Additional exercise does not change hospital or patient outcomes in older medical patients: a controlled clinical trial

Natalie A de Morton[1,2], Jennifer L Keating[1], David J Berlowitz[2], Bruce Jackson[3] and Wen K Lim[2]

[1]Monash University [2]Northern Health, Victoria [3]Dandenong Hospital Australia

Question: What are the effects of additional exercise on hospital and patient outcomes for acutely-hospitalised older medical patients? **Design**: Controlled clinical trial. **Participants**: 236 patients aged 65 or older admitted to an acute care hospital with a medical illness between October 2002 and July 2003. **Intervention**: The experimental group received usual care plus an individually tailored exercise program administered twice daily from hospital admission to discharge. The control group received usual care only. **Outcome measures**: The primary outcome was discharge destination. Secondary outcomes were measures of activity limitation (Barthel Index, Timed Up and Go, Functional Ambulation Classification), length of stay, and adverse events. **Results**: There was no significant effect of the additional exercise program on any outcome. There were no significant differences between groups for the proportion of the patients discharged to home (RR 0.99, 95% CI 0.86 to 1.14) or inpatient rehabilitation (RR 0.76, 95% CI 0.30 to 1.51) or for measures of activity limitation at hospital discharge. A one day difference in length of stay was identified between groups but this difference was not significant (p = 0.45). There were no significant differences between groups for adverse events: 28-day readmission (RR 1.10, 95% CI 0.65 to 1.86), patient mortality (RR 1.15, 95% CI 0.16 to 8.0), intensive care admission (RR 0.16, 95% CI 0.01 to 3.13) and falls (RR 0.69, 95% CI 0.17 to 2.81). **Conclusion**: Additional physiotherapy intervention during hospitalisation did not significantly improve hospital or patient outcomes. **[de Morton NA, Keating JL, Berlowitz DJ, Jackson B, Lim WK (2007) Additional exercise does not change hospital or patient outcomes in older medical patients: a controlled clinical trial. Australian Journal of Physiotherapy 53: 105–111]**

Key words: Hospitalization, Exercise, Physiotherapy, Physical Fitness, Aged

Introduction

Observational studies from the 1980s and early 1990s consistently reported a high incidence (25–60%) of decline in function for hospitalised older patients (Gillick et al 1982, Warshaw et al 1982, Hirsch et al 1990, Inouye et al 1993). Decreases in strength, cardiovascular fitness, and balance were reported to occur within the first few days of inactivity during hospitalisation (Lazarus et al 1991). Patients performed a limited amount of physical activity during hospitalisation (Lazarus et al 1991) and deterioration was thought to be a consequence of hospitalisation rather than the medical illness (Gillick et al 1982, Creditor 1993, Inouye et al 1993).

There have since been a number of important changes in hospital conditions for acutely ill medical patients. Early active physiotherapy has become a more consistent feature of care and discharge occurs over increasingly shorter time periods. It is possible that the extent to which deconditioning can be ameliorated and function can be enhanced might be influenced by the amount of exercise prescribed for medical inpatients. However, very few studies have investigated the effects of additional exercise in this patient population. Only one published randomised controlled trial has investigated the effects of exercise for acutely hospitalised older adults (Siebens et al 2000). In this trial, the experimental group exercised during hospitalisation and for one month following discharge and achieved significantly better mobility than the control group. In Australia, two trials have been conducted that compared intervention outcomes with historical control data. In one trial, an early walking program was initiated (n = 313) in a geriatric unit (Kurrle 2001). The number of patients discharged to rehabilitation was reduced from 154 (during the six month pre-implementation period) to 16 during the six month post-intervention period. This resulted in six rehabilitation beds being closed and savings to the hospital of $192 000. In 2002, a trial of a functional maintenance program in another Australian acute hospital, found similar effects (Berney et al 2003). These data, reported only in abstracts, indicate that the effects of early mobilisation are likely to be visible and quantifiable if tested in an Australian acute hospital setting.

In this trial, we sought to evaluate the effects of additional exercise for acutely-hospitalised older medical patients. The research question was:

1. What are the effects of additional exercise on patient and hospital outcomes?

The primary hypothesis was that exercise intervention for hospitalised acute general medical patients would reduce the requirements for inpatient rehabilitation. The secondary hypothesis was that the intervention would improve hospital outcomes and measures of patient activity limitation at acute hospital discharge. In addition, in this trial, we sought to identify difficulties and likely benefits associated with conducting a larger trial.

Method

Design: This controlled trial was conducted in a 225-bed public hospital that offers acute, secondary, and some tertiary services. Patients admitted with a general medical condition were allocated to one of two medical wards, depending on the availability of beds, by an allocating officer who was unaware that the trial was being conducted. Before the trial began, a coin toss had randomly allocated the experimental intervention to one of the wards. The two wards were adjacent and identical in size, shape, room configuration, and furnishings. A review of the two wards during the preceding 12 month period (1/7/01 to 30/6/02) indicated that there were no significant or important differences between them for patient gender, age, length of stay or discharge destination.

Participant recruitment occurred within 48 hours of ward admission. Participants were identified from a daily (weekdays) medical ward list. The project physiotherapist determined eligibility on both wards which meant that the recruiter was not blinded to group allocation. All eligible patients were invited to participate in the trial. Patients were informed that they would be assigned randomly to one of two groups but were not told which group received the experimental intervention, ie, they were blinded to group allocation. Since all patients in one ward were in the experimental group and all patients in the other ward were in the control group, contamination was limited because patients would not observe other patients receiving more or different therapy.

The project physiotherapist designed and prescribed an additional exercise program for each participant in the experimental group. A multidisciplinary team that did not include staff involved in the trial made discharge planning decisions.

Baseline measurements included data relating to patient age, gender, place of residence, gait aid use prior to hospital admission, Charlson co-morbidity score (Charlson et al 1987) APACHE 11 severity of illness score (Knaus et al 1985), and measures of activity limitation (see outcome measures). The project physiotherapist performed non-blinded admission and discharge assessments. Admission measurements occurred within 48 hours of medical ward admission while discharge measurements occurred within 48 hours of discharge.

One month or more after hospital discharge, participants' clinical notes were searched to identify those who were readmitted during the 28 day period following discharge and also to extract information relating to each patient's primary medical illness and adverse events during hospitalisation. Length of stay data were gathered by staff blinded to group allocation.

Data were also extracted from clinical notes to enable calculation of APACHE 11 and Charlson co-morbidity scores. The APACHE 11 is a severity of illness scale with a score range from 0 to 71, where higher scores represent increasing severity of illness during the first 24 hours of hospital admission. The Charlson Index classifies comorbid conditions according to risk of mortality. One year mortality rates in a medical population have been reported to be 12%, 26%, 52% and 85% for Charlson scores of 0, 1–2, 3–4, and greater than 5 respectively (Charlson et al 1987).

The hospital ethics committee granted approval to conduct the study. Approval to analyse trial data was obtained from Monash University Ethics Committee. Informed consent was gained from participants before data was collected.

Participants: Patients were eligible for inclusion if they had a general medical condition, were aged 65 or older, were admitted to either of the two medical wards, and were assessed within 48 hours of admission. Participants were excluded if they were admitted to hospital from a nursing home, were assessed to need nursing home level of care or palliative care, had suffered a stroke or a condition for which mobilisation was contraindicated (eg, deep vein thrombosis or fracture), were too medically unwell to ambulate or exercise, or were readmitted having previously participated in the study.

Intervention: The control group received usual care while the experimental group received usual care and an additional exercise program. Usual care included daily medical assessment, 24 hour nursing assistance, and allied health service on referral from medical, nursing or other allied health staff. Four teams delivered general medical care and were not ward specific whereas nursing staff were ward specific.

The additional exercise program was designed by a physiotherapist and consisted of exercises for the upper limb, lower limb, and trunk. It included four exercise levels (Level 1: Bed exercise program, Level 2: Sitting exercise program, Level 3: Standing exercise program, and Level 4: Stairs exercise program). The project physiotherapist (with four years of clinical experience) prescribed the program level and individually tailored the exercises to safely challenge each patient in the experimental group. The additional exercise program was supervised twice daily, five days per week by a certified allied health assistant beginning on the day of recruitment. Approximately 20 to 30 minutes were allocated for each exercise session. Patients with reduced exercise tolerance exercised more frequently for shorter periods. Gravity, body weight, and light weights were used for resistance whenever possible. Exercise resistance was increased when patients could perform 10 repetitions. Patients were also encouraged to increase exercise repetitions and their walking distances as tolerated.

Outcome measures: The primary outcome measure for this study was discharge destination. Patients who were discharged back to their preadmission residence were considered to have returned home. Secondary outcomes were measures of activity limitation on the Barthel Index (Mahoney and Barthel 1965), Timed Up and Go (Podsiadlo and Richardson 1991), and the Functional Ambulation Classification (Holden et al 1986). The Barthel Index and Timed Up and Go were selected due to their frequent clinical use in this patient population, while the Functional Ambulation Classification was selected to provide a measure of walking ability over a short distance and to assess people who were unable to perform the Timed Up and Go.

The Barthel Index measures level of patient independence in 10 activities of daily living: feeding, transfers, personal hygiene, toilet transfers, bathing, walking, stairs, dressing, and bladder and bowel continence. The Barthel Index is scored out of a maximum possible score of 100. Wherever possible it was scored using patient response when asked each item on the scale. When this was not possible or there were concerns about the cognitive status of the patient,

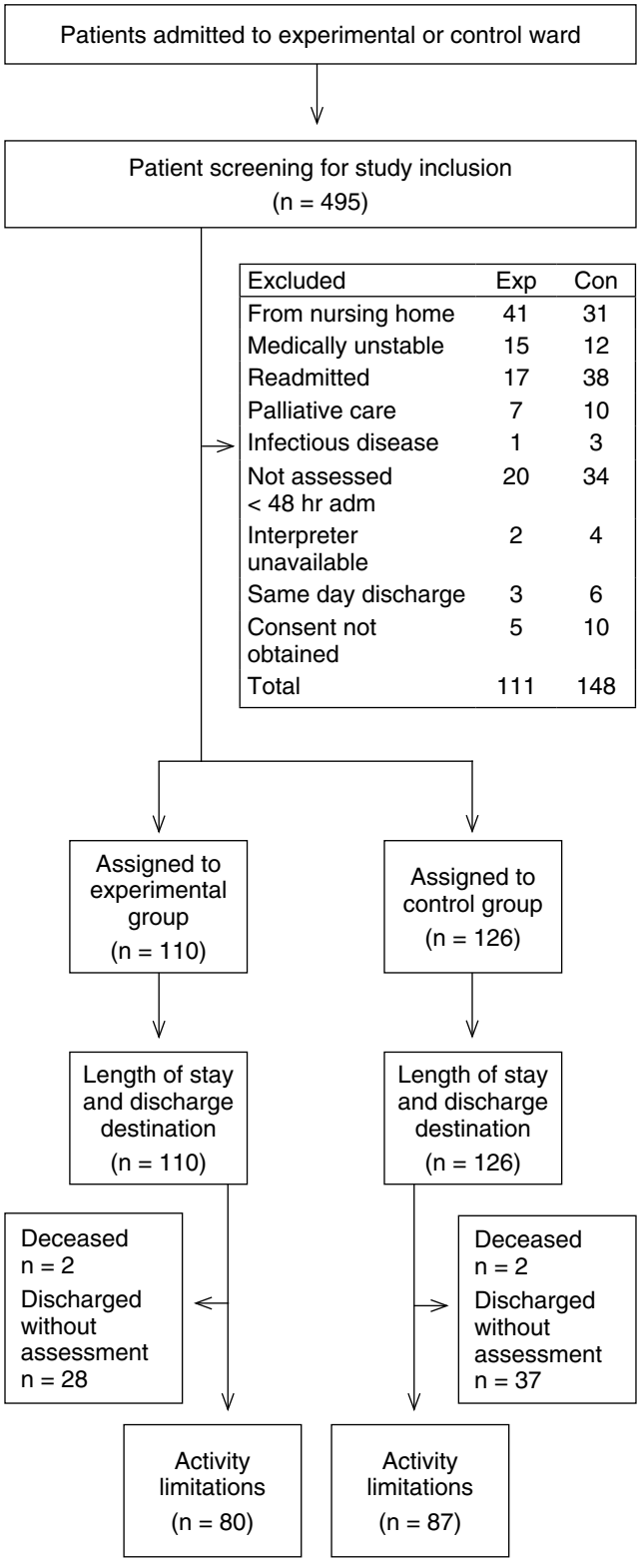

Figure 1. Flow of participants through the trial.

family members and nursing staff assisted in completing the assessment. The Barthel Index has been widely reported to be valid and reliable in neurological rehabilitation populations.

The Timed Up and Go measures the time taken (in seconds) to rise from a chair, walk three metres, turn around and return to sit on the chair (Podsiadlo and Richardson 1991). Only patients who could perform this test independently, or with supervision, or with a gait aid (if required) received a score.

The Functional Ambulation Classification categorises patients according to their ability to ambulate over a 10 foot distance (Holden et al 1986) where a score of 1 is unable to ambulate or requires assistance of more than one person, and 6 is independent on uneven surfaces, stairs and inclines. However, the classification was modified for use in this study because it was not always possible to assess outdoor mobility due to the nature of some patients' acute medical illnesses. In addition, equipment requirements for testing stairs and inclines were a practical limitation to its administration in the acute care setting. Instead, patients were asked if they would currently be able to ascend and descend a flight of 7 steps (with a rail) and a ramp independently. If a patient answered 'Yes' to this question, the patient was tested ambulating over a four metre length of foam to replicate an uneven terrain. Patients received a score of 6 if this was completed safely without assistance.

Other outcomes measured were length of stay and adverse events (28-day readmission, mortality, intensive care admission, and number of falls).

Data analysis: Sample size calculations were performed to achieve a power of 0.8 and 95% confidence. To detect a 10% reduction in discharges to inpatient rehabilitation, 105 patients were required in each group. Results of a similar trial (Berney et al 2003) indicated between group differences of 7 Barthel units at hospital discharge (SD 15.2). Assuming similar outcomes, 72 participants in each group were required to detect a similar outcome. It was anticipated that 100% of discharge destination data would be available. Some loss to follow up was anticipated for activity limitation data.

Analysis was by intention-to-treat. Groups were compared at hospital discharge for all outcomes. The distributions of all continuous data were assessed for normality. Between-group comparisons of normally distributed data were performed with independent t-tests. Non-normally distributed data were compared with the Mann-Whitney U statistic. Relative risks and their 95% confidence intervals were used to report group differences in proportions. Continuous variables were also assessed for relationships between baseline scores and outcome. If a significant relationship was found, analysis of covariance (ANCOVA) was conducted to test the effect of the intervention when controlling for the confounding effects of baseline scores on outcome (Vickers and Altman 2001). Alpha was set at 0.05.

Results

Flow of participants through the trial: Between October 2002 and July 2003, 495 patients were screened; 251 were eligible for inclusion, and 236 (48%) participated in the study. There were 126 patients allocated to the control group and 110 to the experimental group (Figure 1). The experimental group was, on average, 2.1 years older than the control group ($p = 0.03$), although this small difference has no apparent clinical importance. All other characteristics were similar between groups (Table 1). Barthel Index scores indicated moderate dependency in activities of daily living (Shah et al 1989), ranging from completely dependent to independent. Functional Ambulation Classification scores indicated an ability to ambulate over a 10 foot level surface

Table 1. Characteristics of participants.

Characteristic	Con (n = 126)	Exp (n = 110)	*p* value
Age, mean (SD)	78 (7)	80 (8)	0.03#
Gender (% female)	54	55.5	0.82†
APACHE 11 severity of illness score, mean (SD)*	13.1 (4.4)	13.1 (5.0)	0.95#
Charlson co-morbidity score, mean (SD)	2.1 (1.9)	2.4 (2.1)	0.36#
Primary presenting medical condition, number (%)			0.63†
Respiratory	42 (33)	31 (28)	
Circulatory	27 (21)	22 (20)	
Digestive	8 (6)	12 (11)	
Genitourinary	7 (6)	9 (8)	
Other	42 (33)	36 (33)	
Place of residence, number (%)			0.75†
Home alone	27 (21)	21 (19)	
Home with family/spouse	86 (68)	73 (66)	
Hostel	11 (9)	13 (12)	
Rehabilitation hospital	2 (2)	2 (2)	
Other acute hospital	0 (0)	1 (1)	
Gait aid use prior to hospital admission, number (%)			0.20†
None	64 (51)	47 (43)	
SPS	25 (20)	21 (19)	
Frame	25 (20)	36 (33)	
Other	12 (10)	6 (6)	

Con = control, Exp = experimental. SPS = single point stick. *APACHE scores were unable to be calculated for 4 patients (2 in each group) due to missing hospital clinical histories. #Independent t-test, †chi squared test

with supervision, ranging from unable to ambulate to independent ambulation on level and non level surfaces.

For discharge destination, length of stay, and adverse events, data were available for 100% of participants. For the Barthel Index and Functional Ambulation Classification, 29% of participants were not measured at hospital discharge. For the Timed Up and Go, 37% of participants were not measured at hospital discharge. Participants without discharge measurements of activity limitations were not significantly different in characteristics from those with discharge measurements.

Compliance with trial method: Referrals for usual physiotherapy care were received for 96% of the control group and 94% of the experimental group. Both groups received a median of 3 sessions (IQR 2 to 5) of usual physiotherapy care ($p = 0.50$). Participants in the control group received a median of 80 minutes (IQR 40 to 145) and the experimental group received a median of 90 minutes (IQR 40 to 131) of usual physiotherapy care ($p = 0.81$).

Effect of intervention: Patient data were analysed as though all patients received experimental or control interventions as allocated. There was no significant effect of the additional exercise program on any outcome (Tables 2 and 3). The majority of patients in both groups (78%) were discharged from hospital to home and there was no significant difference between groups (RR 0.99, 95% CI 0.86 to 1.14). Furthermore, there was no significant difference between groups for the proportion of patients discharged to inpatient rehabilitation (RR 0.76, 95% CI 0.30 to 1.51).

No differences between groups for any measure of activity limitation were found at hospital discharge. Activity limitation data were analysed using all available data and using a number of different methods for dealing with missing data (eg, last observation carried forward). As results did not vary with different methods of analysis, analyses of all available data are reported.

A significant relationship between admission and discharge scores was found for the Barthel Index ($r = 0.84$, $p < 0.01$) and Timed Up and Go ($r = 0.87$, $p < 0.01$). ANCOVA, adjusting for the effects of admission Barthel Index score and age, indicated a non-significant difference between groups for discharge Barthel Index scores ($p = 0.15$). Similarly, ANCOVA adjusting for the effects of admission Timed Up and Go score and age indicated no significant difference between groups for discharge Timed Up and Go scores ($p = 0.63$). Nonparametric testing of discharge Functional Ambulation Classification scores indicated no statistically significant differences between groups ($p = 0.63$).

A one day difference in length of stay was identified between groups but this difference was not significant ($p = 0.45$).

There were no significant differences between groups for adverse events: 28-day readmission (RR 1.10, 95% CI 0.65 to 1.86), patient mortality (RR 1.15, 95% CI 0.16 to 8.0), intensive care admission (RR 0.16, 95% CI 0.01 to 3.13), and falls (RR 0.69, 95% CI 0.17 to 2.81).

Discussion

Table 2. Number of participants (%) in each category, relative risk (95% CI) of difference between groups on discharge.

Category	Groups		Difference between groups
	Exp (n = 110)	Con (n = 126)	RR Exp relative to con
Discharge destination, number (%)			
Home	85 (77)	98 (78)	0.99 (0.86 to 1.14)
Inpatient rehabilitation	12 (11)	18 (14)	0.76 (0.30 to 1.51)
Nursing home	4 (4)	4 (3)	1.15 (0.29 to 4.47)
Hostel	3 (3)	2 (2)	1.72 (0.29 to 10.10)
Other acute hospital	1 (1)	2 (2)	0.57 (0.05 to 6.23)
Deceased	2 (2)	2 (2)	1.00 (0.96 to 1.03)
Other	3 (3)	0 (0)	8.01 (0.42 to 153.40)
Length of stay, med (IQR) *(days)*	5.0 (3.0 to 9.75) (n = 108)	6.0 (3.25 to 9.75) (n = 124)	$p = 0.45$
Adverse events, number (%)			
28-day readmission	22 (20) (n = 108)	23 (19) (n = 124)	1.10 (0.65 to 1.86)
Mortality	2 (2)	2 (2)	1.15 (0.16 to 8.00)
Intensive care admission	0 (0)	3 (2)	0.16 (0.01 to 3.13)
Fall	3 (3)	5 (4)	0.69 (0.17 to 2.81)

Exp = experimental, Con = control, RR = relative risk

Table 3. Groups, difference within groups, and mean (95%CI) difference between groups for activity limitation scores.

Score	Groups				Difference within groups		Difference between groups
	Admission		Discharge		Discharge minus admission		Discharge minus admission
	Exp	Con	Exp	Con	Exp	Con	Exp minus Con
Barthel Index *(0 to 100)* mean (SD)	66 (26) n = 110	68 (26) n = 126	79 (23) n = 80	75 (26) n = 87	12 (16)	10 (14)	3 (–1 to 7) $p = 0.15$*
Barthel Index *(0 to 100)* median (IQR)	70 (50 to 90)	75 (45 to 90)	85 (66 to 100)	85 (60 to 100)	10 (0–20)	10 (0–15)	
TUG *(s)* mean (SD)	35 (30) n = 89	30 (28) n = 93	36 (65) n = 74	26 (21) n = 75	–10 (19) n = 66**	–5 (10) n = 59**	–0.9 (–4.3 to 2.6) $p = 0.63$*
TUG *(s)* median (IQR)	23 (15 to 44)	21 (16 to 32)	20 (14 to 37)	19 (13 to 28)	–3 (–12 to 0)	–3 (–6 to 0)	
FAC (1 to 6) mean (SD)	4.0 (1.5) n = 110	3.9 (1.6) n = 126	4.8 (1.2) n = 80	4.7 (1.3) n = 87	0.7 (1.0)	0.8 (1.3)	–0.1 (–0.5 to 0.3)
FAC *(1 to 6)* median (IQR)	4.0 (4.0 to 5.0)	4.0 (3.0 to 5.0)	5.0 (4.2 to 5.4)	5.0 (4.0 to 5.5)	0.5 (0–1)	0 (0–1)	$p = 0.63$***

Exp = experimental, Con = control; * = ANCOVA used for between-group difference with admission score and age as covariates; ** = only able to be calculated for patients who completed a TUG assessment at both hospital admission and discharge; *** = Mann-Whitney U test

The addition of an individually-tailored exercise program to usual care services did not significantly improve patient or hospital outcomes for acutely hospitalised older medical patients in this study. Patient characteristics in this population are typically heterogenous and many factors are likely to determine outcomes. There is also the potential for these factors to cause a highly variable response to an exercise intervention across trial participants. Therapist opportunity to progress patient programs was also often limited by the short duration of an acute hospital admission. In the current acute care setting, the widespread provision of usual care physiotherapy services may account for the finding that patients did not, on average, demonstrate the functional decline previously reported during admission for these patients. This, combined with short length of stay, provide little opportunity for effects of additional exercise (if they indeed occur) to be observable. It is also possible that the prescribed exercise dosage in this trial was not sufficient to influence outcome for this patient population.

Significant reductions in healthcare utilisation were not observed in this trial and contradict the significant findings reported in two Australian hospital trials that employed historical control groups (Kurrle 2001, Berney et al 2003). The trial design employed in these two trials did not control for other changes in hospital practice that may have occurred contemporaneously with the experiment and factors other than the intervention might explain the disparity with our trial results. Acute hospital length of stay was not significantly influenced by the additional exercise intervention in this study. Our results support the findings of Siebens and colleagues (2000) who reported that a similar exercise intervention did not have a significant effect on acute hospital length of stay in an older medical and surgical patient population.

Contrary to the many reports of substantial functional decline in hospitalised older adults (Gillick et al 1982, McVey et al 1989, Hirsch et al 1990, Inouye et al 1993, Palmer 1995, Sager et al 1996), few patients were found to deteriorate in their functional ability between acute hospital admission and discharge in this study. The minimal detectable change in Barthel Index scores is approximately 10 Barthel Index units (Collin et al 1988, Green et al 2001). An average improvement of approximately 10 Barthel Index points was observed in both the control and the experimental groups. Decline in Barthel Index score of 10 points or greater occurred in only 4.6% (4/87) of patients in the control group and 2.5% (2/80) of patients in the experimental group. Additionally, patients in the control group did not, on average, demonstrate functional decline. The provision of usual physiotherapy care to almost all patients may have prevented the functional decline observed in other trials.

In future trials, improved targeting of patients likely to respond to the intervention may demonstrate benefits of additional exercise. Alternatively, ongoing exercise intervention immediately after hospitalisation may improve the activity limitation outcomes of medical patients, as observed by Siebens and colleagues (2000).

This study has identified that three activity limitation measures commonly used in older populations, the Barthel Index, Timed Up and Go, and Functional Ambulation Classification, have significant limitations when applied to an older acute medical population. The Timed Up and Go had a floor effect with approximately 23% of patients unable to complete a Timed Up and Go test at hospital admission. This floor effect was predominantly due to patients being unable to transfer from sit to stand without assistance. The Barthel Index was developed for measuring independence in activities of daily living of rehabilitation patients (Mahoney and Barthel 1965) and in this study showed a ceiling effect with approximately 20% of trial participants scoring 95 or 100 at hospital admission. Consequently, the Barthel Index did not capture change adequately in those patients with modest limitations at hospital admission. The Functional Ambulation Classification was able to categorise all patients according to their ambulatory ability but appears to be a relatively insensitive measure of change for this patient population. On average, both groups improved in their Barthel Index scores by a clinically important amount between admission and discharge but improved, on average, by only one point between admission and discharge on the Functional Ambulation Classification.

Since the function of older acute medical patients typically ranges from bed bound to high levels of independent mobility, many other currently available activity limitation measures are likely to have similar limitations in this patient group. Measures that require patients to stand, eg, Functional reach (Duncan et al 1990), Berg Balance scale (Berg et al 1989), are likely to have a floor effect, and measures that do not contain items more difficult than those in the Barthel Index, eg, Functional Independence Measure (Keith et al 1987), are likely to show a ceiling effect. These observations indicate the need for an outcome measure that can measure change in activity limitation sensitively for acute medical inpatients across a broad spectrum of abilities.

This preliminary trial has limitations. Patients were not individually randomised to group, there was a high loss to follow up for activity limitation outcome data, and these measurements were not performed by a blinded assessor. Despite these potential sources of bias, no effect of the intervention was identified for any outcome. In addition, only one physiotherapist and one allied health assistant were involved in the prescription and administration of the exercise intervention in this trial, and this limits the generalisability of the trial results.

In conclusion, this trial did not identify any significant effect on patient or hospital outcomes of additional exercise for acutely hospitalised older medical patients. Changes to usual care hospital practices that now include the provision of higher usual physiotherapy care services may have precluded an effect associated with additional exercise in the experimental group. In addition, an outcome measure that can sensitively measure changes in activity limitations for patients ranging from bed bound to high levels of independent mobility is required for future trials where participants span a wide range of function.

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Correspondence: Natalie de Morton, Department of Physiotherapy, School of Primary Health Care, Faculty of Medicine, Nursing and Health Sciences, Monash University-Peninsula Campus, PO Box 527, Frankston, 3199, Victoria, Australia. Email: natalie.demorton@med.monash.edu.au

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