( $\pm$  SD) and categorical data using frequency (%). Statistical significance was set at  $\alpha \leq 0.05$  with 95% confidence intervals (95% CI) reported for all model estimates. Analyses were performed using statistical analysis system SAS 9.3 (SAS Institute Inc. Cary NC).

Baseline fall-incidence rates were calculated as number of falls/resident/year using fall data from 6-months prior to enrolment.

We used negative binomial regression to determine the incidence rate ratio (IRR) of fall rates between intervention and control groups at trial completion as the primary endpoint and secondarily as activity-adjusted fall rates i.e., falls per 100 hours walked. Similar negative binomial models were built for fall injury rates, hospitalizations, and fractures.

Logistic regression was used to compare fallen /not fallen during the trial period and fallen 2 or more times/not fallen during the trial period between intervention and control groups.

Pre specified subgroup analyses were performed to determine the impact of cognitive impairment (MoCA scores  $\geq 18/30$ ), physical capacity (SPPB scores  $\geq 8/12$ ) and compliance (adherence to the intervention) on outcomes. We defined compliance as those who attended  $\geq 50\%$  of the classes available to them (equivalent to 1 hour per week, i.e.,  $\geq 48$  classes over 12 months or  $\geq 25$  classes over 6 months), comparable with attendance rates reported by Hewitt et al, 2018.<sup>11</sup> Noncompliance was defined as those who could have attended  $\geq 1$  hour per week of classes in the intervention group but did not. Compliance models excluded participants enrolled for  $< 6$  months, those who died, were discharged, became immobile or entered palliative care before they could attend enough classes.

To estimate the effect of compliance on fall rates we used a complier average causal effect (CACE) analysis.<sup>26</sup> Based on our definition of compliance, we identified characteristics of compliers and created a dichotomous variable indicating observed compliance status in the



intervention group. We used a linear mixed-effect model to predict compliance in the intervention group with baseline measures as predictors. The resulting model was then used to estimate the control group's compliance probability. The compliance model was weighted using the probability of compliance for the control group and the observed compliance for the intervention group.

Repeated measures generalized linear mixed-effects models with a random intercept per individual within facility, and time, treatment and time-by-treatment interaction as fixed effects were used to compare change in ambulatory activity and physical capacity between groups. We also compared changes in ambulatory activity, physical capacity between groups at 6-months-baseline using generalized linear models.

#### *The Impact of COVID-19*

The COVID-19 pandemic impacted the trial, with three suspensions to recruitment, intervention delivery and on-site assessments during the trial due to government-mandated lockdowns to prevent COVID-19 transmission. The first two lockdowns averaged  $11 \pm 7$  and  $2 \pm 4$  weeks respectively, depending on the facility. 'Lockdown' refers to the periods when New Zealand was at its highest COVID-19 alert levels and LTC facilities closed to visitors, restricted services, and staff movements.<sup>27</sup> Facilities adopted varied approaches. Typically, residents were grouped into smaller cohorts for meals and activities to minimize interactions, but facilities continued to offer cohort-based or one-on-one activities and residents were not confined to their rooms. Residents were isolated from family, and staff faced social isolation and stringent infection control protocols. However, staffing levels were upheld and resident care was not impacted.<sup>27, 28</sup> No facility experienced a COVID-19 outbreak during the trial.

To compensate for the trial suspensions, we extended intervention delivery, and 6- and 12-month assessment points by an equivalent amount of time, ensuring at least 12 weeks (24 classes) prior to assessment points.

We stopped the intervention and on-site assessments before trial completion, with data monitoring committee approval due to the repeated suspensions (Supplementary Figure 1). However, data collection for falls, deaths, and hospitalizations continued for the trial duration, including during lockdowns, meaning an additional 4 months of these data were collected in a third of facilities.

We used an autoregressive–moving-average (ARMA) model to determine whether the fall rates of the two treatment arms changed during lockdown periods.

## **Results**

Participants were recruited between November 30, 2018, and March 25, 2021.

Participant flow is shown in Figure 1, with reasons withdrawal listed in Supplementary Table 1. COVID-19 lockdowns delayed 6- and 12-month assessments for 166 (63%) of the intervention group and 172 (66%) of the control group. Among the facilities, 13 of 25 completed 12-months, 11 completed 6-months and one facility had completed <6 months at trial cessation. At that point, 37% of the intervention group and 35% of the control group had not finished the final 6 months of the 12-month trial (Supplementary Table 2). Due to these COVID-related delays, the average trial period extended from 12 months to  $20.8 \pm 9.3$  months, with a median of 21.6 months (interquartile range 14.4-27.4).

### *Baseline characteristics*

Participants (n=520) with a mean age of  $84 \pm 8$  years were included (Table 1). There were no strongly imbalanced factors that required adjustment. Average MoCA scores of  $14 \pm 7$ , indicated moderate cognitive impairment. Average SPPB scores of  $5 \pm 3$  and time spent

ambulatory ( $1.3 \pm 0.7$  hours over 24 hours) indicated low physical capacity and low activity levels.

#### *Adherence to the exercise program*

Each facility scheduled approximately 50 sessions over the first 6 months and 96 sessions over 12 months (allowing for public holidays and physical therapist absences due to illness or leave). Class attendance between groups was similar. Main reasons for nonattendance of classes offered were declining to attend (51%), another activity, e.g., family visit (18%), or illness (13%). Over the 12-month period, 20% (n=51) of intervention and 21% (n=53) of the control attended  $\geq 48$  classes (Figure 2A). Over the first 6 months, 29% (n = 75) of intervention and 25% (n=65) of the control group attended  $\geq 25$  classes (Figure 2B).

#### *Falls Outcomes*

Table 2 summarizes falls during the trial period. There was no difference in fall rate or falls per 100 hours walked between intervention and control groups at 12-months [IRR 1.0 (95% CI: 0.8, 1.3) and IRR 1.2 (95% CI: 0.8, 1.6), respectively]. There was also no difference in fall risk [hazard ratio (HR) 1.1 (95% CI: 0.9, 1.4)], repeat fallers or fallers sustaining an injury at 12-months.

The ARMA model of fall rates for intervention and control arms indicated that COVID-19 lockdowns had no significant impact on fall rates ( $p = 0.80$  for the control and  $0.75$  for the intervention arm) (Supplementary Figure 2).

#### *Subgroup analyses*

There was no difference in fall rate or risk between the intervention (n=38) and control participants (n=40) with better physical capacity at 12-months [IRR 0.9 (95% CI: 0.4, 2.1) and IRR 0.7 (95% CI: 0.4, 1.3) respectively] (Supplementary Table 3).

There was also no difference in fall rate or risk between the intervention (n=66) and control participants (n=70) with better cognition (MOCA  $\geq$  18/30) at 12-months [IRR 1.1 (95% CI: 0.7, 1.7) and IRR 1.1 (95% CI: 0.7, 1.8) respectively] (Supplementary Table 3).

Because classes stopped prior to 12-months in 11 facilities, we undertook a sensitivity analysis for adherence over 12 months (attendance of  $\geq$  48 classes) and over the first 6 months (attendance of  $\geq$  25 classes) using CACE analysis. Fall rates did not differ between the high adherence intervention (n=51) and control groups (n=88) at 12 months [IRR 0.8 (95% CI: 0.6, 1.1)] (Supplementary Table 4A). Nor was there any difference in fall rate between the high adherence intervention group (n=68) and the control group (n=58) over the first 6 months [IRR 0.7 (95% CI: 0.5, 1.1)] (Supplementary Table 4B).

*Changes in ambulatory activity and physical capacity.*

The average time between baseline and the 6-month assessments was  $10.4 \pm 2.7$  months, due to COVID delays. We had insufficient 12-month data to compare changes to secondary outcomes (ambulatory activity and physical capacity) due to death and deterioration of participants' mobility during COVID-related delays, and the trial cessation prior to trial completion. Instead, we compared changes in secondary outcomes between baseline and 6-month assessments.

Step count declined by 3% over the 10-month period (544 steps/day, 95% CI [181, 908]), with no significant difference between groups. When compared to the control group (n=24), step count was better preserved in intervention group participants (n=24) with higher adherence (attendance  $\geq$  50% of classes) (p=0.02) (Supplementary Table 5).

SPPB scores declined by 1.3% over the 10-month period (0.6 points, 95% CI [0.3, 0.8]), with no significant difference between intervention and control groups (Supplementary Table 6).

### *Adverse Events*

No serious adverse events (cardiac events, stroke, injurious falls) occurred during the exercise classes. One non-injurious fall was reported during an exercise class.

### **Discussion**

This large clinical trial of exercise for falls prevention enrolled a representative group of LTC residents, including those with dementia and physical frailty, common in LTC. We found no effect of a physical therapist-led balance and strength group exercise program on fall rate compared with a control activity, independent of age, gender, or level of care.

The planned intervention met best practice for exercise mode, intensity, and duration protocols.<sup>8, 18</sup> However, it fell short in terms of dose, mainly due to early intervention discontinuation in over a third of participants and class interruptions caused by COVID-19. This likely explains the lack of impact. The recommended exercise dose for reducing falls in community-dwelling older individuals is 50 hours over 6 months.<sup>18</sup> However, the Sunbeam trial found that attending at least 30 hours (60% of classes) reduced fall rates in LTC settings,<sup>11</sup> a threshold we did not achieve.

When we considered only participants with attendance of  $\geq 25$  hours (50% of classes), we still found no reduction in falls, although this may reflect the lack of power due to the small sample size. However, those with better adherence may still have benefitted to some degree. At 6 months, ambulatory activity was better preserved in this group without increasing falls. The limited sample size and wide confidence intervals make this speculative but encouraging. Our cohort had a high baseline fall rate (<3.5 falls per person-year) and low physical and cognitive scores. Apart from COVID-19, low attendance at sessions was an issue, possibly linked to dementia and physical frailty. Our 6-month attendance rates were approximately half that of trials involving participants with better physical and cognitive function.<sup>10, 11, 29</sup>

The main reason for non-attendance “declining to attend”, aligns with findings in participants with moderate/severe cognitive impairment, where “declining to attend” also accounted for half of missed sessions.<sup>9</sup> Similar rates and reasons for non-attendance in our control exercise group suggest these participants were generally disinclined to engage in structured group exercise, regardless of the content.

Notably, a high-intensity exercise program involving LTC dementia residents with similar fall rates to ours also failed to reduce falls,<sup>12</sup> although adherence rates were not reported.

Furthermore, the efficacy of the Sunbeam program was reduced in participants with mild/moderate cognitive impairment, despite similar attendance rates to the whole sample.<sup>29</sup>

This raises the question of whether exercise alone effectively addresses fall risk factors in residents with cognitive impairment. Our aim to investigate whether better cognition or physical capacity would lead to improved outcomes was limited by small subgroup sizes, underscoring the need for further research in this area. Our recommendation is to repeat this trial outside of a pandemic, incorporating exercise within a multi-domain approach.

The study’s strengths included broad inclusion criteria, measurement of ambulatory activity in LTC,<sup>30</sup> and adjusting fall risk for ambulatory activity.<sup>31</sup> Falls-free activity may be an important outcome, indicating benefits without increasing fall risk.<sup>13, 16</sup>

The main limitation was the study's premature termination, which affected both dosage and our ability to detect effects. As we lacked 12-month assessments for a substantial portion of the sample, our power to detect differences in fall rates between groups smaller than 30%

(using all other assumptions from original sample size calculation, which powered the study to detect a 25% difference) was limited.

### **Conclusions**

When compared to seated, no-resistance exercises, the *Staying UpRight* group balance and strength exercise program did not prevent falls in intermediate and high-care LTC residents.

The most likely reason was inadequate dose, primarily due to COVID-19 related interruptions and early trial termination. Exercise that does not meet the recommended dose and frequency to prevent falls may be insufficient to reduce falls in LTC residents.

### **Conflict of Interest**

The authors declare there are no conflicts of interest.

## References

1. Deandrea, S, Bravi, F, Turati, F, et al. Risk factors for falls in older people in nursing homes and hospitals. A systematic review and meta-analysis. *Arch Gerontol Geriatr* 2013;56(3):407-415.
2. Wabe, N, Seaman, KL, Nguyen, AD, et al. Epidemiology of falls in 25 Australian residential aged care facilities: a retrospective longitudinal cohort study using routinely collected data. *Int J Qual Health Care* 2022;34(3) (no pagination).
3. Büchele, G, Becker, C, Cameron, ID, et al. Predictors of serious consequences of falls in residential aged care: Analysis of more than 70,000 falls from residents of Bavarian nursing homes. *J Am Med Dir Assoc* 2014;15(8):559-563.
4. Health Quality & Safety Commission New Zealand. Falls & Fractures Outcomes Framework; Accessed 8th August 2023.
5. Pointer, S. Trends in hospitalised injury due to falls in older people, 2007–08 to 2016–17. *Injury Research and Statistics Series*. Canberra: Australian Institute of Health and Welfare; 2019.
6. Sherrington, C, Fairhall, NJ, Wallbank, GK, et al. Exercise for preventing falls in older people living in the community. *Cochrane Database Syst Rev* 2019;2019(1)
7. Cameron, ID, Dyer, SM, Panagoda, CE, et al. Interventions for preventing falls in older people in care facilities and hospitals. *Cochrane Database Syst Rev* 2018;9.
8. Montero-Odasso, M, van der Velde, N, Martin, FC, et al. World guidelines for falls prevention and management for older adults: a global initiative. *Age Ageing* 2022;51(9).
9. Whitney, J, Jackson, SHD, Martin, FC. Feasibility and efficacy of a multi-factorial intervention to prevent falls in older adults with cognitive impairment living in residential care (ProF-Cog). A feasibility and pilot cluster randomised controlled trial. *BMC Geriatr* 2017;17(1).
10. Arrieta, H, Rezola-Pardo, C, Gil, SM, et al. Effects of multicomponent exercise on frailty in long-term nursing homes: a randomized controlled trial. *J Am Geriatr Soc* 2019;67(6):1145-1151.
11. Hewitt, J, Goodall, S, Clemson, L, et al. Progressive resistance and balance training for falls prevention in long-term residential aged care: a cluster randomized trial of the Sunbeam program. *J Am Med Dir Assoc* 2018;19(4):361-369.



12. Toots, A, Wiklund, R, Littbrand, H, et al. The effects of exercise on falls in older people with dementia living in nursing homes: a randomized controlled trial. *J Am Med Dir Assoc* 2019;20(7):835-842.e831.
13. Klenk, J, Becker, C, Palumbo, P, et al. Conceptualizing a Dynamic Fall Risk Model Including Intrinsic Risks and Exposures. *J Am Med Dir Assoc* 2017;18(11):921-927.
14. Lord, SR, March, LM, Cameron, ID, et al. Differing risk factors for falls in nursing home and intermediate-care residents who can and cannot stand unaided. *J Am Geriatr Soc* 2003;51(11):1645-1650.
15. Klenk, J, Kerse, N, Rapp, K, et al. Physical activity and different concepts of fall risk estimation in older people-results of the ActiFE-Ulm study. *PLoS One* 2015;10(6):e0129098-e0129098.
16. Del Din, S, Galna, B, Lord, S, et al. Falls risk in relation to activity exposure in high-risk older adults. *J Gerontol A Biol Sci Med Sci* 2020;75(6):1198-1205.
17. Kerse, N, Shaw, L, Walker, D. Staying Upright in Rest Home Care trial: Final report June 2009. The University of Auckland; 2009.
18. Sherrington, C, Michaleff, ZA, Fairhall, N, et al. Exercise to prevent falls in older adults: an updated systematic review and meta-analysis. *Br J Sports Med* 2017;51(24):1750-1758.
19. Taylor, L, Parsons, J, Taylor, D, et al. Evaluating the effects of an exercise program (Staying UpRight) for older adults in long-term care on rates of falls: Study protocol for a randomised controlled trial. *Trials* 2020;21(1).
20. 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(2):M85-M94.
21. Podsiadlo, D, Richardson, S. The Timed "Up & Go": a test of basic functional mobility for frail elderly persons. *J Am Geriatr Soc* 1991;39(2):142-148.
22. Nasreddine, ZS, Phillips, NA, Bédirian, V, et al. The Montreal Cognitive Assessment, MoCA: a brief screening tool for mild cognitive impairment. *J Am Geriatr Soc* 2005;53(4):695-699.

23. Buckley, C, Cavadino, A, Del Din, S, et al. Quantifying reliable walking activity with a wearable device in aged residential care: How many days are enough? *Sensors* 2020;20(21):1-12.
24. Del Din, S, Godfrey, A, Rochester, L. Validation of an accelerometer to quantify a comprehensive battery of gait characteristics in healthy older adults and Parkinson's disease: Toward clinical and at home use. *IEEE J Biomed Health Inform* 2016;20(3):838-847.
25. Del Din, S, Galna, B, Godfrey, A, et al. Analysis of free-living gait in older adults with and without Parkinson's disease and with and without a history of falls: identifying generic and disease specific characteristics. *J Gerontol A Biol Sci Med Sci* 2017.
26. Schreijenberg, M, Lin, CWC, McLachlan, AJ, et al. Paracetamol is ineffective for acute low back pain even for patients who comply with treatment: complier average causal effect analysis of a randomized controlled trial. *Pain* 2019;160(12):2848-2854.
27. Ma'u, E, Robinson, J, Cheung, G, et al. COVID-19 and Long-Term Care in New Zealand: impact, measures and lessons learnt. *Country report*. LTCcovid.org, International Long-Term Care Policy Network, CPEC-LSE; 2020.
28. Jackways, T, Manuel, R, Wood, P, et al. Independent review of COVID-19 clusters in aged residential care facilities. Wellington: [Ministry of Health], 2020.
29. Mak, A, Delbaere, K, Refshauge, K, et al. Sunbeam program reduces rate of falls in long-term care residents with mild to moderate cognitive impairment or dementia: Subgroup analysis of a cluster randomized controlled trial. *J Am Med Dir Assoc* 2022;23(5):743-749.e741.
30. Mc Ardle, R, Sverdrup, K, Del Din, S, et al. Quantifying physical activity in aged residential care facilities: a structured review. *Ageing Res Rev* 2021;67.
31. Galik, EM, Resnick, B, Holmes, SD, et al. A Cluster Randomized Controlled Trial Testing the Impact of Function and Behavior Focused Care for Nursing Home Residents With Dementia. *J Am Med Dir Assoc* 2021;22(7):1421-1428.e1424.

## Legends for Tables/figures

**Table 1**

Characteristics and Baseline Measures

	n†	Intervention (n=262)	n†	Control (n=258)	P- value*
Age	260	83.99 (7.66)	253	84.22 (7.51)	
Falls in previous 6 months, n (per-person year)					
Person-years of data		111.02		107.58	
Falls		454 (4.09)		359 (3.34)	0.55
Falls-related injury		82 (0.74)		72 (0.67)	0.31
Falls-related hospitalizations		10 (0.09)		9 (0.08)	0.95
Falls-related fractures		3 (0.03)		1 (0.01)	0.37
Fell in previous 6 months		108 (41.22)		111 (43.02)	0.78
1 fall		46 (17.56)		47 (18.22)	
2 falls		14 (5.34)		26 (10.08)	
≥3 falls		48 (18.32)		38 (14.73)	
Fell resulting in injury		46 (17.56)		47 (18.22)	0.93
Fell resulting in hospitalization		9 (3.44)		6 (2.33)	0.47
Fell resulting in fracture		3 (1.15)		1 (0.39)	0.36
<b>Ambulatory measures, mean (SD)</b>	169		158		
Steps per day		5,010.78 (3,394.39)		5,381.84 (3,306.33)	0.11
Percentage of time walking per day		4.87 (3.03)		5.21 (2.99)	0.11
<b>Assessments, mean (SD)</b>					
Gait speed (3 meters) m/s	261	0.61 (0.39)	253	0.61 (0.4)	0.95
SPPB (0-12)	232	4.59 (2.62)	227	4.83 (2.85)	0.26
TUG (s)	222	29.22 (17.68)	210	30.46 (19.47)	0.57
MOCA (0-30)	217	13.38 (7.04)	218	14.16 (6.72)	0.20
<b>interRAI measures</b>	239		234		
	/		/		
	262		254		
ADL Short Form (0-16), mean (SD)		2.92 (3.12)		2.83 (3.42)	0.29
Disease diagnoses, n (%),					
Musculoskeletal		10 (4.18)		18 (7.69)	0.13
Neurological		86 (35.98)		66 (28.21)	0.14
Cardiopulmonary		94 (39.33)		80 (34.19)	0.14
Psychological		40 (16.74)		31 (13.25)	0.34
Infection		42 (17.57)		41 (17.52)	0.97
Other		51 (21.34)		49 (20.94)	0.88

	n†	Intervention (n=262)	n†	Control (n=258)	P- value*
Cognitive Performance Scale (0-6), n (%)	239		234		0.05
Intact		41 (17.15)		52 (22.22)	
Borderline intact		37 (15.48)		39 (16.67)	
Mild impairment		92 (38.49)		85 (36.32)	
Moderate to very severe impairment		69 (28.87)		58 (24.79)	
Depression rating scale (0-14), n (%)	239		234		0.39
0		145 (60.67)		131 (55.98)	
1		29 (12.13)		39 (16.67)	
2		27 (11.30)		24 (10.26)	
≥3		38 (15.90)		40 (17.09)	
Pain, n (%)					0.06
No pain	239	127 (53.14)	234	106 (45.30)	
Less than daily pain		96 (40.17)		106 (45.30)	
Daily pain but not severe		13 (5.44)		18 (7.69)	
Daily severe -excruciating pain		3 (1.26)		4 (1.71)	
Dyspnoea, n (%)	239	59 (24.69)	234	51 (21.79)	0.42
Fatigue, n (%)	239		234		0.80
None		143 (59.83)		136 (58.12)	
Minimal		72 (30.13)		75 (32.05)	
Moderate-severe		24 (10.04)		23 (9.83)	
<b>Prior hospitalizations</b> n, (per person year)					
Hospitalizations in past 6 months	262	165 (1.26)	258	177 (1.37)	0.51
Acute hospitalizations in past 6 months	262	121 (0.92)	258	132 (1.02)	0.46

SD, standard deviation

\* Controlling for age, gender, and care level

† Indicates number of measurements when values were missing

**Table 2**

Falls during follow-up.

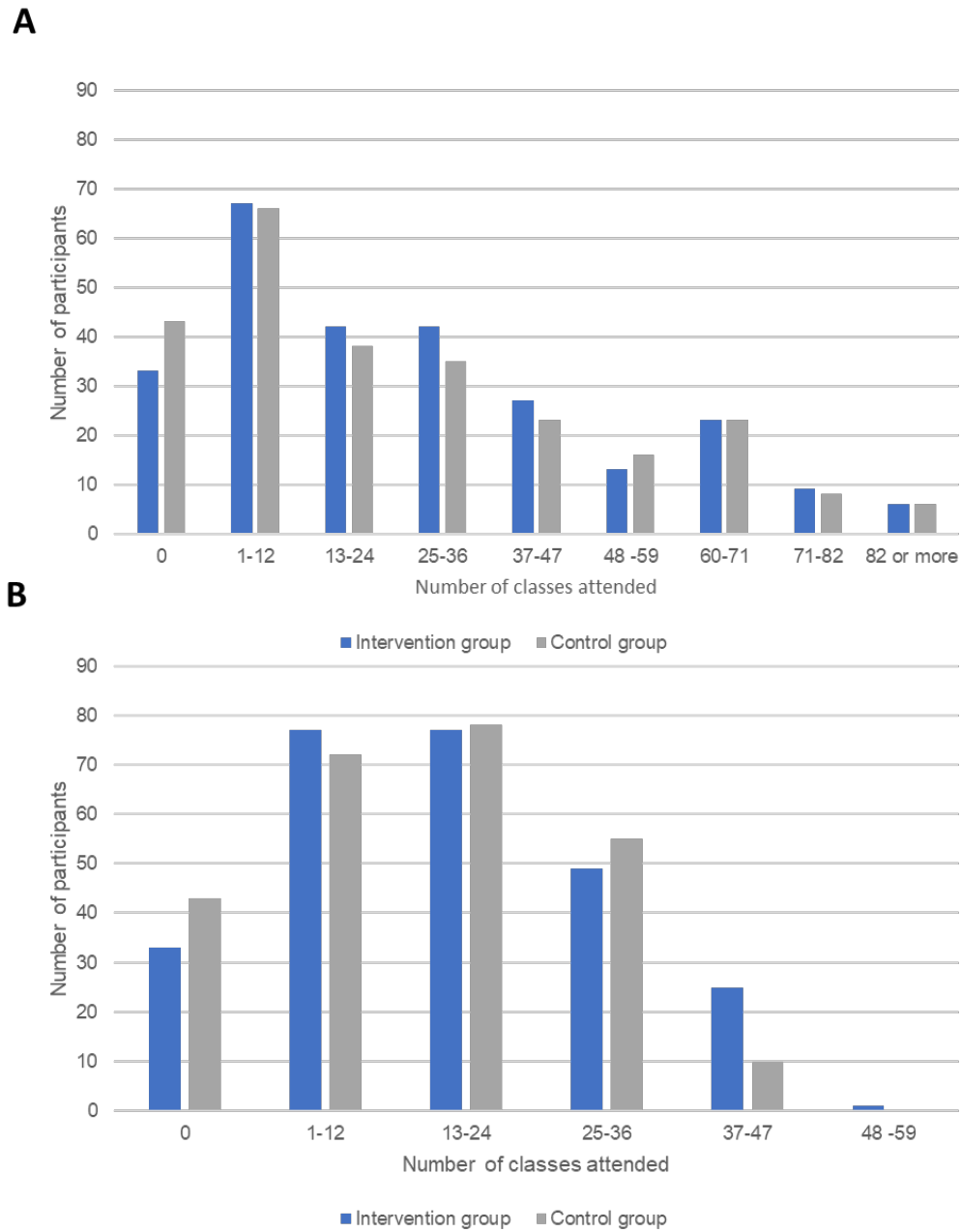
	Intervention (n=262)	Control (n=258)	Regression models: Intervention vs control	
			IRR/HR/OR (95% CI)	P Value
Fall count and fall rates, n (per-person year)				
Falls	1,708 (4.14)	1,690 (4.27)	0.98 (0.76, 1.27) †	0.89
Fall rate adjusted for activity	1,708 (129.76)	1,690 (124.06)	1.15 (0.81, 1.63)	0.42
Injurious falls*	291 (0.71)	304 (0.77)	0.97 (0.73, 1.28) †	0.81
Fall-related hospital admissions	43 (0.10)	51 (0.13)	1.14 (0.50, 2.60) †	0.77
Fall-related fractures	21 (0.05)	20 (0.05)	1.02 (0.64, 1.61) †	0.94
Number and proportion of fallers, n (%)				
Fallers	194 (74.05)	190 (73.64)	1.08 (0.85, 1.36) §	0.56
Repeat fallers (≥2 falls)	166 (63.36)	157 (60.85)	1.13 (0.72, 1.77) ¶	0.61
Fallers sustaining an injury*	116 (44.27)	120 (46.51)	0.89 (0.62, 1.28)	0.52
Fallers requiring hospitalization	34 (12.98)	43 (16.67)	0.73 (0.44, 1.19)	0.21
Fallers sustaining a fracture	18 (6.87)	17 (6.59)	1.05 (0.52, 2.12)	0.88

†IRR from negative binomial regression models, adjusting for falls history, age, gender, and level of care

§HR from Cox's proportional hazards regression adjusting for falls history, age, gender, and level of care

¶OR from logistic regression model adjusting for falls history, age, gender, and level of care

\*Falls resulting in documented soft tissue injury, fracture, head injury, hospitalization



**Fig. 1 Classes attendance over 12 months (A) and over the first 6 months (B)**

**Supplemental Table 1: Class attendance by facility**

A: Class attendance for facilities that completed 12 months.

<i>Facility ID</i>	<i>Control</i>				<i>Intervention</i>			
	<i>n</i>	<i>Mean</i>	<i>SD</i>	<i>Highest number of classes attended</i>	<i>n</i>	<i>Mean</i>	<i>SD</i>	<i>Highest number of classes attended</i>
1	26	28.27	24.14	67	26	33.38	26.97	75
2	12	37.75	25.48	70	13	33.69	38.37	93
3	18	10	13.46	37	17	21.59	17.84	52
4	9	26.44	21.79	55	10	22.3	15.1	47
5	6	26.17	20.15	46	7	38.14	32.01	77
6	12	16.58	19.41	52	11	20.91	32.82	79
7	9	41.89	22.52	72	9	31.33	30.79	82
8	10	36	20.94	73	10	38.1	27.75	68
9	6	76.33	56.51	120	8	19.13	10.89	32
10	10	9.2	9.85	28	9	25.67	30.76	86
11	22	17.32	20.14	65	21	18.24	15.07	62
12	4	25.75	18.04	42	4	28.75	26.68	59
13	19	46.53	34.85	106	22	34	31.15	86
<b>COMBINED</b>	163	28.3	28.2		167	28.1	26.7	

B: Class attendance for facilities that completed 6 months.

<i>Facility ID</i>	<i>Control</i>				<i>Control</i>			
	<i>n</i>	<i>Mean</i>	<i>SD</i>	<i>Highest number of classes attended</i>	<i>n</i>	<i>Mean</i>	<i>SD</i>	<i>Highest number of classes attended</i>
14	8	22.25	24.85	60	7	16.43	23.57	56
15	6	47.33	27.81	75	8	17	18.59	42

16	4	53.25	13.65	70	6	12.33	16.38	43
17	7	30.29	21.75	53	7	30.43	14.71	46
18	5	0	0	0	5	20.2	14.94	34
19	12	10.58	5.58	16	12	24.25	14.45	40
20	9	11	13.19	38	7	11.71	10.87	29
21	5	17.4	11.15	28	3	36.67	31.56	67
22	7	20.14	12.71	34	8	32.13	16.06	47
23	9	28.78	27.57	64	7	47.14	26.08	66
24	13	8.46	9.17	26	13	19.31	15.71	44
25	10	28.2	14.67	45	12	21.33	14.09	37
<b>COMBINED</b>	95	21.0	20.7		88	23.9	18.5	

Facilities 1-13 full year, 15-25 completed 6 months except #18

## Supplemental Table 2

### Reasons for withdrawal

Reasons for withdrawal	Intervention withdrawals		Control withdrawals	
	Randomisation to 6 months <sup>1</sup>	6-12 months <sup>2</sup>	Randomisation to 6 months <sup>3</sup>	6-12 months <sup>4</sup>
Deceased	41	14	44	18
No longer mobile	13	2	7	2
Preference-family	0	0	1	0
Preference-resident	5	0	7	0
Discharged from facility	9	6	11	2
Moved to palliative care	2	1	1	0
Cognitive decline	0	0	2	0
<b>TOTAL</b>	<b>70</b>	<b>23</b>	<b>73</b>	<b>22</b>



### Supplemental Table 3

Subgroup analyses for falls 12 months-baseline

<b>A: High Physical Capacity (SPPB <math>\geq</math>8/12)</b>			<b>Regression models: Intervention vs control</b>	
	<b>Intervention (n=38)</b>	<b>Control (n=40)</b>	<b>IRR /HR/OR (95% CI)</b>	<b>P value</b>
Fall count and fall rates n (per-person year)				
Falls	223 (3.44)	207 (3.16)	0.89 (0.37, 2.14) †	0.79
Injurious falls*	31 (0.48)	30 (0.46)		
Fall-related hospital admissions	1 (0.02)	5 (0.08)		
Fall-related fractures	2 (0.03)	0 (0.0)		
Number and proportion of fallers, n (%)				
Fallers	22 (57.89)	26 (65)	0.68 (0.36, 1.29) §	0.25
Repeat fallers ( $\geq$ 2 falls)	17 (44.74)	17 (42.50)	1.43 (0.44, 4.66) ¶	0.55
Fallers sustaining an injury*	9 (23.68)	11 (27.5)		
Fallers requiring hospitalization	1 (2.63)	5 (12.50)		
Fallers sustaining a fracture	2 (5.26)	0 (0.0)		
<b>B: High Cognition (MoCA <math>\geq</math>18/30)</b>			<b>Regression models: Intervention vs control</b>	
	<b>Intervention (n=66)</b>	<b>Control (n=70)</b>	<b>IRR /HR/OR (95% CI)</b>	<b>P value</b>
Fall count and fall rates n (per-person year)				
Falls	407 (4.00)	592 (5.92)	1.05 (0.66, 1.66) †	0.85
Injurious falls*	90 (0.89)	93 (0.93)		
Fall-related hospital admissions	8 (0.08)	16 (0.16)	0.45 (0.09, 2.19) †	0.32
Fall-related fractures	2 (0.02)	8 (0.08)		
Number and proportion of fallers, n (%)				
Fallers	47 (71.21)	49 (70.00)	1.14 (0.73, 1.78) §	0.56
Repeat fallers ( $\geq$ 2 falls)	40 (60.61)	35 (50.00)	1.48 (0.65, 3.35) ¶	0.34
Fallers sustaining an injury*	30 (45.45)	33 (47.14)		
Fallers requiring hospitalization	8 (12.12)	13 (18.57)		
Fallers sustaining a fracture	2 (3.03)	5 (7.14)		

†IRR from negative binomial regression models, adjusting for falls history, age, gender, and level of care

§HR from Cox's proportional hazards regression adjusting for falls history, age, gender, and level of care

¶OR from logistic regression model adjusting for falls history, age, gender, and level of care

\*Falls resulting in documented soft tissue injury, fracture, head injury, hospitalization

**Supplemental Table 4**

**4A.** Change in outcomes 12 months-baseline for the high adherence group (attendance of  $\geq 48$  classes over 12 months)

	<b>Intervention (n=51) vs control (n=88**)</b>		<b>Intervention: complier (n=51) vs non-complier (n=90)</b>	
	IRR	p-value	IRR	p-value
Falls per person-year	0.81 (0.60, 1.09)	0.17	0.79 (0.52, 1.21)	0.28
SPPB (0-12)*	1.14 (0.72, 1.80)	0.57	1.04 (0.55, 1.97)	0.89
Balance score (0-4)*	1.27 (0.92, 1.75)	0.14	0.93 (0.61, 1.43)	0.75
Gait speed over 3 meters*	1.08 (0.85, 1.38)	0.52	1.12 (0.80, 1.56)	0.51
Chair stand score (0-4)*	1.07 (0.84, 1.35)	0.60	1.06 (0.76, 1.49)	0.71
TUG (s)*	0.39 (0.05, 3.27)	0.39	0.08 (0.00, 2.52)	0.15
Time spent walking (%)*	1.65 (0.98, 2.77)	0.06	1.31 (0.68, 2.51)	0.42

\*\*Equivalent sample size after weighting

**4B.** Change in outcomes 6 months-baseline for the high adherence group (attendance of  $\geq 25$  classes over 6 months)

	<b>Intervention (n=68) vs control (n=58)</b>		<b>Intervention: complier (n=68) vs non-complier (n=148)</b>	
	IRR	p-value	IRR	p-value
Falls per person-year	0.64 (0.34, 1.21)	0.17	0.74 (0.48, 1.15)	0.18
SPPB (0-12)*	0.99 (0.48, 2.02)	0.97	0.89 (0.53, 1.49)	0.66
Balance score (0-4)*	1.35 (0.87, 2.09)	0.18	0.93 (0.68, 1.27)	0.65
Gait speed over 3 meters*	0.93 (0.67, 1.29)	0.66	1.08 (0.85, 1.37)	0.51
Chair stand score (0-4)*	0.91 (0.66, 1.26)	0.58	0.97 (0.77, 1.22)	0.77
TUG (s)*	2.28 (0.03, 170.70)	0.71	0.16 (0.007, 3.29)	0.23
Time spent walking (%)*	1.38 (0.55, 3.46)	0.48	0.52 (0.27, 1.00)	0.05

\*Change between first and second measurements, adjusted for the time between

**Supplemental Table 5**

Changes in ambulatory activity 6-months-baseline.

	<b>n</b>	<b>Intervention</b>	<b>n</b>	<b>Control</b>	<b>p-value*</b>
<b>Total sample</b>					
Months between baseline and 6-month assessment <sup>‡</sup>	151	10.12 (2.47)	153	10.42 (2.68)	
Steps per day (over 24 hours)	67	-123.82 (1,334.18)	59	-526.16 (1,267.56)	0.07
Time spent walking per day (%)	67	-0.14 (1.27)	59	-0.47 (1.18)	0.12
<b>High adherence (≥48 classes)</b>					
Months between baseline and 6-month assessment <sup>‡</sup>	45	9.47 (2.45)	62**	10.53 (1.60)	
Steps per day (over 24 hours)	24	-9.98 (906.42)	24**	-581.15 (794.60)	0.02
Time spent walking per day (%)	24	-0.10 (0.91)	24**	0.44 (0.11)	0.06
<b>High physical capacity (SPPB ≥8/12)</b>					
Months between baseline and 6-month assessment <sup>‡</sup>	27	10.31 (2.52)	24	10.23 (2.74)	
Steps per day (over 24 hours)	11	104 (1,246.05)	12	-776.4 (1,960.57)	0.38
Time spent walking per day (%)	11	0.04 (1.40)	12	-0.72 (1.71)	0.46
<b>Cognition (MOCA ≥18/30)</b>					
Months between baseline and 6-month assessment <sup>‡</sup>	44	9.83 (2.24)	40	10.09 (2.94)	
Steps per day (over 24 hours)	25	-277.76 (1,749.31)	21	-877.98 (1,727.39)	0.21
Time spent walking per day (%)	25	-0.25 (1.68)	21	-0.72 (1.62)	0.27

Measures are mean (SD)

\* Analyses controlling for age, gender, and level of care

‡Measures adjusted to 6-months from actual months between baseline and 6-month assessment points.

\*\*Equivalent sample size after weighting

**Supplemental Table 6**

Changes in physical capacity 6 months-baseline.

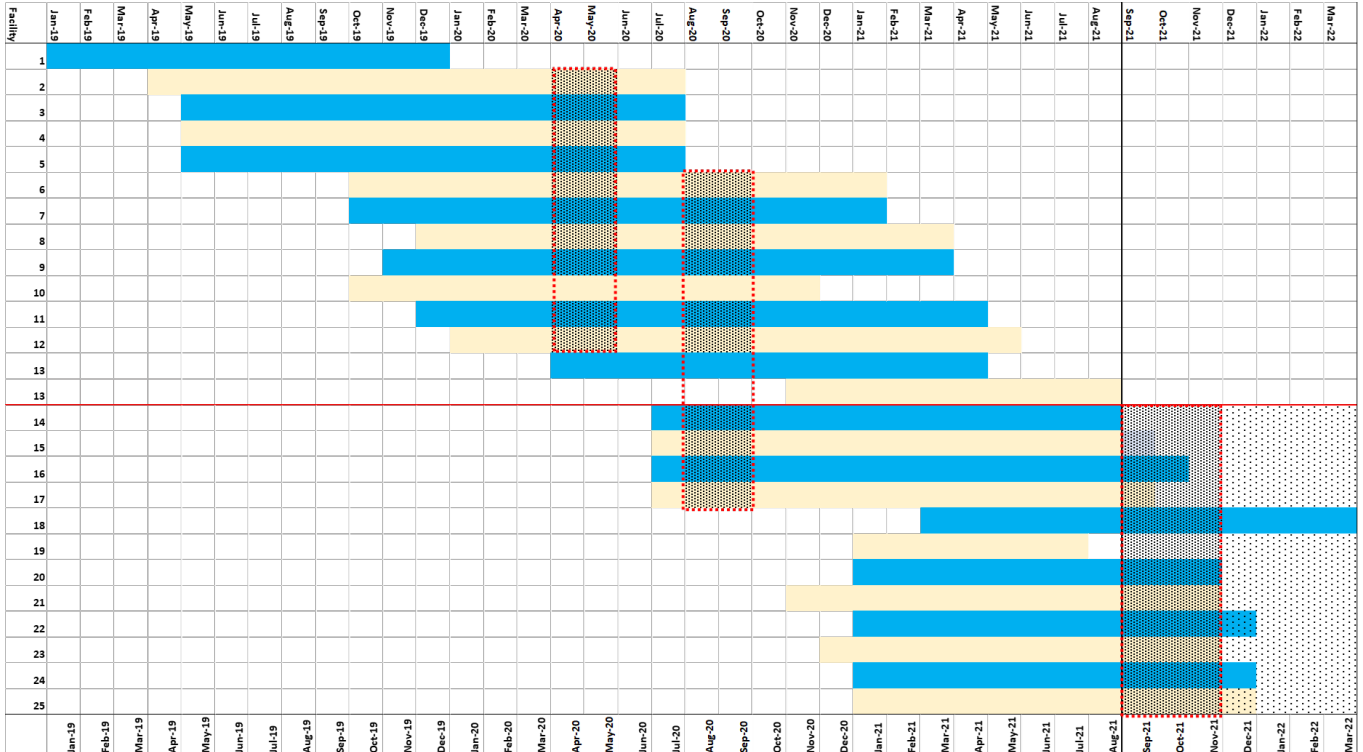
	<b>n</b>	<b>Intervention</b>	<b>n</b>	<b>Control</b>	<b>p-value*</b>
<b>Total sample</b>					
Actual months between baseline and 6-month assessment <sup>‡</sup>	151	10.12 (2.47)	153	10.42 (2.68)	
Gait speed (s) over 3 meters	147	-0.1 (0.72)	149	-0.08 (0.62)	0.77
SPPB (0-12)	128	-0.29 (1.39)	129	-0.37 (1.39)	0.61
TUG (s)	118	1.91 (7.95)	114	1.4 (7.35)	0.70
<b>High adherence (≥48 classes)</b>					
Actual months between baseline and 6-month assessment <sup>‡</sup>	45	9.47 (2.45)	62**	10.53 (1.60)	
Gait speed (s) over 3 meters	30	-0.01 (0.88)	35**	0.06 (0.35)	0.85
SPPB (0-12)	24	-0.49 (1.27)	29**	-0.37 (0.84)	0.86
TUG (s)	24	0.83 (5.08)	26**	1.59 (3.93)	0.60
<b>High physical capacity (SPPB ≥8/12)</b>					
Actual months between baseline and 6-month assessment <sup>‡</sup>	27	10.31 (2.52)	24	10.23 (2.74)	
Gait speed (s) over 3 meters	26	-0.32 (0.72)	23	-0.12 (0.46)	0.41
SPPB (0-12)	26	-1.19 (1.54)	23	-1.05 (1.87)	0.86
TUG (s)	25	2.29 (4.32)	22	0.53 (2.89)	0.27
<b>Cognition (MOCA ≥18/30)</b>					
Actual months between baseline and 6-month assessment <sup>‡</sup>	44	9.83 (2.24)	40	10.09 (2.94)	
Gait speed (s) over 3 meters	42	-0.12 (0.80)	39	-0.25 (0.77)	0.73
SPPB (0-12)	40	-0.19 (1.44)	36	-0.26 (1.52)	0.87
TUG (s)	39	2.84 (7.69)	34	0.8 (6.10)	0.20

Measures are mean (SD)

\* Analyses controlling for age, gender, and level of care

‡Measures adjusted to 6-months from actual months between baseline and 6-month assessment points.

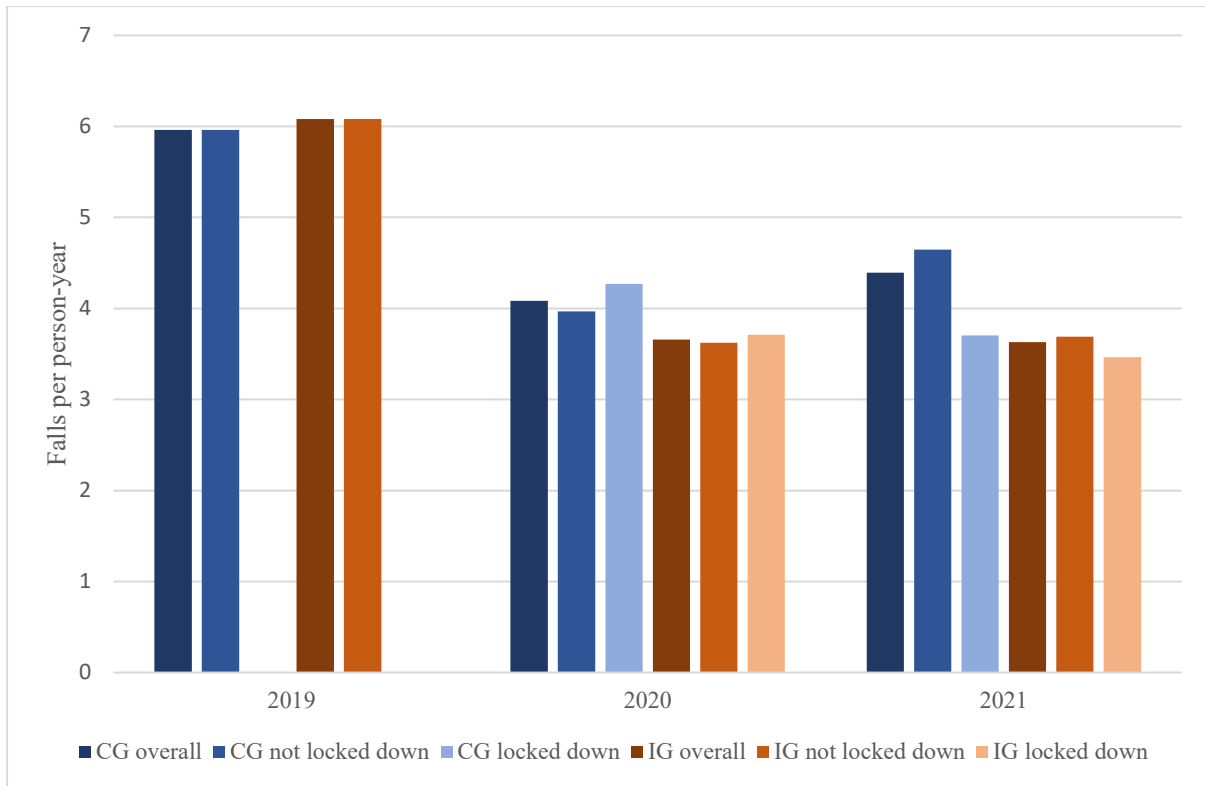
\*\*Equivalent sample size after weighting



1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17

**Supplemental Figure 1.** COVID impact on study timeline by facility

Intervention timeline by facility, with COVID closure periods (*shaded and outlined*) for individual facilities (Closures began March 25th, 2020 (for  $76 \pm 15$  days, depending on the facility, August 12th, 2020 ( $51 \pm 27$  days) and August 17th, 2021) Facilities ( $n=13$ ) above the *red horizontal line* completed all assessment points. Two facilities (labelled 10 and 13) continued classes during closure periods. Facility #13 is listed twice because there were 2 start dates for separate sections of the facility. Facilities below the *red horizontal line* ( $n=11$ ) completed baseline and 6-month assessment points. One facility (# 18) completed the baseline only. The trial stopped at the point depicted by the *vertical black line* (September 29th, 2021). Thirteen of the 25 facilities completed the 12-month trial period, 11 completed 6-months and 1 facility completed <6 months before the Data Monitoring Committee stopped the trial (September 30<sup>th</sup>, 2021) because of the COVID-related delays. We collected fall data for each facility's projected study period, irrespective of intervention cessation during closures or trial cessation.



18

19 **Supplemental Figure 2.** Fall rate of Staying UpRight participants after randomisation by  
 20 year

21 Abbreviations: CG control group; IG intervention group

22 ‘Lockdown’ refers to the periods when New Zealand was at its highest COVID-19 alert  
 23 levels and long term care facilities closed to visitors, restricted services, and staff movements.

24 An autoregressive moving-average model of the daily fall rate of those randomised to each  
 25 arm indicated that COVID-19 lockdowns had no significant impact on falls (a p-value of 0.80  
 26 for the control arm and 0.75 for the intervention arm).

27 In 2019, participants experienced approximately 6 falls per person-year, with no COVID-19  
 28 lockdowns. Fall rates decreased in 2020 and 2021, both during and outside of lockdowns.

29 The difference between the 2019 fall rate and the subsequent years is due to a different

30 subsample of participants, as those who began the study in the early stages had completed it  
31 by 2020.

32