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Research

Additional structured physical activity does not improve walking in older people (> 60 years) undergoing inpatient rehabilitation: a randomised trial

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KEY WORDS

Mobility limitation Rehabilitation Exercise therapy Hospitalisation Randomised controlled trial



ABSTRACT

Questions: Among older people receiving inpatient rehabilitation, does additional supervised physical activity lead to faster self-selected gait speed at discharge? Does additional supervised physical activity lead to better mobility, function and quality of life at discharge and 6 months following discharge? Design: Multi-centre, parallel-group, randomised controlled trial with concealed allocation, assessor blinding, and intention-to-treat analysis. Participants: Older people (age > 60 years) from two Australian hospitals undergoing rehabilitation to improve mobility. Intervention: Participants received multidisciplinary care, including physiotherapy. During hospital rehabilitation, the experimental group (n = 99) spent additional time daily performing physical activities that emphasised upright mobility tasks; the control group (n = 99) spent equal time participating in social activities. Outcome measures: Self-selected gait speed was the primary outcome at discharge and a secondary outcome at the 6-month follow-up. Timed Up and Go, De Morton Mobility Index, Functional Independence Measure and quality of life were secondary outcomes at discharge and tertiary outcomes at the 6-month follow-up. Results: The experimental group received a median of 20 additional minutes per day (IQR 15.0 to 22.5) of upright activities for a median of 16.5 days (IQR 10.0 to 25.0). Gait speed did not differ between groups at discharge. Mean gait speed was 0.51 m/s (SD 0.29) in the experimental group and 0.56 m/s (SD 0.28) in the control group (effect size -0.06 m/s, 95% CI -0.12 to 0.01, p = 0.096). No significant differences were detected in other secondary measures. Conclusion: While substantial gains in mobility were achieved by older people receiving inpatient rehabilitation, additional physical activity sessions did not lead to better walking outcomes at discharge or 6 months. Trial registration: ACTRN12613000884707. [Said CM. Morris ME, McGinley JL, Szoeke C, Workman B, Liew D, Hill KD, Woodward M, Wittwer JE, Churilov L, Danoudis M, Bernhardt J (2018) Additional structured physical activity does not improve walking in older people (> 60 years) undergoing inpatient rehabilitation: a randomised trial. Journal of Physiotherapy 64: 237-244]

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Introduction

Healthcare systems are being challenged globally by the ageing population. The hospitalisation rate of people aged > 85 years in the USA is more than five times greater than that of people aged < 65 years.¹ People aged > 65 years accounted for 49% of Australian hospital bed days in 2014 to 2015.² Rates of emergency admissions to hospitals in the UK have increased in this group.³ Some older people require inpatient rehabilitation after an acute hospital admission to enable them to return to their previous living

arrangements and lifestyle; however, mobility remains suboptimal for many older people at discharge.^{4–6} A systematic review found that the usual-pace gait speed in older people in subacute settings was 0.53 m/s (95% CI 0.44 to 0.62),⁶ which was well below mean speeds of 1.2 to 1.3 m/s in healthy older adults. Gait speed is associated with disability, institutionalisation, falls and mortality,⁷ and is predictive of community activity levels.⁸ Gait speed is responsive to changes in walking ability,⁹ and increases in gait speed are associated with improvements in overall health status.¹⁰ It has been suggested that gait speed is the 'sixth vital sign' for

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1836-9553/© 2018 Australian Physiotherapy Association. Published by Elsevier B.V. This is an open access article under the CC BY-NC-ND license (http://creativecommons. org/licenses/by-nc-nd/4.0/). older people.¹¹ It is therefore imperative to optimise gait speed during rehabilitation.

It is acknowledged that bed rest and inactivity in hospital are detrimental for mobility and function.¹² Low levels of physical activity in rehabilitation have been recorded;^{13–15} however, there are no evidence-based physical activity guidelines for older adults receiving inpatient rehabilitation. Increasing physical activity through structured interventions could lead to better outcomes in older adults. Existing evidence is conflicting. A systematic review by Peiris et al¹⁶ demonstrated that providing an additional average of 19 minutes of physiotherapy per day to hospitalised patients led to improved walking.¹⁶ The average age of participants in the review was 70 years, so the results may not be applicable to an older population. A more recent review, which was published after the present study commenced and was limited to subacute settings, found that providing additional after-hours or weekend rehabilitation services did not impact on walking speed.¹⁷ Both reviews included trials focused on specific conditions, such as stroke, and while both reviews included studies that provided additional rehabilitation or physiotherapy, the content and method of delivery of the additional services were variable. This multisite, randomised controlled trial was the logical next step following a promising pilot trial,¹⁸ which demonstrated the safety and feasibility of increasing physical activity in older people during rehabilitation.

Therefore, the research questions for this multicentre, parallelgroup, randomised controlled trial were:

- 1. Among older people receiving inpatient rehabilitation, does additional supervised physical activity lead to faster selfselected gait speed at discharge?
- 2. Does additional supervised physical activity lead to better mobility, function and quality of life at discharge and 6 months following discharge?

Method

Design

The study was a multicentre, parallel-group, randomised controlled trial with concealed allocation, intention-to-treat analysis, and blinding of investigators and assessors. It examined the effect of additional supervised physical activity in older people receiving in-hospital geriatric rehabilitation in the metropolitan area of Melbourne, Australia. At baseline, the mobility of participants was classified as non-ambulant or ambulant, as summarised in Table 1. Randomisation was stratified by site and mobility classification. After baseline data collection, participants were individually randomised to 'enhanced physical activity' (experimental group) or 'usual care plus matched face-to-face contact time' (control group), according to a computer-generated randomisation procedure performed by a third party. Group assignment was only available to intervention staff and project managers (JW, MD). Outcomes were measured at discharge and 6 months later. The trial was overseen by a management committee and an independent data safety monitoring committee. The full protocol has been published.¹⁹

Participants

All people admitted to four participating geriatric rehabilitation wards at two hospitals were screened. People admitted to these units are typically medically stable, but have complex health conditions requiring multidisciplinary management or rehabilitation to maximise function. Eligible patients were aged > 60 years and had a goal to 'improve mobility or walking', which was determined by admission referral or the treating therapist. Participants were excluded if: there were medical restrictions limiting mobilisation, goals were non-weight bearing, they were enrolled in another randomised trial, or the primary reason for admission was carer training or residential care placement. Informed consent was obtained from the participant or 'responsible person' within 48 hours of admission, with interpreters utilised as necessary.

Intervention

Both groups received usual care provided by a multidisciplinary team throughout their inpatient rehabilitation. This included input from physiotherapy, occupational therapy, nursing and medical staff, with additional input from other allied health staff as indicated. Therapy was individualised and addressed identified rehabilitation goals, which generally focused on maximising functional independence to facilitate hospital discharge. Typically, participants received one or two sessions of physiotherapy a day on weekdays. There was a limited physiotherapy service on weekends at both sites, with priority given to patients requiring assessments or treatment to facilitate discharge. To monitor usual care activities, usual care physiotherapy staff recorded, in 5-minute

Table 1

Functional classification of participants and summary of activities for experimental group.

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Level	Function	Intervention	
1	Patient is unable to transfer out of bed without maximum assistance (two persons or a hoist) and has poor static and dynamic sitting balance (unable to sit independently).	Bed exercise program (including lower limb, upper limb and abdominal strength and bed mobility) and sitting balance exercises.	
2	Patient can transfer out of bed with assistance from one person, has independent sitting balance, but is unable to stand independently. Requires moderate assistance from two people to walk.	Sitting exercise program including targeted lower limb strengthening exercises. Sit to stand exercises, standing balance exercises, stepping/marching on the spot as able (using rails/gait aids for safety as indicated). Activities from the previous level may be included if specifically indicated. For example, if the participant is unable to perform full range movement against the effects of gravity, specific lower limb muscle strengthening exercises may be performed on the bed.	
3	Patient can walk with minimal assistance of one person.	Walking exercises, sit to stand exercises, standing balance exercises, and step up exercises. Targeted lower limb strength exercises (where possible closed chain or functional strengthening exercises).	
4	Supervision only or independence with ambulation. Requires minimal assistance or supervision on stairs.	Stairs exercises, walking exercises (including outdoor mobility), step up exercises, standing balance exercises. Targeted lower limb strength exercises as indicated (where possible closed chain or functional strengthening exercises)	

increments, time spent performing activities in therapy sessions for all participants.

Experimental group

The main aim of the experimental intervention program was to increase the amount of time that participants spent performing upright activities, such as standing or walking. The intervention was delivered daily (including weekends) throughout the inpatient stay. On weekdays, the target was to achieve an additional 19 minutes of upright activity per day,¹⁸ delivered during one to two sessions in the late afternoon and early evening. On weekends, the target was to achieve an additional 31 minutes over two sessions per day.¹⁵ Intervention protocol guides were specified for participants according to their functional level, which was reviewed at each session (summary provided in Table 1; full details available from authors). The program consisted of multimodal exercise (practice of functional tasks including balance and gait training, strength training and aerobic training) and was individually tailored. Sessions were provided by a physiotherapist or physiotherapy assistant not otherwise involved in care provision. Time spent performing activities were recorded in 5-minute increments.

Control group

To compensate for the additional social interaction received by experimental group participants, control group participants undertook additional social activities with minimal impact on mobility, including card or board games, conversation, reading or upper limb exercises. Sessions were conducted seated in a chair or bed and provided by a physiotherapist or physiotherapy assistant. The target was to match the experimental group's face-to-face time. Time involved in these sessions was recorded.

Outcome measures

All outcomes were obtained by a trained assessor who was blinded to group allocation. Full details on outcome measures have been previously published¹⁹ and are summarised below.

Primary outcome

The primary outcome measure was self-selected gait speed on hospital discharge, which was assessed by the 6-m walk test²⁰ with the usual indoor gait aid. Gait speed was selected as it is clinically important, valid and responsive to change.^{7–10} Participants unable to complete the test were given a score of 0 m/s.

Secondary outcomes

Gait speed was measured 6 months after discharge. Other secondary outcomes at discharge included additional measures of mobility, function, health-related quality of life, and rehabilitation length of stay. Length of stay was not registered as an outcome on the trial registry, although it was identified as a secondary outcome in the published protocol.¹⁹ Additional mobility measures were the Timed Up and Go test^{21,22} and the De Morton Mobility Index.^{23–25} The Timed Up and Go test times performance as the person stands from a chair, walks 3 m, turns around, returns to the chair and sits down. The De Morton Mobility Index assesses a range of mobility tasks such as getting in and out of bed, standing from a chair, and walking; it is scored using a 100-point Rasch analysed scale.^{23–25} Function was measured using the Functional Independence Measure.²⁶ Health-related quality of life was assessed using the EuroQol health questionnaire and EuroQol Visual analogue scale.²⁷

Tertiary outcomes

Tertiary outcomes of mobility, function and quality of life were obtained 6 months after discharge using the Timed Up and Go,^{21,22} De Morton Mobility Index,^{23–25} Functional Independence Measure,²⁶ EuroQol health questionnaire, and EuroQol Visual analogue scale.²⁷

Data on mortality, unplanned re-admissions to an acute service, and falls²⁸ were monitored throughout the study, as described previously.¹⁹

Schedule of assessments

Baseline assessment was completed within 48 hours of admission. In addition to primary and secondary outcome measures, demographic and clinical data were obtained, including: age, gender, height, weight, acute length of stay, cognition using the Mini Mental State Examination,²⁹ frailty using the modified Fried Frailty Index,^{30,31} comorbidities using the Charlson Comorbidity Index,³² depression via the Geriatric Depression Scale,³³ medications, self/carer reported falls in the last 12 months, and social situation.

Participants were discharged from hospital once the identified goals were achieved or the treating team decided that the participant was unlikely to benefit from further rehabilitation. Discharge dates were determined by the usual care staff, who were blinded to group assignment; intervention staff had no input into discharge decisions. Completion date of residential care paperwork was used in lieu of actual discharge date for participants discharged to residential care. Discharge assessment was completed in hospital within 48 hours of discharge. Self-selected gait speed (primary outcome) was the primary endpoint. In addition to primary and secondary outcome assessments, discharge destination and service referrals were collected. The final assessment was conducted 6 months after discharge at the participant's residence.

Blinding, contamination and monitoring

Intervention staff could not be blinded and were not involved in other aspects of care. Assessments were performed by assessors blinded to group allocation, and this blinding was monitored. Assessors were not involved in other aspects of care. With the exception of project managers (JW, MD), investigators were blinded. To minimise contamination, usual care staff were not informed of specific study aims or group assignment. Intervention sessions were delivered outside routine therapy times, minimising the risk of inadvertently unblinding usual care physiotherapy staff and blinding was monitored in this group. It was unfeasible to monitor blinding across all usual care staff due to the large number of staff involved; however, pilot data indicated that usual care staff across all disciplines remained blind to group allocation.¹⁸

Intervention activity was monitored throughout the study, and feedback provided to intervention therapists by the project manager to ensure delivery of intervention 'dosage'. Participants in both groups had activity levels monitored for up to 5 days using a SenseWear armband[®].^{34–36} Data were processed using its commercial software^a. Physical activity time was obtained, with the threshold set at 1.5 metabolic equivalents to capture light-intensity activity.³⁷ For data to be included the device had to be worn for a minimum of 3 days and for at least 85% of each 24-hour period.

Data analysis

Sample size estimation was based on the experimental group achieving an increase in gait speed of at least 0.10 m/s,^{9,10} compared with the control group (estimated mean gait speed 0.46 m/s, SD 0.18).⁴ This represents a substantial meaningful change in gait speed.⁹ With a two-tailed significance threshold alpha of 0.05 and power to yield a statistically significant result set at 90%, a sample size of 69 participants in each group was required. To account for 14% of participants being unable to complete the walk test on discharge⁴ and additional loss to follow-up,¹⁸ a sample size of 198 participants was targeted.³⁸

The full statistical analysis plan is provided as Appendix 1 on the eAddenda. Study data were collected and managed using REDCap electronic data capture tools.³⁹ REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies. Analysis was conducted using commercial statistical software^b. The primary analysis was conducted on an intention-to-treat basis using data from all randomised participants. Primary outcome values that were missing due to participants' death were imputed as 0. An independent adjudication panel, blinded to group assignment, reviewed records for participants who did not complete the discharge assessment to determine whether the participant was capable of completing a 6-m walk test at discharge. If the person was judged as unable to complete the test, the missing value was imputed as 0 m/s. If the person was judged as able to complete the test, the baseline measure was carried forward. It was assumed that the remaining missing data were missing at random, and a sensitivity analysis was conducted that considered a range of plausible alternative assumptions.⁴⁰

Differences in primary, secondary and tertiary endpoints between the two arms of the study were tested independently at the 0.05 level of significance. No formal adjustments were undertaken to constrain the overall Type I error associated with the secondary and tertiary analyses. Their purpose was to supplement evidence from the confirmatory primary analysis to help fully characterise the treatment effect and results from the secondary and tertiary analyses were interpreted accordingly.

Primary outcome

Between-group differences in the primary outcome measure, self-selected gait speed on discharge, were assessed using a linear regression model with robust standard errors estimation using the treatment group as an independent variable, discharge gait speed as the dependent variable, and baseline gait speed as a treatment covariate for adjustment purposes. In addition, as outlined in the statistical analysis plan (Appendix 1), subgroup analysis was undertaken for age (60 to < 75, 75 to < 85, or \geq 85 years), cognition (Mini Mental State Examination \geq 27 or < 27), baseline mobility (non-ambulant or ambulant), primary diagnosis (musculoskeletal, cardiopulmonary, neurological, or restorative care), comorbidities (Charlson Comorbidity Index < 5 or \geq 5), frailty (not frail < 3, frail \geq 3) and study site (Site 1 or Site 2). While the study was not powered for subgroup analysis, this allowed exploration of characteristics that may have impacted on the effectiveness of the intervention.

Secondary and tertiary outcomes

Between-group differences in gait speed 6 months after discharge, other secondary outcome measures at discharge, and tertiary outcomes at 6 months were assessed using a linear regression model with robust standard errors estimation, with the treatment group as an independent variable, the value of the specific outcome at discharge or 6 months as the dependent variable, and the value of the same outcome at baseline as a treatment covariate for adjustment purposes. The robustness of all analyses were further investigated using median regression.



Figure 1. Design and flow of participants through the trial.

Results

Flow of participants through the study

Participants were recruited between 28 January 2014 and 14 April 2015. Trial flow is presented in Figure 1 and baseline characteristics in Table 2. Differences in admission diagnosis were noted, with larger proportions of participants with musculoskele-tal conditions in the control group and restorative care in the experimental group. Groups were comparable on other baseline variables.

Compliance with study protocol

Details of the amount of physical activity undertaken in the usual care and experimental sessions are presented in Table 3 on the eAddenda. Participation in intervention sessions was high, with 82% of intended sessions delivered to the experimental group and 89% of intended sessions delivered to the control group. During intervention sessions, participants in the experimental group performed a median of 20 minutes of upright physical activities (including sit to stand practice, standing balance, walking and stairs). During usual care physiotherapy sessions, the experimental group spent around 2.5 minutes less performing upright activities compared with the control group, although this was not significant. SenseWear data were not available for all participants; the device was contraindicated or not tolerated by some participants. Data showed substantial variability between participants, but negligible difference between groups (Table 3 on the eAddenda).

Table 2

Baseline characteristics of the participants.

Trial quality data confirmed usual care physical therapy staff and outcome assessors remained blinded to group assignment (Table 4 on the eAddenda).

Effect of the intervention

The primary outcome analysis showed no significant betweengroup differences in gait speed at discharge, as shown in Table 5. Mean gait speed was 0.51 m/s (SD 0.29) in the experimental group and 0.56 m/s (SD 0.28) in the control group (effect size -0.06 m/s, 95% CI -0.12 to 0.01, p = 0.096). Gait aid usage during the discharge assessment was similar in both groups. For further details about gait aid use, see Table 6 on the eAddenda.

The planned subgroup analyses (Figure 2, with further detail available in Table 7 on the eAddenda) revealed neither significant treatment effect nor significant treatment by subgroup interaction for age, baseline mobility, primary diagnosis, Charlson Comorbidity Index classification, or frailty on the primary outcome. There was a significant treatment by subgroup interaction for cognition (p = 0.020); outcomes favoured the control group for participants classified as cognitively impaired. While there was no significant treatment by study site interaction, outcomes favoured the control group for Site 1 (p = 0.029). Sensitivity analysis for the missingness at random assumption was conducted as outlined in the statistical analysis plan and confirmed the findings of the main analysis.

Secondary outcomes at discharge are presented in Table 5 and confirm no between-group differences in mobility (Timed Up and Go, De Morton Mobility Index), function (Functional Independence Measure) or quality of life (EuroQol health questionnaire, EuroQol visual analogue scale) at discharge. There was no between-group

Characteristic	Exp	Con
	(n=99)	(n=99)
Age (yr), median (IQR)	81 (77 to 88)	81 (77 to 87)
Gender, n male (%)	40 (40)	45 (45)
Body mass index (kg/m^2) , median (IQR)	24.3 (20.9 to 29.2)	25.0 (22.5 to 28.9)
Social situation before admission, n (%)		
private residence alone	33 (33)	33 (33)
private residence with others	55 (56)	58 (59)
residential care	6 (6)	5 (5)
other	5 (5)	3 (3)
Location admitted to rehabilitation from, n (%)		
acute hospital	96 (97)	95 (96)
home	1 (1)	3 (3)
other	2 (2)	1 (1)
Primary admission diagnosis, n (%)		
musculoskeletal	29 (29)	45 (46)
cardiopulmonary	9 (9)	9 (9)
neurological	11 (11)	18 (18)
restorative care ^a	50 (51)	27 (27)
Acute length of stay (d) , median (IQR)	13 (9 to 20)	11 (8 to 15)
Charlson Comorbidity Index, median (IOR)	2 (1 to 3)	2(1 to 4)
Medications (n), median (IQR)	5 (4 to 6)	5 (4 to 6)
Taking \geq 4 medications, n (%)	78 (79)	78 (79)
Frailty Index ^b	2 (2 to 3)	2(1 to 3)
Falls in previous 12 months, n yes (%)	20 (20)	14 (14)
Non-ambulant:ambulant	25:74	24:75
Able to do 6-m walk test, n ves (%)	64 (65)	66 (67)
Gait aid for 6-m walk test, n (%)		
none/single-point stick	7 (11)	9 (13)
2 or 4-wheel frame	51 (80)	48 (73)
other	6 (9)	9 (14)
Gait speed (m/s) , median $(IOR)^{c}$	0.30 (0.00 to 0.52)	0.30 (0.00 to 0.54)
Able to do TUG test, n ves (%)	58 (59)	62 (63)
TUG test (s), median (IOR)	24 (19 to 37)	28 (22 to 40)
DEMMI $(0 \text{ to } 100)$, mean (SD)	36(24 to 48)	36(27 to 44)
TOTAL FIM (18 to 126), mean (SD)	77 (62 to 92)	80 (65 to 94)
MMSE (0 to 30), median (IQR)	24 (20 to 27)	25 (21 to 28)
Geriatric Depression Scale (0 to 30), median (IQR)	5 (3 to 7)	4 (3 to 7)

Con=control group, Exp=experimental group, DEMMI=De Morton Mobility Index, FIM=Functional Independence Measure, MMSE=Mini Mental State Examination, TUG=Timed Up and Go test.

^a Restorative care includes reconditioning after surgery or medical illness.

^b n=94 in each group.

^c A score of 0 m/s was imputed for participants unable to complete 6-m walk test.

Table 5

Mean (SD) of groups, and mean (95% CI) difference^a between groups for outcomes at discharge and 6 months after discharge.

Month 6 Outcome Discharge Groups Effect size p-value Groups (95% CI) Exp Con Exp Con (n = 79)(n = 88)(n = 91)(n = 78)0.51 0.56 0.58 (0.35) Gait speed (m/s), mean (SD) -0.06 0.096 0.65 (0.32) (0.29)(0.28)(-0.12 to 0.01) 71 73 Able to complete 6 m walk, n 82 85 (93) (93) (90)(94)ves (%) TUG score (s), mean (SD) 24.0 ^b -0.5 21.8 26.0 0.724 28.2 (12.6)(20.1)(30.6)(-3.5 to 2.4) (14.1)Able to do TUG, n ves (%) 77 85 67 71 (89)(92)(85)(91)DEMMI (0 to 100), mean (SD) 496 517 -11 0 479 501 544 (17.0)(15.4)(-4.3 to 2.0) (20.2)(19.0)(n = 85)(n = 89)(n = 78)(n = 77)TOTAL FIM (18 to 126), mean 95.7 99.0 -1.5 0.521 96.7 103.0 (SD) (22.8)(19.5)(-5.4, 2.5) (26.8)(19.7)(n = 79)(n=94) (n=92) (n=79) EQ5D (-0.59 to 1.00), mean (SD) 0.60 0.62 -0.03 0.499 0.56 0.56 (0.29)(0.28)(-0.11 to 0.05) (0.34)(0.36) (n = 81)(n = 88)(n = 73)(n = 78)EQ-VAS (0 to 100), mean (SD) 64 65 -2 0.866 60 66 (20)(18) (-7 to 8) (20)(19) (n=79) (n=88) (n = 69)(n = 77)Rehabilitation length of stay 20.2 19.5 $OR = 0.94^{d}$ 0.693

(d), mean (SD)(11.4)(11.2)(0.68 to 1.3) 0.622 0.867 Living situation, n (%) 23 (23) 22 (22) 18 (18) 17 (17) home alone home with someone 44(44)49 (49) 44 (44) 44 (44) 21 (21) residential care 16(16)13(13)21 (21) acute hospital 6(6) 3(3) 0(0)0(0)died 1(1)1(1)7(7)12(12)other 8 (8) 11(11)1(1)1(1)unknown 4(4)4(4)4(4)1(1)

Con = control group, Exp = experimental group, DEMMI = De Morton Mobility Index, EQ5D = EuroQol, EQ-VAS EuroQol visual analogue scale, FIM = Functional Independence Measure, MMSE = Mini Mental State Examination, TUG = Timed Up and Go.

Shaded cells = primary outcome.

^a Effect sizes are mean between-group differences adjusted for the corresponding baseline score (except where noted).

^b Includes imputed values for participants unable to complete discharge assessment.

^c Median regression not significant.

^d The effect size for the length of stay outcome is a generalised odds ratio, which is interpreted as the odds of a randomly selected experimental group participant having a shorter length of stay than a randomly selected control participant.

^e Data reported for n = 99 for experimental and control groups. Fisher exact test used to test for differences between groups.

difference in gait speed 6 months after discharge. At 6 months, the control group scored significantly higher on the EuroQol Visual analogue scale (p = 0.035); however, differences were not significant when median regression models were used. No other between-group differences were detected in tertiary outcomes at 6 months.

No between-group differences in mortality, acute hospital readmission or falls were detected in either intervention or follow-up phases (Tables 8 and 9 on the eAddenda).

Discussion

A structured, supervised physical activity program, which provided an additional median of 20 minutes of upright mobility per day, did not lead to improved gait speed at hospital discharge in older people receiving a multidisciplinary inpatient rehabilitation program. Furthermore, secondary measures of mobility, function and quality of life did not differ at discharge or 6 months, and length of stay did not differ between groups. Both groups showed clinically meaningful improvements in mobility and function during a comparatively brief (median 16 to 18 days) inpatient stay, which likely reflected a combination of usual care and natural recovery. For example, median gait speed improved at least 0.22 m/s in both groups, representing a substantial change in gait speed.⁹ However, additional supervised physical activity did not confer additional benefit. The trial was conducted in Australia; however, results are arguably generalisable to other countries with similar inpatient programs for frail older people.

Effect size^a

-0.09

(-0.18 to 0.01)

1.9

(-3.1 to 6.8)

-34

(-8.8 to 2.1)

-4.3

(-10.3 to 1.6)

-0.04

(-0.14 to 0.07)

-7

(-13 to 0)

(95% CI)

n-value

0.065

0.452

0 2 2 2

0.152

0.483

0.035

Subgroup analysis results must be interpreted cautiously given the risk of Type 1 error; however, the significant treatment by subgroup interaction for cognition warrants consideration. Treatment outcomes favoured the control group in participants with cognitive impairment; thus, the possibility that increased physical activity may negatively impact on walking outcomes in people with cognitive impairment must be contemplated. The alternate possibility that the 'social interaction' provided to the control group had a favourable impact on outcomes, particularly in people with cognitive impairment, should also be considered. Given the increasing prevalence of cognitive impairment in the ageing community, further exploration of interventions specifically tailored to maximise rehabilitation outcomes in this group is warranted.

Findings were supported by the robust trial methodology. Withdrawals were low (2%) and there were minimal missing primary outcome data. Over 90% of admitted patients were eligible for recruitment, and baseline characteristics confirm that this was an older group with a range of underlying medical conditions and comorbidities including cognitive impairment. Acute hospital length of stay for both groups was substantially longer than the average public hospital length of stay of 5.5 days, ⁴¹ which again reflects complexity. This study controlled for the additional social interaction associated with



Figure 2. Subgroup analysis for primary outcome: gait speed (m/s) at discharge. Significant treatment by subgroup interaction for cognition (p = 0.020). Con = control group, Exp = Experimental group, MMSE = Mini Mental Status Examination.

intervention

delivery. The intervention protocol emphasised upright mobility tasks and allowed for individual tailoring. The 'dosage' of the physical activity intervention was delivered as intended and efforts to minimise contamination appear to have been successful. However, SenseWear data, which measured physical activity during therapy and non-therapy times, did not differ between groups. This may indicate that physical activity was modified outside therapy times. While other clinical staff (eg, nursing) may have modified usual care delivery, pilot data indicated that staff across all disciplines remained blind to group assignment.¹⁸ Furthermore, given day-to-day variation in nursing workload and workload pressures in a busy hospital, it is unlikely that there were systematic changes in care delivered to trial participants. Nonetheless, it is possible that participants themselves may have modified activity outside structured therapy times. SenseWear data were only collected for a short period of time, typically near the beginning of rehabilitation, thus data may not reflect activity patterns later in the rehabilitation period.

A limitation of this study is that exercise intensity was not measured. Given the high level of disability in many participants and evidence that physical activity time was low, the focus in this study was on increasing time. The low rate of consent in people screened and eligible was a further limitation. The main reason for not gaining consent was inability to do so within 48 hours, largely due to inability of recruitment staff to contact participants in a timely manner. People with cognitive impairment or limited English may have been under-represented due to the additional logistics for these groups. A number of people declined enrolment; this group may be less willing to engage in additional rehabilitation. Alternate study designs, such as cluster randomisation, may overcome these issues. Gait speed may have been influenced by gait aid use,⁴² however usage was similar between groups and thus unlikely to impact overall findings. Despite randomisation, differences in the proportions of participants with musculoskeletal conditions and restorative care were observed, which may have influenced the results. However, these classifications represent a number of underlying primary diagnoses, which individually are unlikely to differ substantially between groups. Furthermore, primary diagnosis is only one component of the medical history for this complex cohort. Nonetheless, strategies to ensure greater similarity in admission diagnosis, such as stratification, should be considered in future.

Few adequately powered randomised trials have examined mobility outcomes in this specific population and setting. A recent randomised trial found that feedback via accelerometers on daily walking time increased time spent walking in this population, but this did not translate to improvements in gait speed or mobility at study exit (hospital discharge or 4 weeks after enrolment).⁴³ In contrast, another recent randomised trial⁴⁴ found an additional six 1-hour circuit classes over 2 weeks improved standing balance at 2 weeks and mobility (measured using the Short Physical Performance Battery) at 2 weeks and 3 months in older people (mean age > 81 years) undergoing inpatient rehabilitation. While there are methodological differences between these studies, the conflicting results highlight the importance of identifying critical components of interventions and emphasise the importance of further research into this complex patient group to ensure rehabilitation programs are evidence based and match the needs of older people.

The optimum 'dosage' of physical activity to maximise mobility outcomes for older patients undergoing hospital-based rehabilitation remains unclear. Given the prevalence of cognitive impairment in elderly people, the relationship between cognitive impairment, physical activity, social interaction and rehabilitation outcomes warrants further exploration. Future research should also consider methodologies that maximise inclusion of eligible potential participants.

What was already known on this topic: Some older people require inpatient rehabilitation after an acute hospital admission; however, mobility remains suboptimal for many of them at discharge. Inactivity in hospital is detrimental for mobility and function, yet low levels of physical activity in rehabilitation have been recorded.

What this study adds: Among older people receiving inpatient rehabilitation, additional supervised physical activity did not lead to faster self-selected gait speed at discharge or improvements in other outcomes of rehabilitation.

Footnotes: ^a SenseWear Version 8.0 software, SWA, BodyMedia, Pittsburgh, USA. ^b Stata v13IC, StataCorp, College Stations, USA

eAddenda: Appendix 1, Tables 3, 4, 6, 7, 8, and 9 can be found online at https://doi.org/10.1016/j.jphys.2018.08.006.

Ethics approval: The La Trobe University, Austin Health, and Monash Health Human Ethics Committees approved this study. The trial was also registered with The University of Melbourne (Ethics ID 1340834) and Curtin University (HR 25/2014). All participants or the 'person responsible' gave written informed consent before data collection began.

Competing interest: Nil.

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