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Effects of physical activity on depressive symptoms in older caregivers: The IMPACCT randomized controlled trial

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Abstract

Objectives: Physical activity (PA) can reduce depressive symptoms but has not been tested amongst depressed older caregivers and their care-recipients. The aim of this single-blind randomized controlled trial was to investigate the effect of a 6-month tailored PA program on depressive symptoms in older caregivers.

Method: Caregivers were included if they had scores of ≥ 5 on the 15-item geriatric depression scale (GDS-15). Care-recipients could have any type of physical, mental or cognitive condition requiring support. The PA intervention group completed an individualized program based on the Otago-Plus Exercise Program. The primary outcome was improvement in depressive symptoms in caregivers measured at six and 12 months.

Results: Two hundred and twelve participants (91 dyads and 30 caregivers only) were randomized using a 3:3:1 ratio to PA intervention, social-control, and usual-care control groups. There were no significant differences in depressive symptoms of the caregivers between the three groups at 6 months or 12 months. However, more than 50% of caregivers in all three groups no longer had a GDS-15 score ≥ 5 at 6 months. Further analysis revealed that caregivers in the PA group caring for someone with a standardised mini-mental state examination (SMMSE) score ≥ 24 had significantly less depressive symptoms than those caring for someone with a SMMSE score < 24 compared with social-control ($p < 0.02$) and usual-care groups ($p < 0.02$).

Conclusions: A PA intervention may be beneficial for some caregivers in reducing symptoms of depression but may not be as beneficial to caregivers of people living with cognitive impairment.

KEYWORDS

caregivers, depression, physical activity

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Key points

- Physical activity (PA) may help to reduce depression, stress and burden in caregivers.
- This study investigated the effects of an individually tailored, home-based PA intervention for both caregivers and care-recipients, of 6 months' duration, on improving depressive symptoms in older caregivers.
- A PA intervention may be beneficial for caregivers in reducing symptoms of depression but may not be as beneficial to caregivers of people living with cognitive impairment.

1 | INTRODUCTION

In Australia, family caregivers provide approximately 80% of all care for older people who require care¹ contributing an estimated \$77.9 billion per year.² Unfortunately, caregiving can come at a cost, not only financially, but physically and mentally, particularly as many caregivers are older themselves. In Australia, 89.9% of primary caregivers are family members, and more than 50% of primary caregivers aged over 55, with the 55–64 year old age group accounting for almost a quarter (24%) of all primary caregivers.³ Sixty per cent of older Australian caregivers experience psychological distress and the distress prevalence increases with more unmet needs for support.⁴

There is a strong link between caregiver wellbeing and the levels of function and dependence of the person they care for.⁵ Cross-sectional studies have consistently found negative outcomes for caregivers, such as increased strain, depression, and burden, associated with functional limitations of the care-recipients.^{6–8} With the aging of the global population and rising workforce participation amongst women who provide the majority of informal care, there is an increasing gap between the number of caregivers needed and the numbers available to provide care.² It is therefore critical that interventions are found that reduce depression, stress and burden for caregivers to ensure that current and future caregivers are able to sustain care over time, minimizing adverse effects on their physical and mental health.

Evidence from randomized controlled trials indicates that PA can improve depressive symptoms in older people.^{9–12} PA can also be beneficial for caregivers.¹³ Loi et al.¹⁴ identified five intervention studies investigating the effect of PA on caregivers' psychological state. A walking intervention improved depression, perceived stress and burden in older women caring for a relative living with dementia.¹⁵ Decreases in burden and level of depression were observed for caregivers completing muscle relaxation exercises¹⁶ and improvements in depression and perceived stress were seen in studies incorporating flexibility and stretching components to a walking program.^{17,18}

Providing a program that *both* caregivers and care-recipients can engage in simultaneously may increase motivation, enhance social participation and overcome other barriers.¹⁹ Enabling programs to be done at home could lead to better adherence since it eliminates the need for respite care or transportation. In a study by Lamotte et al.,²⁰ four controlled trials explored exercise interventions involving both the person living with dementia and their caregivers. While these interventions were found to be feasible, the main focus was on

enhancing the care-recipients' mental health with positive effects on caregivers' burden and depression. Current intervention studies targeting depressive symptoms have primarily concentrated on caregivers supporting people with dementia.^{21,22} However, the potential advantages of these interventions for caregivers with other conditions have not yet been investigated. Therefore, the current study investigated whether a joint PA program for caregivers and care-recipients with any condition could improve depressive symptoms in both groups.

The primary aim of this study was to investigate the effects of an individually tailored, home-based PA intervention of 6 months' duration for dyads, on improving depressive symptoms in older caregivers, with the primary hypotheses being that (a) caregivers in the PA intervention would have more improvement of their depressive symptoms compared to caregivers in the social-control or usual care conditions; and (b) a higher proportion of caregivers involved in the PA intervention would be less depressed compared to caregivers in the social-control or usual care conditions. Secondary aims were to investigate whether the PA intervention would: (a) improve caregiver burden, activity and function; (b) sustain improvement in caregiver depressive symptoms improvement over 12 months; and (c) improve care-recipient depressive symptoms, activity, function; and reduce health service usage such as hospitalizations and residential care admissions. A sub-group analysis was included to investigate whether the care-recipient's level of cognitive impairment would influence the outcomes of the intervention, as caring for someone with dementia has been found to negatively impact on healthy behaviors including PA.²³

2 | METHOD

The study was a RCT, as described on the Australian and New Zealand Registry of Clinical trials (ACTRN12612000094875 18/01/2012), based on the CONSORT guidelines.²⁴ The full study protocol has been previously published.²⁵

2.1 | Participants

Caregivers were included if they were: (a) aged 55 years or over; (b) providing informal care (that is, unpaid) for a person aged ≥ 60 years old living at home with dependence in at least one activity of daily living; (c)

living with the care recipient or living close by as to be "on call" (i.e., within a 5 min drive); and (d) had a score of ≥ 5 on the geriatric depression scale (GDS-15) (GDS -15). Caregivers could also nominate to be involved in the study if their care-recipient declined involvement. Care-recipients were included if they had an informal caregiver who also agreed to be in the study, as well as fulfilling the following criteria: (a) aged ≥ 60 years old; (b) living at home with their caregiver or within a 5 min drive; and (c) dependent in at least one activity of daily living. Informed consent was assessed via the ability to: 1. Understand the information provided; 2. Be able to retain and communicate what this information entailed; 3. Weigh up the potential benefits and consequences if participating or not participating in the research; and 4. Be able to communicate the decision. Participants who were unable to provide informed consent were excluded.

2.2 | Recruitment procedures

Participants were recruited through caregiver support agencies, community aged care services and via extensive media and promotional activities throughout Victoria, Australia. Interested caregivers underwent telephone screening to ensure their eligibility. Baseline assessments were administered within 4 weeks of screening. If baseline assessment was not possible within the four weeks, the GDS-15 was readministered to ensure results accurately reflected caregiver depression.

2.3 | Sample size calculation

Based on data from Kerse et al.¹⁰ which identified that 30% of their participants in their social control group endorsed depressive symptoms, our initial power analysis determined a sample size of 273 dyads overall (including 20% extra for anticipated dropouts).²⁵ This included 93 dyads in both the intervention and social-control groups and 28 in the usual-care group, randomly allocated to groups in a 3:3:1 ratio.

2.4 | Intervention

All participant caregivers and their care-recipients in the PA intervention group received a visit by an experienced physiotherapist who prescribed individualized PA programs for each of them to do at home based on each individual's physical assessment. Each participant was asked to complete the assigned exercises for approximately 30 min, 5 days each week for a period of 6 months. The intervention was based on the Otago-Plus Exercise Program. The Otago-Plus program includes the original Otago Exercise program and more challenging exercises. The program was designed to deliver a variety of balance and strengthening exercises, plus a walking program for participants who required a greater level of challenge in their exercises than the original Otago program provided.²⁶

This initial visit was followed by 5 additional monthly home visits, where the physiotherapist reviewed and modified the exercise programs as needed. The initial assessment visit took between 60–80 min to complete. Subsequent visits were completed in approximately 50 min.

2.5 | Control groups

Social-control: The social-control group was implemented to account for possible beneficial social effect of the PA intervention.¹⁰ These participants received the same number and duration of visits as the intervention group. These comprised 5 visits over a 6 month period and involved a trained social worker engaging in semi-structured discussions about any topics of interest to the dyad, excluding discussion of anything pertaining to PA. Time allocated for these visits mimicked that allocated for the PA intervention.

Usual-care: These participants received no visits except for data collection purposes. All three groups were visited for data collection purposes at baseline, 6 months, and 12 months and received monthly phone calls for service use.

2.6 | Randomization

Participants were randomly assigned to one of three groups in a 3:3:1 sequence: the PA intervention, the social-control group and the usual-care group. Allocation was concealed through a computer-generated random numbers sequence, undertaken via an external organization. Random permuted blocks of 7, 14 and 21 were utilized within the allocated groups.²⁵ Researchers undertaking follow-up assessments and phone calls were blinded to group allocation for the duration of the trial.

2.7 | Data collection

A full list of measures used in this study for both caregivers and care-recipients has been described previously.²⁵ Data were collected at three time-points for all three groups.

2.7.1 | Psychological measures

The GDS-15²⁷ is a valid and reliable shortened version of the GDS-30, which has 15 statements asking about the biological and cognitive symptoms of depression, with yes/no responses. Higher scores indicate more depressive symptoms. A cut-off ≥ 5 suggests clinical depression.

The Zarit Burden Interview (ZBI)²⁸ has 22 statements asking about carer burden with a five point Likert scale for responses. Higher scores indicate increased carer burden, with scores between 0 and 21

indicating little/no burden, 22–40 mild/moderate burden, 41 to 60 moderate/severe burden, and scores 61 to 88 severe burden.

2.7.2 | Function and physical activity

The Human Activity Profile measures 94 activities rated as “still doing”, “stopped doing” or “never did”.²⁹ The Adjusted Activity Score (HAPASS) is calculated by subtracting the number of lower number activities listed as “stopped doing” from the highest numbered activity still being done. Higher scores indicate greater activity levels.

The 100-point Modified Barthel Index consists of ten self-care and mobility items, with higher scores indicating increasing independence.³⁰

Care-recipients' cognition was tested using the Standardised Mini-Mental State Examination (SMMSE)³¹ which has good reliability and sensitivity for detecting cognitive impairment. A score <24 suggests at least mild cognitive impairment, which was the score used for the pre-planned subgroup analysis to investigate whether care-recipient cognition would affect the outcomes of the intervention.

2.7.3 | Adherence

Caregivers were asked to maintain a diary detailing changes in PA levels for themselves and/or their care recipient, as well as health service use (the number of primary care and specialist visits), incidents and adverse events (such as falls and hospital admissions), community service use (such as respite) and changes to employment status.

2.8 | Ethical considerations

Ethics approval was obtained through the Melbourne Health Human Research Ethics Committee (HREC Reference Number 2012.041) and from the Grampians/Ballarat HREC (HREC Reference Number: HREC/12/BHSSJOG/73). Protocols were developed to ensure that participants with high levels of depression (GDS-15 > 11) were referred to appropriate health professionals.

2.9 | Statistical analysis

All participants data were analyzed in the group allocated in the randomization. The primary outcome, a) the proportion of caregivers with GDS-15 scores ≥ 5 at 6-month follow-up; and b) caregiver GDS score (continuous) at 6-month follow-up, adjusted for baseline GDS score, was analyzed using logistic and linear regression respectively. For secondary outcomes, the effect of the intervention was analyzed using logistic regression for dichotomous outcomes, linear regression for normally distributed continuous outcomes and quantile regression for skewed continuous outcomes. For all analyses the

corresponding baseline variable was included in analysis when the outcome was continuous. A sub-group analysis was performed across care recipients' SMMSE score using a likelihood ratio test for an interaction between dichotomized SMMSE scores and allocated group. This outcome variable in this sub-group analysis was care giver GDS-15 (continuous); this was varied from the pre-planned analysis of the GDS-15 (dichotomized) because of insufficient numbers. Stata 15 and Statistical Package for Social Sciences version 27 (IBM) were used for all analyses.

3 | RESULTS

From March–September 2016, two hundred and twelve individual participants were recruited, consisting of 91 dyads and 30 individual caregivers (see Figure 1 for more information). An initial timeframe of 18 months was provided for recruitment, but this was extended by a further 24 months due to slow recruitment.

A variety of recruitment strategies were used, including direct mail-outs from caregiver support agencies, researcher attendance at caregiver support groups, advertisement in print media and promotion via medical practitioners and case-managers as well as “word of mouth”, with direct mail-outs being the most successful approach accounting for 37% of eligible participants. Despite these efforts, we were unable to recruit the number required.

At the 6-month follow-up 61/91 (67.0%) of dyads remained in the study, 1 dyad (1.1%) supplied some data but was unable to complete the assessment and 12/91 (13.2%) of the caregivers from the dyads became caregiver-only participants due to death of the care-recipient or care-recipient withdrawal from the study for other reasons. Of the 30 caregiver-only participants, 7 (23.3%) withdrew at 6-month and 1 (3.3%) did not complete the 6 months follow up. At 6 months there were 61 dyads and 34 caregiver-only participants.

A similar mean level of depression at baseline was reported by caregivers who remained in the study (GDS 8.1, SD = 2.2) and those who withdrew (GDS 8.1, SD = 2.9). Those withdrawing from the study did report higher average caregiver burden (ZBI 45.4, SD = 17.2) than those remaining in the study (ZBI 38.8, SD = 15.1). Otherwise, caregiver age, gender and activity levels were similar across those withdrawing from the study and those who remained. At the 12-month follow-up, 47/91 (51.6%) of the original dyads remained in the study (Figure 1).

Adherence to the PA intervention was self-reported using diaries by participants. There were no adverse or reportable events. There were 18 caregivers and 4 care-recipients who scored GDS>11 and were referred to their GP as per the risk protocol.

3.1 | Caregiver characteristics

The mean age of the participating caregivers ($N = 121$) at baseline was 69.8 (SD = 8.7) years and 82.6% were female (Table 1). Most

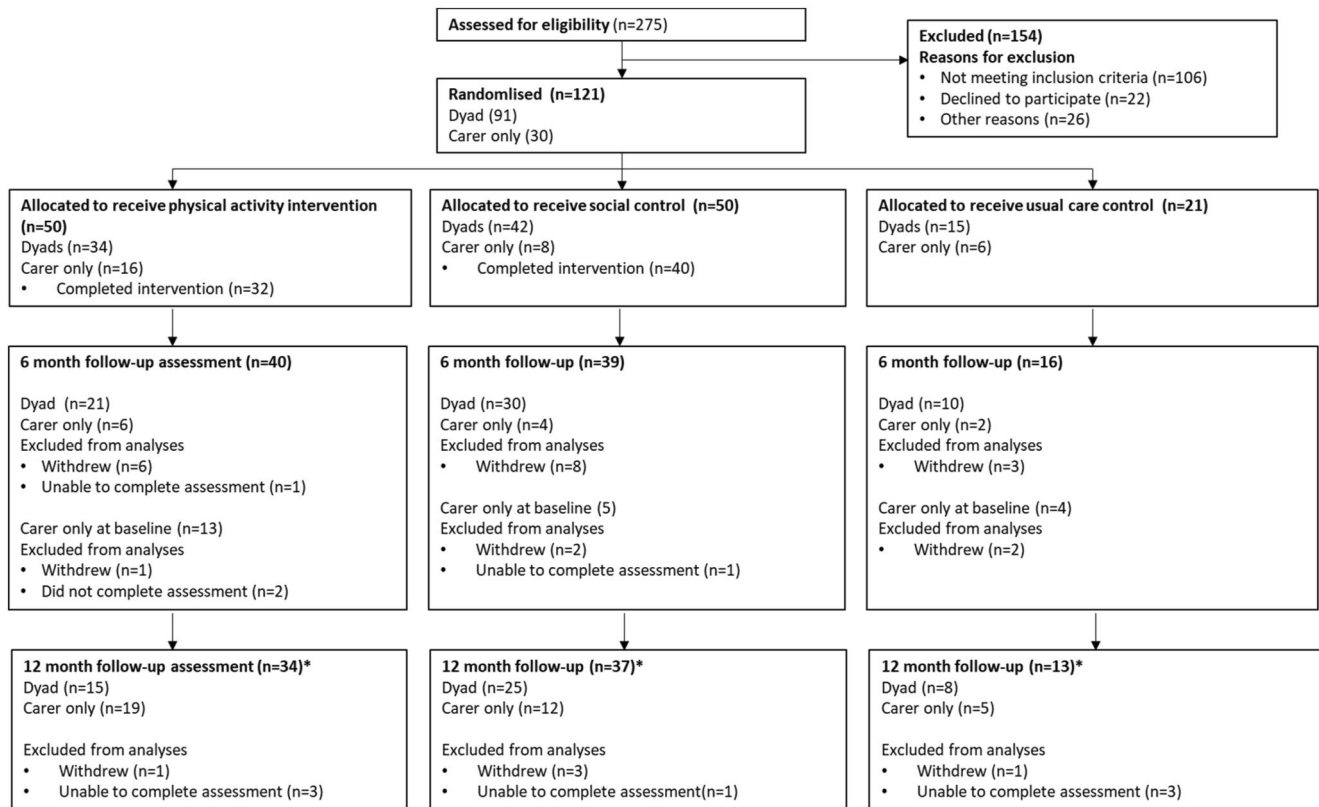


FIGURE 1 Participant flowchart. *Five participants completed the 12 months follow-up but not the 6 months follow-up (physical activity group: 2 participants, social intervention group: 2 participants, usual care: 1 participant).

commonly the caregiver was the care-recipient's spouse (78.5%) and English was the preferred language for the majority of caregivers. Caregivers reported caring for an average of 104.8 (SD = 54.5) hours per week and 30.6% of caregivers were on anti-depressant medication. The most common health conditions of caregivers were: arthritis or other physical disorders, stroke/neurological conditions and osteoporosis (Table 1). Overall, for all caregivers, the mean GDS-15 score was 8.1 (SD = 2.4, range 5–14). The mean ZBI score was 40.6 (SD = 15.7, range 8–79), indicating moderate burden. The average HAPAAS score was 60.1 (SD = 14.6, range 21–82), suggesting moderate activity.

3.2 | Care-recipient characteristics

The mean age of the 91 care-recipients was 77.7 (SD = 8.7) and 27.5% were female (Table 2). At baseline, the mean SMMSE score was 22.2 (SD = 8) and almost half (n = 37, 43%) of care recipients had an SMMSE <24, suggesting cognitive impairment. The mean Barthel Score was 77.1 (SD = 24.7, range 2–100) indicating at least mild impairment in ADLs. Their mean HAPAAS score was 41.9 (SD = 19.2, range 5–75), suggesting low activity levels. Care-recipients' mean GDS score was 4.8 (SD = 3.4, range 0–13). Care-recipients in the usual care group were less likely to be female ($p = 0.03$).

3.3 | Effect of the physical activity intervention

Of the caregivers who remained in the study for 12 months, their GDS-15 scores at baseline, six- and 12 months were 7.9 (SD = 2.2), 4.3 (SD = 2.8) and 4.1 (SD = 3.0), respectively, for the whole sample. There was a significant decrease in the number of depressive symptoms $F(1.85, 404.01) = 79.95, p < 0.001$, only from baseline to 6 months (3.6, 95% Confidence Interval [CI] 2.8, 4.5, $p < 0.001$). There was a similar significant improvement in depressive symptoms from baseline to 6 months, but not from 6 to 12 months.

There were no significant differences found in the proportion of depressed caregivers at 6 months between the PA intervention and social control groups (OR 1.06, 95% CI 0.44, 2.56, p value 0.91) and the PA intervention and usual care control groups (OR 1.51 95% CI 0.46, 4.94 p value: 0.50). There were no differences in the GDS-15 scores among the three groups (Table 3). However, over 50% of caregivers in all three groups no longer had a GDS-15 score indicative of depression. No difference was found for the caregiver-specific outcomes in burden, function and activity, nor in care-recipient depressive symptoms, activity or function (Table 3). No difference was found in the primary outcome between the PA intervention and control groups at 12 months (proportion of caregivers who were no longer scored) GDS-15 ≥ 5 (Table S1).

At 6 months adjusted for baseline GDS, caregivers in the PA group caring for someone without cognitive impairment (SMMSE

TABLE 1 Caregiver baseline demographic characteristics.

Caregiver characteristics	Physical activity intervention group (n = 50)	Social control group (n = 50)	Usual-care control group (n = 21)	Total sample (n = 121)
Age, mean (SD)	70.7 (8.7)	69.6 (8.8)	67.9 (8.8)	69.8 (8.7)
Female n (%)	42 (84.0)	40 (80.0)	18 (85.7)	100 (82.6)
Born in Australia n (%)	35 (70.0)	31 (62.0)	11 (52.4)	77 (63.6)
English as preferred language n (%)	41 (82.0)	42 (85.7)	18 (90.0)	101 (84.9)
Education level (highest)				
Primary n (%)	1 (2.0)	0	0	1 (0.8)
Secondary n (%)	17 (34.0)	26 (52.0)	9 (42.9)	52 (43.0)
Tertiary n (%)	26 (52.0)	17 (34.0)	10 (47.6)	53 (43.8)
Unknown n (%)	6 (12.0)	7 (14.0)	2 (9.5)	15 (12.4)
Relationship to care-recipient				
Spouse/partner n (%)	42 (84.0)	37 (74.0)	16 (66.7)	95 (78.5)
Child n (%)	8 (16.0)	13 (26.0)	3 (14.3)	24 (19.8)
Sibling n (%)	0	0	2 (9.5)	2 (1.7)
Entered as a dyad in the study n (%)	34 (68.0)	42 (84.0)	15 (71.4)	91 (75.2)
Measures				
Mean GDS-15 score (SD)	7.8 (2.1)	8.5 (2.6)	7.9 (2.7)	8.1 (2.4)
Mean zarit burden inventory	41.9 (15.0)	40.3 (15.9)	35.9 (16.9)	40.6 (15.7)
Mean human activity profile (SD)	62.1 (15.9)	60.0 (15.4)	61.2 (11.7)	61.0 (11.7)
Health conditions of caregiver				
Dementia n (%)	0	0	0	0
Cancer n (%)	7 (14.0)	4 (8.0)	6 (28.6)	17 (14.1)
Heart disease n (%)	9 (18.0)	9 (18.0)	5 (23.8)	23 (19.0)
Asthma/COPD n (%)	6 (17.1)	5 (12.2)	3 (21.4)	14 (15.6)
Osteoporosis n (%)	11 (22.0)	13 (26.0)	3 (14.3)	27 (22.5)
Diabetes n (%)	2 (4.0)	13 (26.0)	3 (14.3)	18 (14.9)
Stroke or other neurological disorder n (%)	8 (16.0)	13 (26.0)	6 (28.6)	27 (22.3)
Arthritis or other physical disorder n (%)	44 (88.0)	46 (92.0)	20 (95.2)	111 (91.7)
Anti-depressant medications prescribed n (%)	34 (68.0)	33 (66.0)	17 (81.0)	37 (30.6)
Employed in paid work n (%)	4 (8.0)	3 (6.0)	1 (4.76)	8 (6.61)
Mean hours of care per week provided to the care recipient (SD)	102.9 (53.9)	106.2 (52.0)	105.9 (63.6)	104.8 (54.5)
Primary reason care-recipient requires care				
Dementia n (%)	14 (28.0)	16 (32.7)	5 (23.8)	35 (29.2)
Stroke/neurological n (%)	17 (34.0)	11 (22.5)	6 (28.6)	34 (28.3)
Mental health disorder n (%)	3 (6.0)	2 (4.1)	2 (9.5)	7 (5.8)
Other physical disorder n (%)	16 (32.0)	20 (40.8)	8 (38.1)	44 (36.7)

Abbreviations: COPD, chronic obstructive pulmonary disease; GDS-15, geriatric depression scale 15; SD, standard deviation; SMMSE, standardized mini mental state examination.

TABLE 2 Care recipient baseline demographic characteristics.

Care-recipient characteristics	Physical activity intervention group (n = 34)	Social control group (n = 42)	Usual-care control group (n = 15)	Total sample (n = 91)
Mean age, years (SD)	77.6 (9.0)	78.6 (7.9)	75.2 (10.2)	77.7 (8.7)
Female n (%)	9 (26.5)	14 (33.3)	2 (13.3)	25 (27.5)
Born in Australia n (%)	20 (58.8)	25 (59.5)	5 (33.3)	50 (55.0)
English as preferred language n (%)	28 (82.4)	35 (83.3)	12 (85.7)	75 (83.3)
Education level (highest)				
Primary n (%)	0	0	0	0
Secondary n (%)	13 (38.2)	23 (54.8)	8 (53.3)	44 (48.4)
Tertiary	18 (52.9)	13 (31.0)	6 (40.0)	37 (40.7)
Unknown n (%)	3 (8.8)	6 (14.3)	1 (6.7)	10 (11.0)
Mean SMMSE (SD)	23.2 (8.3)	20.8 (7.7)	23.7 (7.8)	22.2 (7.9)
SMMSE < 24 (%)	10 (31.3)	22 (56.4)	5 (33.3)	37 (43.0)
Mean GDS-15 score (SD)	4.8 (3.9)	5.1 (3.0)	4.0 (3.0)	4.8 (3.4)
Mean modified Barthel index (SD)	80.6 (24.5)	77.8 (24.4)	70.9 (26.3)	77.8 (24.7)
Mean human activity profile adjusted activity score (SD)	36.9 (21.1)	31.5 (20.1)	33.1 (20.23.1)	33.7 (20.9)
Health conditions of care-recipient				
Dementia n (%)	14 (42.4)	19 (45.2)	3 (21.4)	36 (40.5)
Cancer n (%)	7 (20.6)	11 (26.2)	6 (42.9)	24 (26.7)
Heart disease n (%)	10 (29.4)	9 (21.4)	6 (42.9)	25 (27.8)
Asthma/COPD n (%)	6 (17.6)	5 (12.2)	3 (21.4)	14 (15.7)
Osteoporosis n (%)	5 (14.7)	6 (15.0)	3 (21.4)	14 (15.9)
Diabetes (%)	2 (5.9)	16 (38.1)	3 (21.4)	21 (23.3)
Stroke or other neurological disorder n (%)	21 (61.8)	22 (52.4)	6 (40.0)	49 (53.8)
Arthritis or other physical disorder n (%)	29 (85.3)	39 (92.9)	9 (64.3)	77 (91.1)

Abbreviations: GDS-15, geriatric depression scale 15; SD, standard deviation; SMMSE, standardized mini mental state examination.

≥24) had significantly lower depressive scores than those caring for someone with cognitive impairment (SMMSE <24) compared with social-control and usual-care groups (p -value for interaction = 0.016, p value for interaction = 0.018, respectively) (Table 4).

4 | DISCUSSION

This RCT is the first to evaluate the impact of a PA intervention on depression for older caregivers, compared to social-control and usual-care conditions. In summary, while over 50% of caregivers in all three groups showed improvement in depressive symptoms, there were no significant differences between groups in either the primary outcome, that is, the proportion of people depressed or in reduction of depressive symptoms, or any secondary outcomes. However, subgroup analysis suggested that the PA intervention may be of benefit to a subset of caregivers that are supporting individuals without cognitive impairment.

Whiteford et al.³² estimated that 23% of cases of untreated depression remit within 3 months and 53% within 12 months. Remission might explain a substantial proportion of the recovery. The overall improvement could also be a placebo effect, as just being enrolled in a study and expecting improvement could explain the overall changes in depression across all groups. A placebo effect has been noted in previous depression studies, with a 35%–40% response to placebo being a consistent response rate across 25 years' of placebo controlled pharmaceutical trials.³³ While it could explain the improvement in the PA and social-control groups, it is unlikely to be a factor in the usual care group.

The usual care condition was not completely devoid of contact from researchers. All participants were contacted once a month to complete the measures relating to PA, health service use and any adverse events or changes to employment status and had three home visits for baseline, 6-month and 12-month data collection. These phone calls were brief but did give the caregiver participant an opportunity to talk to a researcher. The improvement in this group

TABLE 3 Effect of the intervention on outcomes at 6 months (n = 95).

Caregiver	Physical activity (n = 40)		Social control (n = 39)		Usual care control (n = 16)		Physical activity intervention versus usual-care control regression coefficient (95% CI), p-value
	Baseline mean (SD)	6 months mean (SD)	Baseline mean (SD)	6 months mean (SD)	Baseline mean (SD)	6 months mean (SD)	
	n = 40	n = 39	n = 16				
GDS-15 ≥ 5 (%)	40 (100)	39 (100)	16 (100)	18 (46.2)	6 (37.5)	1.51 (0.46, 4.94), 0.50	1.51 (0.46, 4.94), 0.50
Mean GDS-15 (SD)	7.8 (2.1)	8.3 (2.3)	8.1 (2.4)	5.0 (3.2)	4.6 (3.1)	-0.53 (-1.86, 0.81), 0.44	-0.19 (-1.96, 1.58), 0.83
Mean ZBI (SD)	41.3 (15.1)	37.5 (14.7)	35.8 (16.0)	38.1 (16.8)	29.9 (13.8)	-1.64 (-6.20, 2.92), 0.48	4.56 (-1.12, 10.24), 0.11
Mean HAPAAS (SD)	62.5 (16.8)	59.8 (16.4)	59.9 (12.6)	59.9 (15.3)	59.4 (18.0)	1.49 (-2.01, 4.99), 0.40	1.42 (-2.93, 5.76), 0.52
Care- recipient	n = 21	n = 30	n = 10				
Mean GDS-15 (SD)	4.8 (3.9)	5.1 (3.0)	4 (3.0)	4.5 (2.7)	4 (3.7)	-0.55 (-2.02, 0.92), 0.45	0.06 (-2.44, 2.56), 0.96
Mean HAPAAS (SD)	37.0 (21.1)	31.5 (20.1)	33.1 (23.1)	34.6 (22.9)	32.9 (21.7)	0.97 (-8.93, 10.87), 0.84	3.41 (-10.71, 17.55), 0.62
Median MBI (IQR)	91 (68.3-99.3)	85 (56.5, 93.5)	85 (64.8-98.0)	92 (61.2, 98.3)	81 (75.5, 91.5) 81.1 (14.4)	-4.00 (-15.58, 7.58), 0.50	-2.03 (-23.23, 19.18), 0.90

Abbreviations: GDS-15: geriatric depression scale-15 item ZBI: zarit burden interview HAP: human activity profile adjusted activity score MBI: modified barthel index: IQR: interquartile range.

TABLE 4 Sub-analysis of caregivers caring for care-recipients who have cognitive impairment (MMSE <24) compared to those who do not and corresponding Geriatric Depression Scores.

	Mean GDS score (95% CI)	
	MMSE <24 (n = 30)	MMSE \geq 24 (n = 65)
Usual care control	3.5 (1.3)	4.9 (3.5)
Social control group	5.0 (3.3)	5.1 (3.2)
Physical activity group	7.4 (2.5)	3.6 (2.7)
	Adjusted mean difference in GDS score at 6 months ^a (95% CI)	
	Physical activity group compared to usual care	Physical activity group compared to social control
MMSE <24	2.57 (-0.86, 6.00)	2.07 (-0.28, 4.42)
MMSE \geq 24	-1.07 (-3.07, 0.93)	-1.21 (-2.90, 0.47)
p value for interaction	0.042	0.028

Abbreviations: CI: confidence interval GDS: geriatric depression scale, MMSE: mini-mental state examination.

^aAdjusted for baseline GDS score.

could potentially be explained by the Hawthorne effect, that is, changes in outcomes due to being a participant in research³⁴ and the social benefit of these contacts.

While Otago-Plus is an individually tailored evidence-based PA program and provides the benefits of a personalized program prescribed by a physiotherapist,²⁶ caregivers themselves were not consulted in the development of the intervention, or in planning their PA prescription according to their exercise preferences. Co-designing PA interventions with older people may lead to the development of interventions that result in better satisfaction with the intervention, better adherence, increased levels and improved PA.³⁵ There were no changes to the caregivers' physical function and activity with our study which has been found previously³⁶ possibly due to the short duration of the intervention. Similarly, there were no improvements in the care-recipients' outcomes, due to the chronicity of their nominated health conditions that impact on physical function and mobility. We also were not able to measure the participants' adherence to the Otago-Plus program, except through self-report, so it is possible that poor adherence affected our results.

A different primary outcome such as self-efficacy, coping style or mastery may have provided an indication of whether other psychological benefits, aside from reduction of depressive symptoms, were achieved. Increased self-efficacy can be an outcome of completing PA^{37,38} and this may translate into improved coping mechanisms and ability to manage the demands of providing care.

We did have a novel finding from our sub-group analysis which suggested that the PA intervention might improve depressive symptoms more so in caregivers who were providing support for individuals who did not have significant cognitive impairment. Caring for someone with dementia is reported to be the most challenging

and burdensome compared to other conditions.³⁹ It is therefore likely to be more difficult for this group of caregivers to introduce a PA intervention into their already challenging daily care routines. Future studies should focus on caregivers who care for people without significant cognitive impairment to see whether this promising finding can be replicated.

This study had a number of limitations, primarily the failure to recruit the numbers required to meet our initial power calculation. The fact that it was so challenging to recruit caregivers to the study demonstrates the difficulty of getting caregivers involved in research, especially if they are providing the hours of care and experiencing the level of burden that the caregivers in this study reported—thus co-design would be an important methodological consideration in further research. Furthermore, a PA intervention, even one that is done at home and can be done with the person they care for may still be perceived as burdensome, adding to the care already being provided, and we had significant attrition of participants over the duration of the study. The variability of the care-recipient sample, in terms of their needs and the heterogeneity of their conditions were also limitations, given the small numbers.

In spite of these, strengths of our study included longitudinal follow-up, the use of a manualized and potentially replicable PA program and the inclusion of the social-control and usual-care comparison groups. We still were able to recruit almost 100 dyads into this RCT.

Results from this study reinforce our understanding that family caregivers provide a substantial contribution in supporting older care-recipients to remain living at home and experience high levels of burden. There is a need for further research to investigate other approaches to support longer term well-being for caregivers with depressive symptoms. Future studies should aim to recruit larger numbers of caregivers, targeting specific care-recipient groups, alternative outcome measures and incorporating co-design to further explore the benefits of PA and other potentially beneficial interventions.

AUTHOR CONTRIBUTIONS

David Ames, Kirsten J. Moore, Nicola T. Lautenschlager, Briony Dow, Elizabeth V. Cyarto, Melissa A. Russell, Kirsten J. Moore, Lynette Mackenzie and Terence Haines designed the study. Melissa A. Russell, Samantha M. Loi, Frances Batchelor and Steven M. Savvas conducted statistical analyses. Briony Dow, Sue Malta, Samantha M. Loi and Ellen Gaffey drafted the manuscript. All authors reviewed and provided feedback on the manuscript.

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CONFLICT OF INTEREST STATEMENT

The authors declare none.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Additional supporting information can be found online in the Supporting Information section at the end of this article.

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