Title: Exergame and cognitive training for preventing falls in community-dwelling older people: a randomized controlled trial.

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ABSTRACT

Exergame training, in which video games are used to promote exercise, can be tailored to address cognitive and physical risk factors for falls and is a promising method for fall prevention in older people. Here we performed a randomized clinical trial using the *smart±step* gaming system to examine the effectiveness of two home-based computer game interventions, seated cognitive training and step exergame training, for fall prevention in community-dwelling older people, as compared to a minimal-intervention control group. Participants 65 years or older (n=769, 71% female) living independently in the community were randomized to one of three arms: cognitive training using a computerized touch pad while seated; exergame step training on a computerised mat; or control (provided with an education booklet on healthy ageing and fall prevention). The rate of falls reported monthly over 12 months, the primary outcome of the trial, was significantly reduced in the exergame training group compared to the control group (IRR=0.74, 95%CI=0.56 to 0.98), but was not statistically different between the cognitive training and control groups (IRR=0.86, 95%CI=0.65 to 1.12). No beneficial effects of the interventions were found for secondary outcomes of physical and cognitive function and no serious intervention-related adverse events were reported. The results of this trial support the use of exergame step training for preventing falls in community-dwelling older people. As this intervention can be conducted at home and requires only minimal equipment, it has the potential for scalability as a public health intervention to address the increasing problem of falls and fall-related injuries.

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INTRODUCTION

Falls in older people are a significant public health issue, contributing to mobility-related disability and loss of independence, and are the second leading cause of unintentional injury deaths worldwide.[1] Given the ageing of populations worldwide, the number and impact of falls is projected to grow, creating demands on health care systems that will be difficult to meet[2] as well as devastating impacts on individuals and their support circle. Effective fall prevention strategies that can be readily scaled for widespread implementation are therefore urgently needed.

There is robust evidence from Cochrane and other systematic reviews indicating exercise, and in particular balance training, can prevent falls in older people.[3, 4] However, uptake, adherence and methods for ongoing delivery remain a challenge.[5] In addition, few fall prevention interventions have explicitly addressed the training of cognitive functions, despite consistent findings that reduced cognitive function is associated with balance, gait and mobility impairments and is an independent risk factor for falls.[6] Indeed, there is growing evidence that cognitive training can improve mobility and gait speed[7, 8] in addition to cognitive functions.[9, 10]

Interactive computer games can deliver cognitive training (also known as brain training) while presenting motivating characteristics such as entertaining goal-directed tasks, progressive challenges, immediate feedback and target scores to maximise adherence. Gamified training is a promising method for delivering evidence-based fall prevention exercise as it can facilitate exercise adherence[11] and can be tailored to address cognitive and physical risk factors for falls.[12, 13] Several small trials of exergame training have found improved dynamic balance,[14] balance confidence,[15] and cognitive functions including processing speed, attention, visuo-spatial skills and executive functioning in older people.[16,17] There is preliminary evidence that exergames may prevent falls in older people.[18] However, no definitive, appropriately powered, randomised controlled trial has been conducted to determine whether exergame training or cognitive training can prevent falls in older people.

To address this research gap, we developed the *smart±step* in-home computerised gaming system that can be played either using a touch pad while seated (cognitive training) or by stepping on target panels on a step mat (exergame training). We hypothesised that both training programs would reduce falls and improve physical and cognitive functions in community-living older people.

RESULTS

One thousand and nine people were screened for eligibility between 27 October 2016 and 10 May 2019 (Figure 1). Of these, 769 were included and randomly assigned to either exergame training (n=252), cognitive training (n=262) or control group (n=255). Fifty-three participants withdrew from the study during the 12-month trial period (exergame training, n=21; cognitive training, n=23; control group, n=9) and 61 participants in the intervention groups discontinued the intervention but continued to contribute falls (primary outcome) data (exergame, n=42; cognitive, n=23). Those who withdrew were on average 2.5 years older than those that completed the study, yet not different in gender or number of medical conditions. Table 1 presents baseline characteristics of the three groups, which were similar in age, sex, years of education, body mass index, number of medical conditions and medications taken, hence no adjustments were made to the analyses.

Effect on Primary Outcome – Rate of Falls

The number of falls reported during the 12 month follow up period were 163 for the exergame training group, 197 for the cognitive training group, and 231 for the control group. Table 2 reports the rate of falls across the three groups. The exergame training group had a significantly lower rate of falls than the control group (IRR=0.74, 95%CI=0.56-0.98). The rate of falls in the cognitive training group was lower than in the control group but this difference was not statistically significant (IRR=0.86, 95%CI=0.65-1.13). Post-hoc comparison showed no significant difference in falls between the exergame training group, relative to the cognitive training group (IRR=0.86, 95%CI=0.64-1.16).

Effect on Secondary Outcomes

Fall-related outcomes

The number of fallers in each group for each faller category are reported in Table 2. The proportion of people who reported one or more falls during the 12-month follow-up period was 36.0% for the exergame training group, significantly lower than the control group (48.2%). The proportion of fallers was not significantly different between cognitive training (42.0%) and the control group (48.2%). The proportion of people who reported multiple falls during the 12-month follow-up period was reduced but not statistically significant for the exergame training group (13.9%) relative to the control group (20.0%). However, the proportion of multiple fallers was significantly lower for the cognitive training group (12.6%) relative to control (20%). The proportion of people who reported an injurious fall during the 12-month follow-up period did not differ significantly between the exergame training (25.0%) and control groups (31.0%), or between the cognitive training group (29.8%) and the control group (31.0%). The proportion of people reporting falls resulting in a fracture did not differ between the exergame training (2.8%) and control groups (2.4%), or between the cognitive training group (4.2%) and the control group (2.4%).

Physical outcomes

Table 3 presents group data for baseline and six-month reassessment of physical and cognitive performance secondary outcomes. There were no significant differences in simple hand reaction time, choice stepping reaction time, inhibitory or Stroop stepping, standing balance (postural sway), leaning balance (coordinated stability), gait or dual-task gait (velocity, variability) and mobility (timed up and go test, short physical performance battery) between exergame training and control groups, or between cognitive and control groups.

Cognitive outcomes

As shown in Table 3, there were no significant differences in neuropsychological performance tests of selective attention and processing speed (Trail Making Test B-A), verbal fluency (Controlled Oral Word Association Test), working memory (Digit Span Test), or global cognition (ACE-R) between exergame training and control groups, or between cognitive training and control groups, at the 6-month reassessment. There was a significant improvement in attention and response inhibition (Victoria Stroop Test efficiency time) for the cognitive training group, compared to control (between group mean difference of 0.292; 95%CI=0.080-0.505).

General and Psychological Health

Table 4 presents group data for general health and psychological health questionnaires, taken at baseline, six- and 12-months post-randomisation. Compared to control, the exergame training group had improved falls efficacy (Icon-FES) and less disability (LLFDI) at six months, and reduced depressive symptoms (PHQ-9) and less disability (LLFDI) at 12 months. There were no significant differences between exergame training and control groups in measures of general health and disability (WHODAS 2.0) or anxiety symptoms (GAD-7) at the six- or 12-month follow up. For the cognitive training group, there were no significant differences in any of the measures of general and psychological health at six and 12 months, compared to control.

Subgroup Analyses

Results of all planned subgroup analyses are reported as extended data (Extended Data Table 1). A significant interaction was evident for previous faller status (did or did not experience a fall in the 12 months prior to enrolment) for the effect of cognitive training on the rate of falls: previous fallers had a significantly reduced rate of falling relative to the control group (IRR=0.63, 95%CI=0.44-0.92), whereas previous non-fallers did not (IRR=1.26, 95%CI=0.86-1.84). No significant interaction was evident for previous faller status for the effect of exergame training on the rate of falls, and no significant interactions were evident for physical status, and cognitive status (Extended Data Table 1).

Pre-specified Process Outcomes

Adverse Events

No serious intervention-related adverse events were reported during the trial. Twelve participants reported acute minor adverse events associated with the intervention. Four participants reported hip pain, three reported knee pain and one reported foot pain associated with the step training, all of which resolved with rest and change to stepping technique. One participant reported wrist and thumb pain and one reported shoulder, neck and upper limb pain associated with the cognitive training. Also, within the cognitive training group, one participant reported dizziness while playing the most immersive game and was subsequently instructed to avoid this game, and another reported the recurrence of symptoms related to stress and subsequently withdrew from the study.

Adherence to the intervention

Regarding adherence to the intervention, including those who withdrew during the trial, participants in the exergame training group trained for an average 79.7 (SD=47.1) minutes per week with an average 3,635 (SD=2,425) mins of total training over 12-month intervention. Reasons for non-participation included participants taking holidays away from their homes and training time lost due to equipment breakages, the latter occurring more so in the exergame training group. Averaged across the 12-month intervention period, 20.6% of exergame training participants reached the goal of 120 mins per week and 50.8% of participants reached the minimum dose of 80 mins per week. Participants in the cognitive group trained for an average 94.7 (SD=43.2) minutes per week with an average 4,463 (SD=2,304) mins of total training over 12 months. Averaged across 12 months, 27.1% of participants in the cognitive training group reached the goal of 120 mins per week and 65.3% of participants reached the minimum dose of 80 mins per week. 127 people in the exergame training and 111 people in the cognitive training group received a phone call at some point during the 12-month study, to encourage improved participation.

System usability and enjoyment

Regarding system usability (System Usability Scale, from 0 to 100), the exergame training group reported an average score of 80.4 (±15.8) at 6 months and 83.3 (±13.9) at 12 months. The cognitive training group reported an average usability score of 82.4 (±12.9) at 6 months and 82.5 (±13.8) at 12 months. On the Physical Activity Enjoyment Scale (possible range 0-50), participants in the exergame training group rated the program an average score of 41.4 (±9.5) at 6 months and 41.5 (±9.9) at 12 months. Participants in the cognitive training group rated their enjoyment of the program an average score of 38.1 (±10.2) at 6 months and 37.0 (±10.6) at 12 months.

DISCUSSION

This is the first fall prevention exergame trial to move beyond fully supervised interventions conducted in research laboratories and health clinics and implement an unsupervised exergame intervention in older people's homes. We found exergame training reduced the rate of falls (with and without adjustment for weekly physical activity levels) and risk of falls in community-dwelling older people, and cognitive training reduced the proportion of multiple fallers and the rate of falls in those who fell in the previous year. Few beneficial effects of the two interventions on secondary outcomes were evident, although participants in the exergame training group reported reduced concerns about falls, fewer disability limitations, and fewer depressive symptoms at retest, and participants in the cognitive training group showed a significant improvement in efficiency in the Victoria Stroop Test of attention and response inhibition. We also report no significant difference between exergame training and cognitive training for the primary outcome, but caution that this is an exploratory analysis that the trial was not powered for and was not pre-specified in our statistical analysis plan.

The exergame training intervention reduced falls by 26% over 12 months, a reduction consistent with previous interventions that have encompassed moderate-high intensity balance training,[4, 19] and supervised virtual reality, exergame and cognitive-motor interventions.[20, 21] In addition, the fall rate remained significantly reduced when adjusting for physical activity levels to account for varying exposure and real-life experience[22] and there was a reduced proportion of fallers in the exergame training group. Thus, it appears that this exergame intervention, which included challenging cognitive and stepping exercises, was effective in preventing falls for relatively healthy community-living older people.

Participants in the exergame training group also reported reduced concern about falling, fewer disability limitations, and fewer depressive symptoms, compared to the control group. These findings reflect psychological and self-perceived capacity gains associated with the exergame training, important factors impacting the quality of life of older people.[23] Similarly, Mirelman and colleagues[20] found improvements in quality of life measures (SF-36 physical and mental health) alongside a reduced rate of falls following a virtual reality treadmill training, compared to treadmill training alone and suggest these gains to be associated with the additional motor-cognitive challenge of virtual reality training. Interventions that successfully improve fall-related self-efficacy and reduce concerns about falling are likely to have meaningful health and quality of life benefits[23] however these results should be considered with caution, given the multiple comparisons.

A meta-analysis of exergame interventions examining physical outcomes (48 studies, 1098 participants) has reported small benefits in overall physical function performance and moderate benefits in balance, strength and endurance.[14] In contrast, the current trial found no significant differences between the exergame and control groups in physical and cognitive performance outcome measures, assessed on a subsample of participants at six months. These findings differ from previous studies including our pilot trials that showed exergame training can improve balance, cognitive processing speed, attention, visuospatial skills and executive functioning.[14, 16, 24] This divergence of results may also reflect the current study being undertaken in a more able and healthy group, in which changes in function are harder to detect.

This study included a seated cognitive training intervention as there is strong evidence that reduced cognition is a significant risk factor for falls[6] and preliminary evidence that cognitive training can improve fall-related physical functions.[12] Cognitive training did not significantly reduce the rate of falls, however, cognitive training participants were less likely to report multiple (2 or more) falls during follow-up, relative to the control group. This may suggest cognitive training is an appropriate fall prevention strategy for recurrent fallers who have poorer sensorimotor function[25], slower walking speed[26], cognitive impairment[27], and frailty[28]. In addition, a planned sub-group analysis revealed the cognitive training significantly reduced the rate of falls in participants who reported falling in the year prior to study enrolment. It is possible that cognitive training has greater benefit in preventing falls for older community dwelling people with lower physical, functional and/or cognitive capacity, but we acknowledge that this finding needs to be treated with appropriate caution.

In terms of secondary outcome measures, the cognitive training group showed a significant improvement in efficiency on the Victoria Stroop Test of attention and response inhibition, compared to the control group, suggesting some cognitive benefit following cognitive training. However, the intervention was not effective in improving other measures of cognitive function or any physical function, disability, general and psychological health measures.

Over the 12 months of the trial, participants in the exergame training group undertook an average 80 minutes of training per week, while the cognitive training group averaged 95 minutes per week. These figures indicate a high level of adherence[29], particularly because they reflect actual time spent training based on the record of active game play. Such valid and precise measures are a major advantage over unverified self-completed exercise rolls and all-or-nothing measures of exercise group participation based on class attendance that are commonly reported. Further, adherence data reflect time spent in balance challenging exercise, which is essential for fall prevention effects but represents a far smaller proportion of intervention time in traditional programs.[19] We acknowledge that when an exercise programme is rolled out to the community there may not be capacity for telephone follow-up, such that average adherence might be lower.

The *smart±step* interventions included gaming features (e.g. high scores, rankings, medals) to provide enjoyable and engaging training experiences and enable the progression of both cognitive and physical challenge. Both the exergame and cognitive training programs proved feasible to administer in that all participants could use the systems, play multiple games and progress through game difficulty levels. Furthermore, reported usability was over 80% for both training groups, while participants rated step training enjoyment approximating 85% and cognitive training around 75%. Finally, no major adverse events related to the interventions were reported, suggesting both step and seated training are safe modes of home-based exercise for older people.

The design of this trial was optimal for examining the efficacy of both the stepping and seated delivery of this *smart±step* intervention against a control group, as all aspects of training with respect to game play, game availability and progression were identical. Other strengths included the large sample size, the automated, accurate recording of intervention adherence, and attempts to minimize the risk of bias through assessor blinding, concealed allocation to groups, gold standard ascertainment of falls, and intention-to-treat analysis. Further, this is the first adequately powered trial of cognitive training on fall outcomes and the first fall prevention exergame trial to move beyond fully supervised small-scale interventions conducted in laboratories or clinics and implement a minimally (digitally) supervised exergame intervention in people's homes. The pragmatic design of the trial should allow ready generalization of the findings and our previous pilot trials have shown this home-based training is safe and feasible for people with multiple sclerosis[30] and Parkinson's disease[31]. The cost-effectiveness of delivering these interventions will be presented in a future companion paper following collation of data from health agencies.

The limitations associated with this study should be considered. First, the primary outcome was self-report despite this being the gold standard approach.[32] Second, it was assumed that participants followed instructions by not allowing other people to use the system, which would artificially inflate training duration. Third, the sample primarily comprised well-educated and high functioning older people, so the findings cannot be generalized to frailer older people. Fourth, more participants withdrew from the exergame training group, compared to the other groups, which likely reflects the requirement to be physically active and/or the increased effort required to set up the mat for training. Furthermore, the custom-made prototype equipment, which incorporated wireless technology for the step mat, rendered it more likely to connectivity issues and breakages than the touchpad, which might have contributed to the relatively reduced average weekly training duration reported in the exergame training group. Fifth, the occasional significant findings in secondary outcomes should be interpreted with caution given the multiple comparisons and chance of Type I error. Finally, participants were not blinded to their intervention, therefore the level of expectancy for preventing falls may have differed between the groups, which may contribute to a placebo effect[33] that might impact the findings. Future studies with convincing placebo interventions would help to understand this effect.

The study findings suggest that a home-based exergame step training program provides a safe and effective means for preventing falls in older people living in the community. Cognitive training also appeared to reduce recurrent falls and falls in those with a history of falls in the past year. As these interventions can be conducted unsupervised and with minimal equipment, they have the potential for scalability as public health interventions to increase the exercise opportunities available to address the increasing problem of falls and fall-related injuries in older people.

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Author Contributions

DLS, SL, KD, JM and MV, conceived and designed the trial. Additional advice regarding design and statistical analyses was given by CS and RH. Funding was obtained by DLS, JM, KD and MV with significant input by SL. JG led software development with input from DS, SL and KD. JT, CH, NS, MR, JL, CC established databases, study manuals, contributed to recruitment, data collection and processing. CH, SL, DS and BT undertook the statistical analyses, have directly accessed and verified the underlying data reported in the manuscript. All authors contributed intellectual input into and approved the manuscript. The authors agree to be accountable for the work and declare that they have no competing interests.

Declaration of Interests

We declare no competing interests.

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Ethics Committee approval

This study was approved by the Human Research Ethics Committee, UNSW Sydney (HC15203) on 8 September 2015.

TABLES:

Table 1. Baseline characteristics of participants randomised to exergame step training, cognitive training and control groups. Values are means (SD) unless otherwise stated.

Variable	**Exergame training group** n=252	**Cognitive training group** n=262	**Control group** n=255
Age (years)	72.6 (5.7)	72.6 (5.5)	72.5 (5.5)
Female gender, n (%)*	178 (70.6)	189 (72.1)	182 (71.4)
Body mass index	27.1 (5.1)	27.1 (4.8)	26.9 (4.9)
Years of education	16.0 (4.2)	16.2 (4.7)	16.0 (4.2)
Accommodation, house, unit or flat, n (%)^	240 (95.2)	249 (95.0)	240 (94.1)
Number of medical conditions[#], median (IQR)	2 (2)	2 (2)	2 (2)
Number of prescription medications, median (IQR)	3 (4)	2 (4)	2 (3)
12-month fall history, n (%)	99 (39.3)	90 (34.4)	94 (36.9)
Hours per week of physical activity (IPEQ)	33.8 (20.9)	34.0(18.5)	33.4 (19.1)
Quality of life (EuroQOL EQ-5D)	1.2 (0.4)	1.2 (0.4)	1.2 (0.4)

* Gender self-reported by study participants, options were: Male; Female.

ˆ Accommodation options were: House / Unit / Flat; Retirement village.

[#] Summed from the presence of heart disease, hypertension, diabetes, stroke, arthritis, osteoporosis, and cancer history.

IPEQ, Incidental and Planned Exercise Questionnaire

Table 2. Effects of exergame step training and cognitive training, compared to control, on fall-related outcomes.

	Exergame Training Group n=252	**Cognitive Training Group** n=262	**Control Group** n=255	**Exergame Training vs Control** RR or IRR (95%CI)	***Cognitive Training vs Control*** RR or IRR (95%CI)
Rate of falls, mean (sd)*	0.68 (1.28)	0.81 (1.55)	1.20 (3.62)	0.74 (0.56-0.98),	0.86 (0.65-1.13)
Person years of follow-up, number	231.2	242.7	246.6		
Number of withdrawn participants	21	23	9		
Days to withdrawal, median (IQR)	13 (38)	91 (138)	80 (69)		
Fallers, number (%)	91 (36.0)	110 (42.0)	123 (48.2)	0.75 (0.61-0.92)	0.87 (0.73-1.05)
Multiple fallers, number (%)	35 (13.9)	33 (12.6)	51 (20.0)	0.69 (0.47-1.03)	0.63 (0.42-0.94)
Injurious fallers, number (%)	63 (25)	78 (30)	79 (31)	0.81 (0.61-1.07)	0.96 (0.74-1.25)
Fracture fallers, number (%)	7 (2.8)	11 (4.2)	6 (2.4)	1.18 (0.40-3.46)	1.78 (0.67-4.75)
Rate of falls per physical activity, mean (sd)^	0.033 (0.085)	0.043 (0.166)	0.052 (0.115)	0.67 (0.49-0.93)	0.79 (0.58-1.08)

* Rate calculated as total number of falls reported divided by months of follow-up.
^ Rate calculated as total number of falls divided by average weekly hours of physical activity.

Table 3: Effects of exergame step training and cognitive training, compared to control, on secondary outcomes of physical and cognitive performance. Group descriptive statistics are presented for baseline and 6-month follow-up and are presented as mean (SD). Significant effects are shown in bold.

	Exergame Training Group n=111		**Cognitive Training Group** n=118		**Control Group** n=120		**Exergame Training *vs* Control** *Adjusted mean difference between groups (95% CI)*	**Cognitive Training *vs* Control** *Adjusted mean difference (95% CI) between groups*
	Baseline	**6 months**	**Baseline**	**6 months**	**Baseline**	**6 months**		
Postural Sway (mm)	176 (109)	153 (82)	190 (115)	162 (85)	191 (129)	162 (99)	2.1 (-0.6 to 4.8)	0.80 (-2.0 to 3.6)
Coordinated Stability (error score)	6.9 (9.2)	6.2 (7.9)	6.0 (7.8)	5.2 (6.7)	6.3 (8.5)	4.9 (6.5)	-0.1 (-0.474 to 0.632)	-0.1 (-0.5 to 0.3)
Single Task Gait Velocity (cm/s)	125.6 (21.3)	123.8 (18.9)	121.6 (22.8)	121.4 (20.5)	123.8 (19.9)	124.5 (18.9)	3.9 (-14.4 to 22.1)	8.2 (-8.9 to 25.2)
Single Task Gait Variability (step time coefficient of variation)	0.033 (0.015)	0.034 (0.014)	0.038 (0.019)	0.035 (0.019)	0.031 (0.012)	0.032 (0.015)	0.0 (-0.0 to 0.1)	0.0 (-0.0 to 0.1)
Dual Task Gait Velocity (cm/s)	105.5 (28.3)	100.3 (27.9)	98.8 (31.4)	99.7 (29.6)	102.7 (26.2)	102.5 (27.5)	11.2 (-8.5 to 30.9)	9.8 (-7.6 to 27.3)
Dual Task Gait Variability (step time coefficient of variation)	0.068 (0.077)	0.083 (0.079)	0.077 (0.082)	0.080 (0.080)	0.075 (0.082)	0.077 (0.072)	0.0 (-0.1 to 0.1)	0.0 (-0.0 to 0.1)

Short Physical Performance Battery (score)	11.2 (1.2)	11.2 (1.2)	10.8 (1.3)	11.1 (1.1)	10.9 (1.2)	11.1 (1.1)	-0.0 (-0.3 to 0.3)	0.1 (-0.2 to 0.4)
Timed Up and Go (s)	8.1 (1.9)	7.8 (1.8)	8.3 (2.2)	8.2 (2.1)	8.2 (1.9)	8.0 (1.9)	-0.1 (-0.7 to 0.4)	0.1 (-0.4 to 0.6)
Hand Reaction time (ms)	224.3 (34.1)	232.5 (40.0)	227.5 (34.4)	228.2 (30.8)	227.6 (36.1)	231.3 (37.8)	37.6 (-10.8 to 86.0)	-26.2 (-71.6 to 19.2)
Choice Stepping Reaction Time (s)	1.11 (0.13)	1.06 (0.13)	1.13 (0.14)	1.10 (0.13)	1.14 (0.15)	1.10 (0.14)	-0.0 (-0.2 to 0.2)	0.1 (-0.1 to 0.2)
Inhibitory Choice Stepping Reaction Time (s)	1.16 (0.13)	1.12 (0.13)	1.19 (0.15)	1.15 (0.14)	1.18 (0.15)	1.16 (0.14)	-0.1 (-0.3 to 0.1)	-0.0 (-0.2 to 0.1)
Stroop Choice Stepping Reaction Time (s)	1.59 (0.33)	1.48 (0.27)	1.60 (0.33)	1.53 (0.26)	1.62 (0.37)	1.53 (0.27)	0.0 (-0.2 to 0.2)	0.1 (-0.1 to 0.3)
Trails Making Test B–A (s)	48.1 (31.0)	48.1 (31.1)	49.7 (29.8)	46.2 (29.1)	48.3 (28.3)	48.5 (31.0)	-1.4 (-11.2 to 8.3)	2.0 (-7.3 to 11.3)
Controlled Oral Word Association Test (correct answers)	47.5 (15.1)	49.7 (14.1)	44.5 (14.0)	47.5 (13.1)	44.7 (13.6)	48.0 (13.1)	0.8 (-5.6 to 7.1)	0.5 (-5.7 to 6.6)
Digit Span Test Forwards (number of recollections)	8.8 (2.6)	9.0 (2.5)	9.1 (2.4)	8.9 (2.4)	8.6 (2.4)	8.9 (2.5)	0.3 (-1.4 to 1.9)	0.2 (-1.6 to 1.9)
Digit Span Test Backwards (number of recollections)	6.5 (2.2)	7.0 (2.5)	6.7 (2.4)	7.0 (2.3)	6.5 (2.5)	6.9 (2.5)	0.4 (-1.1 to 1.8)	-0.5 (-1.9 to 0.9)

Victoria Stroop Test (c/d efficiency time)	1.62 (0.66)	1.43 (0.47)	1.61 (0.62)	1.50 (0.51)	1.55 (0.62)	1.38 (0.46)	0.2 (-0.0 to 0.4)	**0.3 (0.1 to 0.5)**
Victoria Stroop Test errors (c)	2.1 (2.9)	1.1 (1.3)	1.9 (2.7)	1.2 (1.8)	1.6 (2.4)	0.9 (1.3)	-0.2 (-0.4 to 0.0)	-0.0 (-0.3 to 0.2)
Addenbrooke's Cognitive Examination Revised, ACE-R (score)	94.3 (4.0)	95.3 (4.5)	93.9 (4.1)	95.0 (4.0)	93.9 (4.4)	94.6 (4.4)	0.2 (-0.3 to 0.6)	-0.2 (-0.7 to 0.2)

Table 4: Effects of exergame step training and cognitive training, compared to control, on secondary outcomes of self-reported general and psychological health. Group descriptive statistics are presented for baseline and 6-month follow-up and are presented as mean (SD). Significant effects are shown in bold.

	Exergame Training Group n=252			**Cognitive Training Group** n=262			**Control Group** n=255			**Exergame Training vs Control** *Adjusted mean difference between groups (95% CI)*		***Cognitive Training vs Control*** *Adjusted mean difference between groups (95% CI)*	
	0m	6m	12m	0m	6m	12m	0m	6m	12m	6m	12m	6m	12m
Depressive Symptoms (PHQ-9)	2.2 (2.5)	2.0 (2.5)	2.3 (2.9)	2.2 (2.5)	2.0 (2.5)	2.5 (2.9)	2.3 (2.5)	2.2 (2.5)	2.6 (2.8)	0.427 (-0.045 to 0.899)	**0.591 (0.058 to 1.124)**	0.345 (-0.112 to 0.812)	0.376 (-0.160 to 0.0913)
Anxiety Symptoms (GAD-7)	1.8 (2.4)	1.7 (2.4)	2.0 (2.8)	1.7 (2.3)	1.6 (2.2)	1.9 (2.8)	1.8 (2.4)	1.9 (2.5)	2.1 (2.8)	0.084 (-0.342 to 0.510)	0.051 (-0.437 to 0.538)	0.080 (-0.337 to 0.497)	0.088 (-0.412 to 0.589)
Falls Efficacy (IconFES)	16.6 (4.7)	15.0 (3.9)	16.6 (5.0)	16.4 (5.2)	14.9 (4.5)	16.6 (5.4)	17.0 (5.4)	15.4 (5.0)	16.9 (5.6)	-**2.351 (-4.395 to -0.308)**	-1.579 (-3.922 to 0.764)	-1.493 (-3.505 to 0.520)	-1.379 (-3.632 to 0.873)
Disability (WHODAS 2.0)	6.8 (6.4)	6.9 (7.1)	7.3 (7.9)	6.6 (6.7)	7.0 (8.2)	7.1 (7.9)	6.8 (6.6)	7.4 (7.8)	7.8 (8.4)	0.469 (-0.882 to 1.820)	0.162 (-1.342 to 1.665)	0.529 (-0.894 to 1.953)	0.421 (-1.007 to 1.849)
Disability limitations (LLFDI)	76.4 (16.7)	74.3 (19.4)	72.1 (18.5)	77.4 (16.7)	73.6 (19.6)	71.5 (20.8)	78.2 (16.5)	74.2 (18.1)	74.1 (17.7)	-**15.01 (-28.67 to -1.67)**	**-18.36 (-31.93 to -4.78)**	-9.76 (-23.35 to 3.83)	-3.64 (-17.81 to 10.52)

N.B.: PHQ-9, Patient Health Questionnaire; GAD-7, Generalised Anxiety Disorder Scale; IconFES, Iconographic Falls Efficacy Scale; WHODAS 2.0, 12-item WHO Disability Assessment Schedule; LLFDI, Late Life Function and Disability Instrument.

FIGURES:

Figure 1. Trial profile. Numbers of participants who were recruited, randomized, excluded and assessed for the primary outcome are shown.

*Participants discontinued training but continued to provide data for the primary outcome.

^Withdrawn participants were included in the analysis of primary outcome with number of days follow up entered as the exposure term.

Figure 2. The *smart±step* gaming system. (A,B) Illustrations are shown for setup of the system for exergame step training (A) and seated cognitive training. C) The range of *smart±step* games including (clockwise from upper left); Stepmania; Anaconda; Greek Village; Dot Muncher; Brick Stacker; La Cucaracha; Alien Invasion; and Toad Runner.

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METHODS

Study design

The detailed study protocol has been previously published.[34] The trial is a pragmatic assessor-blinded 3-arm parallel RCT that is designed to examine the effectiveness of the computerized *smart±step* system, delivered as seated cognitive training or exergame training, compared to a minimal-intervention control group, on the rate of falls in older people over 12 months.[34] The protocol was approved by the UNSW Sydney Human Research Ethics Committee in September 2015 (HC15203) and prospectively registered on the Australian New Zealand Clinical Trial Registry in September 2016 (ACTRN12616001325493).

Participants

Between October 2016 and May 2019, healthy older people living in the community in Sydney, Australia, were invited to participate via advertisements in newspapers, community group circulars and flyers, and invitations sent to members of a health insurance company. Eligibility criteria were reviewed during an initial screening telephone call following verbal consent and included: age 65 years or older; English-speaking; living in the Sydney metropolitan area; independent in activities of daily living; able to walk 10m without the use of a walking aid; and willing to provide informed consent. Criteria for exclusion were: an unstable medical condition that would preclude safe participation; a neurological condition (such as Parkinson's disease, multiple sclerosis, stroke); an acute psychiatric condition with psychosis; cognitive impairment defined as greater than two errors on the Pfeiffer Short Portable Mental Status Questionnaire[35]; residing in residential aged care, or currently participating in a fall prevention trial. After screening for eligibility, participants provided written informed consent before baseline collection of age, gender, body height and weight, education, living arrangements, quality of life (EuroQOL EQ-5D)[36], and medical history (presence of medical conditions, medication use and fall history).

Randomisation and masking

Following all baseline assessments, participants were randomly allocated to one of three groups by use of an in-house web-based application using permuted random blocks of between six and 15 and an allocation ratio of 1:1:1. An investigator, not otherwise involved in the randomisation or data collection, set up the study and randomisation parameters within the application and generated the randomisations. Participants were registered into the study within the application by an investigator not involved in study assessments or intervention delivery and with the randomisation sequence concealed. The application assigned each newly registered participant to the next allocated group. Allocation concealment was ensured as the randomisation code was only released to non-blinded research staff (those delivering the intervention) and after all baseline assessments had been completed. The collection, entry and monitoring of primary and secondary outcome data was undertaken by staff blinded to group assignment. Participants were not blinded, due to the nature of the interventions. Statistical analyses for the primary outcome were performed by an independent statistician blinded to group allocation and separately replicated by a study investigator.

Interventions

A full description of the interventions has been reported previously.[34] Briefly, all participants received an evidence-based education booklet on healthy ageing and fall prevention. The provision of education material to the control group participants was followed-up with a telephone call (or email when necessary) by a trained Research Assistant, to partially match the staff contact received by participants in the intervention groups.

During an initial home visit, participants in the two active training intervention arms (cognitive training and exergame step training) were provided with a *smart±step* mini personal computer with custom software including eight games. The computer was connected via HDMI cable to display on either the home television or a computer monitor (provided as needed). The exergame training group also received a Bluetooth connected (wireless) step mat and trained by playing games while standing and stepping onto target panels (Figure 2A), which was designed to challenge balance via the requirement for rapid shifts in body centre of mass during stepping. The cognitive training group received a custom-built desktop touch pad and trained by playing the games by pressing target panels with their hands (Figure 2B).

The *smart±step* games were newly developed and/or adapted from popular video games by Neuroscience Research Australia (NeuRA) Software Engineers for the purpose of this research and are not currently available for download or purchase. The *smart±step* games were designed to challenge specific cognitive functions including working memory, visuospatial skills, dual-tasking, inhibition and attention by including these tasks as elements for successful game play, such as accurate hitting of targets, avoiding virtual obstacles, solving spatial orientation problems and rapidly responding to stimuli. Game play was controlled by use of the intervention-dependent peripheral (touch pad or step mat), each with sensing targets that corresponded to forward, backward, left and right moves. The *smart±step* system games included customary gaming features including immediate in-game feedback, game high scores and rankings, incremental game difficulty levels, and medals for achieving target training dose. The prescribed games, dose and progression (described below) were identical for both training groups.

Both cognitive and exergame training group participants received an initial installation (60-120 minutes duration) and follow-up home visit (30-60 minutes duration) from research staff (Exercise Science graduates) which included the in-home set up of all equipment, training in the technical aspects of the *smart±step* system (start-up, shut-down, Wi-Fi connection for monitoring of game play, and basic trouble shooting), game objectives, and assessing safe use and progression. Participants were instructed to undertake 120 minutes of training per week for 12 months. Weekly game play was capped at 150 minutes to help ensure equal doses between the two intervention groups. Participants were encouraged to progress to more challenging levels when confident to do so and to try to beat their highest score (displayed at the end of each game), which was best achieved by playing at higher difficulty levels. Beyond home visits, game difficulty levels were selected by the participant for the remainder of the trial. Additional home visits were provided during the intervention in the event of equipment failure or if participants had extended breaks from using the system due to illness, injury or holidays, etc.

Monitoring

Adherence to the interventions was monitored via automatic data transfer from each participant's *smart±step* personal computer to a centralised database over the internet. Participants who were engaging in less than 80 minutes of training per week for two consecutive weeks (and had not informed the research team of absence or illness) were contacted by telephone to encourage improved participation. In such cases, a Research Assistant would assist with goal setting (gradually incrementing weekly gameplay durations) and help identify and address any barriers to training, with the aim of achieving 120 minutes of training per week.

Outcomes

The prospectively registered primary outcome was the rate of falls over 12 months from the date of randomisation. A fall was defined as 'unintentionally coming to the ground or some lower level and other than as a consequence of sustaining a violent blow, loss of consciousness, sudden onset of paralysis as in stroke or an epileptic seizure'.[32] In line with recommended methods,[37] participants reported falls using monthly calendars for between 12 and 13 months from their baseline assessment. These data were collected monthly regardless of any deviation or discontinuation of the intervention. If a calendar was not returned within two weeks of the end of each month, participants were contacted by telephone to obtain the falls data required. Falls data were checked, reviewed, locked and analysed before group allocation was unmasked.

Secondary fall outcomes included the proportion of people who reported: 1) one or more falls; 2) multiple falls; 3) an injurious fall; and 4) a fall resulting in facture during the 12 months following randomisation, as well as the rate of falls per physical activity. This was calculated for each participant by multiplying the days of follow-up by the average hours of weekly physical activity reported using the Incidental and Planned Exercise Questionnaire (IPEQ)[38]. Physical and cognitive performance secondary outcome measures were assessed in a laboratory at baseline and six months post-randomisation in a subsample of 300 participants, collected during two blocks of time during the trial. Questionnaires of general health and disability, psychological health and falls efficacy were administered at baseline, six- and 12-months post-randomisation for all participants.

Balance was assessed while standing on a foam rubber mat for 30 seconds (standing postural sway)[39] and while leaning near to the limits of stability (coordinated stability)[25]. Gait (velocity and variability) was assessed while walking at usual speed under single- and dual-task conditions (counting backwards by 3s) over a 6m GAITRite system (CIR Systems, Clifton, New Jersey, USA) for three trials each (average calculated). Mobility was quantified using the Timed Up & Go test [40] and the Short Physical Performance Battery; a composite score of standing balance, chair rise ability and walking speed[41]. Reaction time was measured in a simple test involving a light stimulus and finger-press response[39]. Stepping performance was assessed using three stepping reaction time tests; the Choice-, Inhibitory- and Stroop-Stepping Reaction Time tests[42].

Neuropsychological assessments of cognitive functions were undertaken, including the Trail Making Tests (parts A and B) of selective attention and processing speed[43], the Victoria Stroop Test of attention and response inhibition[44], the Controlled Oral Word Association Test for verbal fluency[43], the Digit Span Test for working memory[45], and the Addenbrooke's Cognitive Examination Revised (ACE-R) for global cognition[46].

Psychological outcome measures were assessed using the Iconographical Falls Efficacy Scale (IconFES) for concerns about falling[47], Generalised Anxiety Disorder Scale (GAD-7) for anxiety symptoms[48] and the nine-item Patient Health Questionnaire (PHQ-9) for depressive symptoms[49]. Disability and function were measured using the 12-item WHO Disability Assessment Schedule (WHODAS 2.0)[50] and the Late Life Function and Disability Instrument (LLFDI)[51].

Pre-specified process outcomes[34] included the average weekly and total training duration to indicate adherence to the interventions. Safety was assessed in terms of adverse events, which were defined as any fall or injury related to the interventions or involving the intervention equipment and were requested to be reported immediately and were also queried monthly using the falls calendars. User experience and acceptability was captured with the System Usability Scale (SUS) and Physical Activity Enjoyment Scale (PACES).

All data were collected at Neuroscience Research Australia, Randwick, New South Wales, from October 2016 until July 2020. The secondary outcomes reported here are an abridged list of those in the clinical trial registry.

Statistical analysis

A sample size calculation found 750 participants were required to achieve 80% power to find a 33% reduction in fall rate in the intervention groups compared to control (assuming control group rate of 0.8 fall/person-year), significant at $p<0.05$ with expected over-dispersion of 1.2 and a 20% dropout rate.[34] Our pilot trials[16, 17] indicated that a sub-sample of 300 participants was required to provide 95% power to detect between-group differences in secondary physical and cognitive function outcome measures (effect size f = 0.38, correlation = 0.76, α = 5%, 20% dropout).

The statistical analysis plan was prospectively registered on the OpenScience framework (https://osf.io/uqk5s/) and is included as a Supplemental Note. Group allocation was coded to maintain blinding and data were analysed with an intention-to-treat approach using Stata (version 16, Stata Corp) and SPSS (version 25, IBM Corp). A Data Safety and Monitoring Committee monitored the trial throughout.

The primary outcome of number of falls per person-year (unadjusted) was analysed by an independent statistician (BT), blinded to group allocation, and replicated (SL) using negative binomial regression, with days of follow-up included as an exposure term, to estimate the difference in fall rates between comparison groups (cognitive training versus control, exergame step training versus control) using Stata software (version 16, Stata Corp) to report incidence rate ratios and 95% confidence intervals (CIs). This analysis takes into account all falls during the trial, and the distribution of falls, which is Poisson-like but with a wider, higher tail[52] and has been recommended for evaluating the efficacy of fall prevention interventions for its straightforward approach over survival analysis models and ease of interpretation of incidence rate ratios[53-56].

The secondary fall outcomes were examined using the relative risk statistic with 95% CIs for dichotomous variables, while the rate of falls per physical activity was analysed using negative binomial regression with days of follow up multiplied by average hours of weekly physical activity[38] entered as the exposure term. The effect of group allocation on the continuously scored secondary outcome measures was examined with linear regression models with baseline scores entered as covariates. As the outcomes were categorised by degree of importance (primary and secondary), p-values and confidence intervals were not adjusted for multiplicity.

We report the results of three planned subgroup analyses using a test for statistical interaction. Separately for both intervention groups, we assessed whether the effect size of the intervention differed from control according to reported falls in the previous year (0 v 1+), baseline physical status based on median Physiological Profile Assessment[39] (<0.28 v ≥0.28), and baseline cognitive status based on median ACE-R[46] scores (<95 v ≥95). We did not plan any sub-group analyses related to sex or gender.

Analyses were intention to treat in so far as all participants were analysed in the group to which they were randomised and regardless of the level of compliance to the interventions. No imputation of missing data for the primary or secondary falls outcome measures or adjustments related to level of compliance/withdrawal were undertaken. Missing data for the secondary physical and cognitive outcome measures were imputed using estimated means single imputation as all were found to be missing at random.

Patient and Public Involvement

The *smart±step* training system was developed using consumer design principles. A group of 24 people aged 70 to 97 years who were part of the intervention group of a pilot study using an earlier version of the system[16, 17] were asked to report on their experience regarding usability[11] and results were used to refine the *smart±step* system. There was no other formal patient and public involvement in the study.

Data Availability

The data that support the findings of this study are not openly available due to reasons of confidentiality. Upon reasonable request, individual de-identified participant data (including data dictionaries) will be made available via a RedCap web-based database, after review and approval of a methodologically sound proposal, with a signed data access agreement, in line with Ethics Committee requirements. Please contact Corresponding Author, Daina Sturnieks (d.sturnieks@neura.edu.au). These files will be available from the date of publication until the date stated in the approved request. The study protocol is available as an open access publication [34] and the statistical analysis plan is available on OpenScience Framework (https://osf.io/uqk5s/).