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A home-based, carer-enhanced exercise program improves balance and falls efficacy in community-dwelling older people with dementia

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ABSTRACT

Background: Older people with dementia are at increased risk of physical decline and falls. Balance and mood are significant predictors of falls in this population. The aim of this study was to determine the effect of a tailored home-based exercise program in community-dwelling older people with dementia.

Methods: Forty-two participants with mild to moderate dementia were recruited from routine health services. All participants were offered a six-month home-based, carer-enhanced, progressive, and individually tailored exercise program. Physical activity, quality of life, physical, and psychological assessments were administered at the beginning and end of the trial.

Results: Of 33 participants (78.6%) who completed the six-month reassessment ten (30%) reported falls and six (18%) multiple falls during the follow-up period. At reassessment, participants had better balance (sway on floor and foam), reduced concern about falls, increased planned physical activity, but worse knee extension strength and no change in depression scores. The average adherence to the prescribed exercise sessions was 45% and 22 participants (52%) were still exercising at trial completion. Those who adhered to $\geq$70% of prescribed sessions had significantly better balance at reassessment compared with those who adhered to $<$70% of sessions.

Conclusions: This trial of a tailored home-based exercise intervention presents preliminary evidence that this intervention can improve balance, concern about falls, and planned physical activity in community-dwelling older people with dementia. Future research should determine whether exercise interventions are effective in reducing falls and elucidate strategies for enhancing uptake and adherence in this population.

Key words: dementia, cognitive impairment, accidental falls, prevention, exercise, postural control, fear of falling

Introduction

Falls are common in older people with dementia with more than 60% falling annually (Taylor *et al.*, 2013). Older people with dementia are physically frailer than their cognitively intact peers (Taylor *et al.*, 2013) and falls in this group have a higher risk of mortality, morbidity, injury (including hip fracture), and placement in residential care (Gruber-Baldini *et al.*, 2003; Baker *et al.*, 2011). In 2010, 36 million people worldwide had dementia and this is projected to increase to 115 million by 2050 (Prince *et al.*, 2013). Thus, the monetary and societal costs of falls and disability in older people

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with dementia are substantial and will increase dramatically over the coming decades.

Balance and depressive symptoms have recently been identified as potentially modifiable independent predictors of falls in a large prospective study in community-dwelling older people with dementia (CDWD) (Taylor *et al.*, 2014). Exercise is a potential intervention strategy for both of these risk factors as there is strong evidence to indicate balance training can prevent falls in cognitively healthy older people (Sherrington *et al.*, 2011) and reduce depression in cognitively healthy older people with depressive symptoms (Bridle *et al.*, 2012). Currently, however, there is limited literature examining the effect of exercise as a strategy for improving balance, mood, and falls in CDWD (Vreugdenhil *et al.*, 2012; Pitkäla *et al.*, 2013a; Pitkälä *et al.*, 2013b; Suttanon *et al.*, 2013; Burton *et al.*, 2015; Forbes *et al.*, 2015). Some studies have demonstrated significant positive changes in physical performance using group-based exercise in this population (Pitkälä *et al.*, 2013b). However, group-based activity is often not older people's preference for program delivery (Yardley *et al.*, 2008).

We have previously conducted a pilot feasibility randomized control trial (RCT) examining a home-based fall prevention program which included home hazard reduction and exercise components (Wesson *et al.*, 2013). From this study, we determined that the intervention period needed to be longer. Three months did not provide adequate opportunity, in often sedentary individuals, to progress the exercise program to provide sufficiently challenging balance exercises.

Further research evaluating the effectiveness of home-based exercise programs in improving balance and reducing depressive symptoms (key risk factors for falls) in CDWD are needed to assist in the design of large RCTs powered for falls as the primary outcome measure. This uncontrolled study examined the effect of a six-month home-based, carer-enhanced, progressive, and individually tailored exercise program on balance (measured by sway on floor and foam) and affect (measured by the 15-item Geriatric Depression Scale (GDS)) in CDWD. We hypothesized that the six-month balance and strength training program would improve balance and mood (in those with clinically significant depressive symptoms) in this cohort of CDWD. Secondary outcome measures included concern about falling, physical activity, quality of life (QOL), hand reaction time, knee extension strength, and overall Physiological Profile Assessment (PPA) fall risk score. We also investigated the effect differing exercise program adherence levels had on physical outcome measures.

Methods

Participants

Participants comprised people aged 60+ years, living in the community with a clinical diagnosis of dementia (made by a geriatrician or psychogeriatrician) and either attending a specialty clinic (e.g. Cognitive Disorders Clinic, Memory Clinic, or Aged Care Clinic) or known to dementia services in the local community. Participants had an identifiable and consenting person responsible and/or carer who had a minimum of 3.5 hours a week of face-to-face contact with the participant for the purposes of intervention delivery and fall reporting. Exclusion criteria comprised Mini-Mental State Examination (MMSE) <12/30 (as it was considered people with significant dementia would be unlikely to engage with the intervention), residing in an aged care facility, presence of delirium, acute medical illness, severe psychiatric disorders, progressive neurological diseases (other than dementia), unable to speak English (without a readily available person to interpret), and/or blindness. A pool of 61 potential participants was assessed for eligibility. Of these, 19 were excluded 10 declined (six carer-related), six did not meet the inclusion criteria, one was deceased, and two were unable to be contacted. The study was approved by the South East Sydney Human Research Ethics Committee (HREC reference number 13/032) and consent was obtained from all participants and their person responsible prior to assessment.

Assessment

Participants and their person responsible were interviewed at home for demographic information, presence of medical conditions (specifically: stroke, transient ischaemic attack, heart disease, hypertension, diabetes, arthritis, osteoporosis, chronic lung disease, thyroid disorder, cancer, head injury, dementia, sleep apnoea, and depression), walking aid use, and carer- and participant-reported balance ability. One year history of falls was recorded at baseline.

Physical assessment and fall risk score

All physical assessment tasks were performed in the participants' home at baseline and reassessment. Visual contrast sensitivity was assessed using the Melbourne Edge Test (MET) (Lord *et al.*, 2003). Simple hand reaction time (ms) was measured using a visual stimulus and a finger-press response (score = average of 10 test trials) (Lord *et al.*, 2003). Proprioception was measured using a lower limb matching task primarily involving the knee

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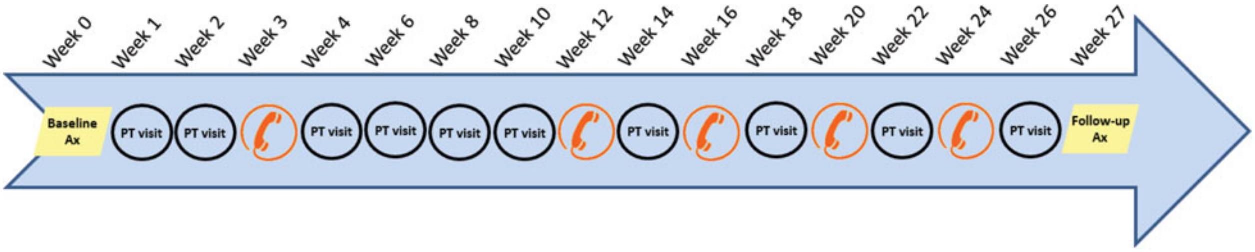

Figure 1. (Colour online) Intervention schedule.
Ax = assessment, PT = physiotherapy.

and ankle joints, while participants were seated with their eyes closed; average error in degrees was recorded for five trials (Lord *et al.*, 2003). Maximal isometric knee extension strength was measured in the dominant leg in a seated position with the hip and knee joints at 90° using a spring guage dynamometer (best of three maximal voluntary contractions measured in kg force) (Lord *et al.*, 2003).

Postural sway, a measure of standing balance, was assessed using a swaymeter that measures displacement of the body at waist level with participants standing on a firm surface (floor) and a foam rubber mat (15 cm thick) with eyes open for 30 s (Lord *et al.*, 2003). Sway on floor and foam are expressed as path length in millimetres and have previously been demonstrated to be associated with falls in older people with and without cognitive impairment/dementia (Lord *et al.*, 2003; Taylor *et al.*, 2012).

The coordinated stability test assesses controlled leaning balance and measures the ability of participants to adjust their body position in a steady and coordinated way. The participant navigated a pen on the end of a rod around a convoluted track placing them at or near the limits of their stability with a swaymeter secured to their waist (Lord *et al.*, 1996). The number of times the participant left the track (1 point) or failed to round a corner (5 points) was recorded and added to give the final error score.

Weighted contributions from five of the above tests (visual contrast sensitivity, hand reaction time, proprioception, knee extension strength, and sway on foam) provide the PPA composite fall risk score that has previously been demonstrated to predict multiple falls with up to 75% accuracy in cognitively intact community- and hostel-dwelling older people (Lord *et al.*, 2003). Similar predictive accuracy has previously been demonstrated in community- and hostel-dwelling cognitively impaired older people (Taylor *et al.*, 2012).

Global cognition, depression, anxiety, concern about falling, the impact of caring for someone with dementia, physical activity, and quality of life

Global cognition was assessed with the Addenbrooke's Cognitive Examination – revised (ACE-R) (Mioshi *et al.*, 2006) and the MMSE. The 15-item GDS (Jongenelis *et al.*, 2005), Goldberg Anxiety Scale (GAS), and the short-form Iconographical Falls Efficacy Scale (iconFES) (Delbaere *et al.*, 2013) were used to assess mood, anxiety, and concern about falling. The impact of supporting a person with dementia was measured using the Zarit Burden Interview (Bedard *et al.*, 2001).

The Incidental and Planned Exercise Questionnaire (IPEQ-W) was administered with the assistance of carers to obtain information on total hours of physical activity, total hours of walking activity, total hours of incidental activity, and total hours of planned exercise over the past week (Delbaere *et al.*, 2010). QOL of the participant was measured using the Alzheimer's Disease-Related Quality of Life Scale (QOL-AD) (score range 13–52) (Logsdon *et al.*, 1999). The ACE-R and MMSE were assessed only at baseline, while the remaining questionnaires and scales were administered at both baseline and reassessment.

Intervention

The intervention consisted of a home-based, carer-enhanced, progressive, and individually tailored exercise program delivered for six-months and designed to address deficits in physical performance identified during assessment, e.g. balance and strength. Over the six-month period there were ten visits from an experienced physiotherapist (Figure 1). The program allowed variation in the schedule based on the physical and cognitive abilities of the participant. Exercises were predominantly balance focused, but also included strength and/or combined strength-balance exercises, e.g. tandem stance, knee extensions +/− weights, sit-to-stand,

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step ups on a block, and sidestepping. Exercises were progressed by increasing the number, time, repetitions, weight and step block height; by reducing base of support, upper limb use, vision and chair height; and by changing the direction and surface (Table S1).

Exercise program adherence and falls

Participants' reported the number of prescribed exercise sessions they undertook in monthly diaries that were returned to the study site in reply-paid envelopes. Adherence was calculated as the percentage of exercise sessions the participant indicated they performed; i.e. (number of exercise sessions performed/number of exercise sessions presecribed) × 100. Falls were also recorded using diaries. The fall definition provided was, "In the past month, have you had any falls including a slip or a trip in which you lost your balance and landed on the floor or ground or lower level?" (Lamb *et al.*, 2005). If a participant/carer failed to return the calendar, a telephone call was made to obtain the participant's exercise and fall-related data.

Statistical analysis

The data were analyzed with SPSS version 22 (SPSS Inc., Chicago, IL). Participants who attempted but were physically unable to perform physical assessment tasks were allocated scores 3SD worse than the baseline mean and were included in the analyses. Participants who, after attempting the task were deemed by the assessing research assistant/physiotherapist as cognitively unable to comprehend and execute the requirements of a physical assessment task were given the mean baseline score for the study population. Independent samples *t*-tests for continuous data and Fisher's exact test for categorical data were used to compare characteristics of those who did and did not complete the reassessment. The McNemar's test for categorical data and the Wilcoxon signed rank test for continuous and ordinal data were used to compare baseline and reassessment scores as they were not normally distributed. Effect size was calculated using the following formula $r = Z/\sqrt{N}$ (where N = number of observations) and based on Cohen's criteria/thresholds these can be interpreted as follows: $r = 0.1$ – small, $r = 0.3$ – medium, $r = 0.5$ – large. Generalized linear models (GLM) were used to determine the effect of adhering to ≥70% and <70% of the prescribed exercise sessions on reassessment performance of physical variables while controlling for baseline performance. Independent samples *t*-tests for normally distributed continuous data, Fisher's exact test for categorical data and Mann–Whitney U test for skewed data were used to compare adherence groups' characteristics. Despite the multiple comparisons made, *p*-values were set at <0.05 and not adjusted to Bonferroni in this exploratory study because such adjustments may increase type II errors (Perneger, 1998).

Results

Forty-two older people with mild to moderate dementia were recruited with a mean ACE-R score of 58 ± 14. Twenty-two (52%) were female and the mean age was 83 ± 7 years (Table 1). Forty-one participants had follow-up falls data; 34% had one or more falls and 24% had two or more falls during the six-month follow-up (Table 1). Thirty-three participants (79%) completed the six-month reassessment (study completers; Figure S1). Of the nine who were not reassessed: one died, two were placed in residential care, four refused, one was unwell, and one withdrew from the study (Figure S1). The study completers were not significantly different to the study non-completers in relation to age ($p = 0.464$), gender ($p = 1.000$), years of education ($p = 0.077$), cognitive performance (ACE-R: $p = 0.208$, MMSE: $p = 0.089$), previous falls ($p = 1.000$) or those who reported falls ($p = 0.411$), and multiple falls ($p = 0.082$) during the six-month follow-up. The non-completers did have significantly more medical conditions ($p = 0.025$) (Table 1).

Effect of the intervention

Primary outcomes – balance and mood

Participants significantly improved in the tests of sway on floor ($Z = -3.350$, $p = 0.001$, $r = -0.412$) and foam ($Z = -2.679$, $p = 0.007$, $r = -0.330$), but did not improve with respect to depressive symptoms measured with the GDS ($Z = -0.402$, $p = 0.687$, $r = -0.049$) (Table 2). Overall, there was a 28% and 20% improvement in sway on floor and foam from baseline, respectively. Of the six participants with clinically significant depressive symptoms (GDS scores ≥5), median scores decreased from 8.0 (IQR 5.0–8.5) at baseline to 6.5 (IQR 3.8–9.0) at reassessment ($Z = -1.289$, $p = 0.197$, $r = -0.159$).

Secondary outcomes

Participants showed a significant reduction in concern about falling (iconFES) ($Z = -2.049$, $p = 0.040$, $r = -0.252$), a significant increase in planned physical activity measured by the IPEQ ($Z = 2.176$, $p = 0.030$, $r = 0.268$), and a significant reduction in knee extension strength at reassessment ($Z = -2.413$, $p = 0.016$,

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Table 1. Participant demographics/characteristics and; previous and prospective falls, and statistical comparison between study completers and non-completers

CHARACTERISTIC	ALL PARTICIPANTS (n = 42)	PARTICIPANTS WHO COMPLETED THE STUDY (n = 33)	PARTICIPANTS WHO DID NOT COMPLETE THE STUDY (n = 9)	*p*-VALUE[a]
Demographics				
Age, years, mean ± SD	83.0 ± 6.5	82.6 ± 6.6	84.4 ± 6.3	0.464
Years of education, years, mean ± SD	10.8 ± 3.4	11.3 ± 3.4	9.0 ± 2.9	0.077
Female, n (%)	22 (52)	17 (52)	5 (56)	1.000
Number of medical conditions, mean ± SD	5.0 ± 1.9	4.6 ± 1.9	6.2 ± 1.4	**0.025**
Living arrangement				
Alone	12 (29)	9 (27)	3 (33)	0.699
Cognitive assessment				
ACE-R, mean ± SD	58.0 ± 13.7	59.4 ± 13.5	52.8 ± 4.2	0.205
MMSE, mean ± SD	21.2 ± 4.1	21.7 ± 3.9	19.1 ± 4.2	0.089
Previous and prospective falls				
Previous falls				
Number of falls in previous year, n	51	33	28	
One or more falls in the year prior to study, n (%)	21 (50)	16 (49)	5 (56)	1.000
Two or more falls in the year prior to study, n (%)	14 (33)	9 (27)	5 (56)	0.133
Prospective falls				
Number of falls during six-month follow-up, n	34	20	14	
One or more falls during six-month follow-up, n (%)[b]	14 (34)	10 (30)	4 (50)	0.411
Two or more falls during six-month follow-up, n (%)[b]	10 (24)	6 (18)	4 (50)	0.082

[a]*p*-value represents statistical comparison between completers and non-completers. [b]n = 1 insufficient follow-up.
ACE-R = Addenbrooke's Cognitive Examination–Revised; MMSE = Mini-Mental State Examination; SD = standard deviation.

$r = -0.297$) (Table 2). There were no significant changes between baseline and reassessment for the remaining secondary outcome measures (Table 2).

Exercise program, progression, and adherence

In study completers, there were a median of 10 (mean 8.4 ± 2.4, range 3–10) physiotherapy visits. The number of exercises and repetitions prescribed and record of when exercises were upgraded at the ten physiotherapy visits are displayed in Table 3. At visit one, a median of 6 (range 3–7) exercises and 96 (range 25–162) repetitions were prescribed (Table 3). By visit 10, a median of 7 (range 0–11) exercises and 168 (range 0–360) repetitions were prescribed (Table 3). At visit one, a median of 2.0 (IQR 1.0–3.0) balance exercises, 2.0 (IQR 0.3–3.0) strength, and 2.0 (IQR 1.0–2.0) combined strength-balance exercises were prescribed. At visit 5, a median of 3.0 (IQR 2.0–3.8) balance exercises, 2.0 (IQR 0.0–2.0) strength, and 2.0 (IQR 2.0–3.0) combined strength-balance exercises were prescribed. At visit 10, a median of 3.0 (IQR 2.0–3.0) balance exercises, 2.0 (IQR 1.0–3.0) strength, and 2.0 (IQR 2.0–3.0) combined strength-balance exercises were prescribed. The cognitive abilities of participants, as determined by the treating physiotherapist, was the most common reason for not progressing the exercise program (at visit 10, n = 12 (36%, or 50% of those who had the tenth physiotherapy visit)). Of the 33 study completers; three (9%) moved to a residential care facility and four (12%) discontinued exercising during the trial period (Table 3).

Study completers (n = 30, n = 3 were missing adherence data) undertook a mean of 45% of prescribed days of exercise and adherence

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Table 2. Effect of the exercise intervention on outcome variables

CHARACTERISTIC	BASELINE (n = 33)	REASSESSMENT (n = 33)	*p*-VALUE
Indoor walking aid use, n (%)	9 (27)	7 (21)	0.500
Self-rated balance, poor and fair, n (%)			
Participant report	14 (42)	10 (30)	0.344
Carer report	19 (58)	13 (39)	0.146
Quality of life, median (IQR)[b]	38 (34–41)	39 (34–41)	0.449
Psychological assessment, median (IQR)			
Geriatric Depression Scale	2.0 (0.5–3.0)	1.0 (0.5–4.0)	0.687
Goldberg Anxiety Scale	0 (0–2)	0 (0–1)	0.260
iconFES	21 (16–26)	17 (14–21)	**0.040**
Zarit Burden Interview[a]	15 (8–23)	16 (8–23)	0.170
Physical assessment, median (IQR)			
Hand reaction time (ms)	264 (229–341)	264 (240–360)	0.422
Knee extension strength (kg)[b]	24 (17–34)	17 (14–25)	**0.016**
Sway on floor (mm)	118 (102–164)	85 (54–128)	**0.001**
Sway on foam (mm)	372 (250–668)	200 (118–909)	**0.007**
Coordinated stability, errors	28 (17–45)	25 (11–57)	0.773
PPA fall risk score, median (IQR)	2.6 (1.5–3.5)	1.3 (0.6–4.2)	0.136
Incidental and Planned Exercise Questionnaire, h/week, median (IQR)[b]			
Planned	0.8 (0.0–1.7)	1.3 (0.5–3.4)	**0.030**
Incidental	13.1 (7.3–25.9)	22.4 (6.5–38.2)	0.332
Walking	2.6 (0.7–4.7)	1.7 (0.7–5.3)	0.897
Total	14.3 (9.0–28.1)	23.6 (7.9–40.4)	0.276

h = hour; iconFES = iconographical–Falls Efficacy Scale; IQR = interquartile range; PPA = Physiological Profile Assessment; wk = week.
[a]n = 32.
[b]Higher values indicate better performance.

decreased over the course of the intervention. During month one, a mean of 63% of the prescribed days of exercise were completed; this decreased to 47% and 34% for month three and six, respectively. At six-months, 22 (52%) of the study completers were still exercising, with only 10 exercising on ≥50% and 5 on ≥70% of prescribed days.

Effect of adherence on physical outcomes

Table 4 displays the participants' physical performance outcomes based on average adherence (≥70% and <70%). There was no significant difference between adherence groups with respect to age ($p = 0.458$), gender ($p = 0.631$), years of education ($p = 0.344$), number of medical conditions ($p = 0.591$), ACE-R ($p = 0.905$), or GDS ($p = 0.811$) scores. Participants who exercised ≥70% of prescribed days demonstrated significantly better balance (less sway on foam) at reassessment compared to those that adhered to <70% ($p = 0.011$, Table 4). There was also a trend for those who adhered ≥70% to have lower PPA fall risk scores at reassessment ($p = 0.075$, Table 4). Including participants (n = 3) who had missing adherence data to the low (<70%) adherence group did not significantly change the results.

Discussion

In this cohort of CDWD, a six-month tailored home-based exercise intervention significantly improved balance, but not mood. The intervention also significantly improved two secondary outcome measures: concern for falls (iconFES) and planned physical activity (IPEQ).

The significant improvement with medium to large effect size in postural sway is encouraging as balance impairment has previously been identified as an important fall risk factor in CDWD (Taylor *et al.*, 2014). Two other RCTs of similar sample size have also demonstrated significant intervention effects in measures of balance (functional reach) with an exercise intervention in older people with Alzheimer's disease with either live-in spouses or daily caregivers when compared to controls (Vreugdenhil *et al.*, 2012; Suttanon *et al.*, 2013). Taken together, these findings suggest that although cerebral processing is affected by the disease process of dementia, exercise interventions are able to yield positive changes in balance (a sensorimotor function relying on central information processing as well as sensorimotor input) in people with mild to moderate dementia.

The exercise intervention did not significantly change GDS scores. Depressive symptoms were

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Table 3. Visit schedule, exercise program and progression, and factors affecting adherence in study completers (n = 33)

	EXERCISE PROGRAM			FACTORS REPORTED AS AFFECTING ADHERENCE AND PROGRESSION									
VISIT	HAD PT VISIT, n (%)	EXERCISES PROGRESSED, n (%)[a]	NO. OF EXERCISES, MEDIAN (RANGE)	NO. OF REPETITIONS, MEDIAN (RANGE)	COGNITION, n (%)	PHYSICAL, (%)	UNWELL/ HOSPITAL, n (%)	UNMOTIVATED/ DECLINED PROGRESSION, n (%)	PAIN, n (%)	CARER-RELATED, n (%)	CEASED EXERCISING, n (%)	NHP, n (%)	PARTICIPANT UNAVAILABLE, n (%)
One	32 (97)	N/A	6 (3–7)	96 (25–162)				1 (3)	1 (3)				1 (3)
Two	31 (94)	27 (87)	6 (0–9)	113 (0–216)		4 (12)	2 (6)		3 (9)				2(6)
Three	33 (100)	27 (82)	6 (0–10)	113 (0–249)	3 (9)	4 (12)	1 (3)	2 (6)	1 (3)				
Four	31 (94)	21 (68)	7 (0–12)	133 (0–275)	6 (18)	3 (9)	5 (15)	1 (3)	3 (9)	2 (6)	1 (3)	1 (3)	1 (3)
Five	28 (85)	17 (61)	7 (0–10)	132 (0–356)	4 (12)	5 (15)	4 (12)	1 (3)	1 (3)	4 (12)	2 (6)	1 (3)	1 (3)
Six	24 (73)	16 (67)	7 (2–10)	156 (48–358)	4 (12)	2 (6)	5 (15)		1 (3)	1 (3)	3 (9)	2 (6)	2(6)
Seven	26 (79)	14 (54)	7 (3–10)	160 (51–383)	7 (21)	4 (12)	2 (6)	1 (3)	1 (3)	3 (9)	3 (9)	2 (6)	1(3)
Eight	26 (79)	10 (38)	7 (0–11)	164 (0–383)	8 (24)	7 (21)		2 (6)	1 (3)	1 (3)	4 (12)	3 (9)	1(3)
Nine	22 (67)	11 (50)	7 (4–13)	154 (16–330)	9 (27)	5 (15)		1 (3)	2 (6)	1 (3)	4 (12)	3 (9)	4(12)
Ten	24 (73)	6 (25)	7 (0–11)	168 (0–360)	12 (36)	5 (15)			1 (3)	2 (6)	4 (12)	2 (6)	3(9)

[a]reported percentage was calculated using those participants that received the scheduled physiotherapy visit as the denominator.
Participant unavailable' category description: participant away on holidays, participant cancelled appointment/s, participant staying with relative after illness, participant not home on therapists' arrival.
No. = number; NHP = nursing home placement; PT = physiotherapy.

Table 4. Effect of average adherence (≥70%, <70% prescribed sessions) on physical outcomes in study completers

	<70% adherence (n = 7)		<70% adherence (n = 23)			
Physical measure	Baseline, median (IQR)	Reassessment, median (IQR)	Baseline, median (IQR)	Reassessment, median (IQR)	Coefficient (CI) associated with <70% adherence[a]	p-value
Hand reaction time, ms	311 (238–382)	304 (249–339)	259 (223–369)	261 (238–382)	113 (−155–382)	0.408
Knee extension strength, kg	22 (18–26)	20 (14–25)	27 (15–35)	17 (14–24)	−2.0 (−8.3–4.2)	0.524
Sway on floor, mm	153 (88–206)	96 (40–134)	117 (101–159)	85 (62–120)	23 (−55–102)	0.565
Sway on foam, mm	372 (296–595)	178 (129–313)	363 (198–671)	242 (124–909)	210 (49–370)	**0.011**
PPA fall risk score	3.1 (2.2–3.4)	1.8 (1.1–2.1)	2.3 (1.3–3.8)	2.8 (0.5–4.2)	1.5 (−0.1–3.0)	0.075

[a]Calculated using generalized linear models using reassessment score as the dependent variable and adherence (≥70%, <70%) as the factor; for each model baseline score was entered as a covariate.
CI = confidence interval; IQR = interquartile range; PPA = physiological profile assessment.

relatively low and this floor effect may have reduced our ability to demonstrate any significant improvements in mood. In the participants with clinically significant depressive symptoms (GDS ≥5, n = 6), there was a non-significant reduction in median GDS score. Future research, in larger studies, should include subgroup analysis of participants with clinically meaningful depressive symptoms as this study was underpowered to detect a significant difference in this sub-group.

The significant reduction in knee extension strength at the end of the trial was unexpected. It is possible that even though the tailored exercise program included balance and strength training (e.g. static balance, step ups, heel raises, knee extensions, and sit-to-stands), the strength component may have been sub-therapeutic. This may have also affected our ability to significantly impact depressive symptoms. Another possible explanation is that without exercise the decline in strength would have been more marked. Pitkäla and colleagues implemented a twice weekly, home-based exercise program for 12 months and although strength was not an outcome measure, they reported a decline in short physical performance battery (SPPB) scores (a validated measure of lower extremity function) and Functional Independence Measure (FIM) scores in the intervention groups. In contrast, a six-month trial by Suttanon *et al.* reported no significant treatment effect for Sit to Stand – rising index (% body weight; force exerted to rise) and though not reported statistically, this surrogate measure of strength did not appear to decline over the trial period (Suttanon *et al.*, 2013). Maximal voluntary contractions, required for the knee extension strength test, are influenced by participant motivation and tester verbal instructions and encouragement (Jung and Hallbeck, 2004). These factors may have also played a role.

The exercise intervention also significantly reduced concern about falls – a known fall risk factor in CDWD (Taylor *et al.*, 2014). This improvement was substantial and clinically relevant as participant mean scores on the iconFES dropped from the third quartile to the lower limits of the second quartile of concern about falls based on population norms (Delbaere *et al.*, 2011).

The individualized balance and strength training program in this study did not routinely include a walking program. A meta-analysis of exercise to prevent falls recommended that walking programs only be prescribed if they do not detract from balance training and brisk walking should not be prescribed in high-risk individuals (Sherrington *et al.*, 2011). Overall, exercise programs that did not include a walking program were more effective in preventing falls (Sherrington *et al.*, 2011). However, walking offers other important health advantages in older people, both with and without dementia. In this study, we found a significant increase in planned physical activity, a non-significant increase in incidental and total physical activity, and a non-significant decrease in walking measured by the IPEQ. Two other studies in older people with Alzheimer's disease have

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included walking programs (Vreugdenhil *et al.*, 2012; Suttanon *et al.*, 2013). However, in one study there was no significant change in physical activity in the intervention group compared to the control group (Suttanon *et al.*, 2013) and in the other, physical activity was not measured (Vreugdenhil *et al.*, 2012). Further research is needed in older people with cognitive impairment/dementia as to the best approach for fall prevention interventions and whether the inclusion of a walking program is warranted, particularly considering its other potential health benefits.

Carers' psychological well-being, as well as the impact of their involvement in the implementation of interventions in CDWD needs to be considered. We found that the impact of caring for participants with dementia using the Zarit Burden Interview did not significantly change between baseline and reassessment. This is reassuring as carers played a major role in program delivery which could have been viewed as onerous. On the other hand, it could be argued that if an intervention had beneficial physical and psychological effects in CDWD, the Zarit Burden Interview score should have improved. This, however, may be difficult to achieve as a previous longer term (one year) exercise intervention RCT conducted in participants with Alzheimer's disease (and their spousal caregiver), found that irrespective of group allocation, participants' physical function (measured by the FIM and SPPB) declined over one year (Pitkäla *et al.*, 2013a). This study did not report how the intervention affected the spousal caregivers in terms of the impact of caring for someone with dementia or other psychological outcomes. Future work in this area should examine the effect home-based exercise programs have on carers of CDWD in longer term trials.

Adherence and exercise progression were influenced by various factors to be expected in a study of CDWD, e.g. nursing home placement, illness, lack of interest in continuing to exercise, and cognitive and carer issues. A large proportion (87%) of participants had their exercise program progressed at the beginning of the intervention (physiotherapy visit 2). However, by the tenth visit only 25% of the participants had their exercise program upgraded and cognitive factors were reported as a dominant factor limiting progression. Despite this, the group significantly improved their balance suggesting that the balance exercises offered sufficient challenge. Future studies, with more participants and statistical power, may be able to assist in determining the effect exercise progression has on physical and fall outcomes. Furthermore, although the intervention schedule was flexible, it may be that in future trials the schedule needs to be more adaptable on an ongoing basis, shaped by an individuals' performance/ability throughout the study period. It is also possible that more specialized training for therapists working with CDWD focusing on functional cognition and how best to work with someone with dementia may lead to better outcomes.

Similarly to exercise progression, adherence decreased over the trial period. Adherence, however, may have been under-reported due to non-returned and sub-optimally completed exercise diaries. Activity monitors and accelerometers offer potential means for more precisely measuring exercise participation in future studies (Brodie *et al.*, 2015). The recommendation that most participants perform the exercises daily may have been too ambitious, and it is likely that many participants exercised only when their carers were available to provide supervision and prompting. In cognitively intact older people, previous literature suggests that the most effective exercise programs for fall prevention have a minimum dose of 2 hours per week and include moderate to high challenge balance training for six-months (Sherrington *et al.*, 2011). A program goal of three to four times per week may be more feasible/achievable and still sufficiently effective. From reviewing the exercise diaries, some participants seemed to prefer other types of exercise (e.g. walking and golf) over the prescribed balance and strength training which negatively affected adherence. In future studies, it is vital that the individualized exercise programs are both tailored to participants' physical and cognitive abilities, as well as being relevant to their lives and interests.

Baseline ACE-R scores were not significantly different between the adherers ($\geq$70%) and non-adherers (<70%) (data not shown). However, apathy and/or reduced executive functioning may have influenced participants' understanding and motivation to continue with the program. Future research should examine cognitive and psychological factors and participant and carer attitudes to the intervention to better understand factors that affect adherence.

Limitations

First, the study has a relatively small sample size. However, the study revealed meaningful and significant changes in continuously scored outcome measures, including one of our primary outcome measures – balance, with moderate to large effect sizes. Second, we did not recruit a control group. Our previous fall prevention feasibility pilot RCT did not demonstrate significant improvements in balance or mood (known independent modifiable

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fall risk factors) (Wesson *et al*., 2013). Hence, the primary aim of this study was to determine whether longer term interventions are efficacious with respect to these outcomes and thus provide important treatment effect data to guide a planned RCT with falls as the primary outcome measure (Close *et al*., 2014). This was of particular importance as previous literature has suggested that even with a fairly intensive 12-month intervention, participants with dementia still decline over time (Pitkäla *et al*., 2013a). The lack of a control group means we were unable to control for factors outside the intervention that may have influenced the outcome measures. In particular, this makes interpretation of the knee extension strength and fall outcomes difficult. However, as the fall prevalence during the six-month intervention is not higher than expected in CDWD, we are confident that the intervention did not cause any harm. Third, participants were not followed up after the six-month intervention, so we are not able to determine if there were any lasting effects of the exercise program. Fourth, results cannot be generalized to participants with more severe dementia (MMSE <12) or those who are unable to speak English (without a readily available interpreter). However, there is no reason to believe that an older person who does not speak English would not benefit from the exercise program. Finally, the response to exercise interventions in older people with dementia may vary depending on their dementia type/pathology. In this study, we used broad inclusion criteria and did not specify dementia type/pathology. Therefore, we are unable to determine whether there were any differential effects of exercise based on this criterion.

Conclusions

This pilot trial of a tailored home-based, exercise program demonstrated significant improvements in balance, concern for falls, and planned physical activity in CDWD. This provides support for further research into exercise as one intervention modality to prevent falls in larger adequately powered RCTs. Additional work is required to elucidate strategies for enhancing uptake and adherence to maximize the effectiveness of fall prevention interventions.

Conflict of interest

The PPA (FallScreen) is commercially available through NeuRA.

Description of authors' roles

MT analyzed the data and drafted the manuscript. JC, SL, HB, and SK reviewed the manuscript. JC was lead investigator of the study. LW, NP, SH, and ER were actively involved in the study. All authors read and approved the final manuscript.

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Supplementary Material

To view supplementary material for this article, please visit http://dx.doi.org/10.1017/S1041610216001629.

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