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Can augmented physiotherapy input enhance recovery of mobility after stroke? A randomized controlled trial

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Objective: To discover if the provision of additional inpatient physiotherapy after stroke speeds the recovery of mobility.
Design: A multisite single-blind randomized controlled trial (RCT) comparing the effects of augmented physiotherapy input with normal input on the recovery of mobility after stroke.
Setting: Three rehabilitation hospitals in North Glasgow, Scotland.
Subjects: Patients admitted to hospital with a clinical diagnosis of stroke, who were able to tolerate and benefit from mobility rehabilitation.
Intervention: We aimed to provide double the amount of physiotherapy to the augmented group.
Main measures: Primary outcomes were mobility milestones (ability to stand, step and walk), Rivermead Mobility Index (RMI) and walking speed.
Results: Seventy patients were recruited. The augmented therapy group received more direct contact with a physiotherapist (62 versus 35 minutes per weekday) and were more active (8.0% versus 4.8% time standing or walking) than normal therapy controls. The augmented group tended to achieve independent walking earlier (hazard ratio 1.48, 95% confidence interval 0.90–2.43; $p=0.12$) and had higher Rivermead Mobility Index scores at three months (mean difference 1.6; −0.1 to 3.3; $p=0.068$) but these differences did not reach statistical significance. There was no significant difference in any other outcome.
Conclusions: A modest augmented physiotherapy programme resulted in patients having more direct physiotherapy time and being more active. The inability to show statistically significant changes in outcome measures could indicate either that this intervention is ineffective or that our study could not detect modest changes.

Introduction

Physiotherapy is a routine component of stroke management, and most stroke patients in hospital see a physiotherapist as part of their care.[1] However research into physiotherapy is relatively scarce and studies have been criticized because they have generally been small and nonrandomized, interventions have been poorly described and monitored, outcome assessments have not been blinded and the outcome measures have not reflected the aims of physiotherapy.[2,3] Consequently, we still

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have insufficient information to inform important decisions about the optimum amount of physiotherapy after stroke.[4] Generally, the amount of physiotherapy a stroke patient receives will be small,[5] vary considerably between hospitals and regions,[1] and be a common source of patient dissatisfaction.[6,7]

Recent systematic reviews[8,9] have indicated that available studies were small and heterogeneous, but suggested that augmented physiotherapy may speed up recovery after stroke. Even a modest gain could be economically attractive if a small increase in therapy input could reduce nursing and 'hotel' costs in hospital.[10]

Several recent trials have evaluated the influence of augmented physiotherapy in improving upper limb function alone[11–13] or a combination of upper limb and lower limb function.[14,15] However, none of these trials have specifically focused on the recovery of mobility, a key target for physiotherapy and a major factor in determining functional outcome and discharge destination after stroke. We therefore designed a multisite randomized controlled trial (RCT) to explore the effect of augmented (intensive) physiotherapy on the recovery of mobility in stroke rehabilitation patients.

Aims

Our primary question was 'Does the provision of additional inpatient physiotherapy after stroke speed up the recovery of mobility?' However, because of the complexity of carrying out physiotherapy trials we included secondary questions to explore the impact of the trial. In particular we aimed to establish if the allocation of augmented physiotherapy input would:

1) increase the amount of time in contact with the physiotherapist,
2) enhance patient activity (particularly standing and walking),
3) reduce impairment,
4) speed up the achievement of mobility,
5) enhance activities of daily living and quality of life,
6) allow patients to return home earlier (and hence permit cost recovery),
7) have no adverse effects.

Methods

We included patients recently admitted to stroke rehabilitation facilities at Stobhill, Drumchapel and Lighturn Hospitals, in Glasgow, Scotland. All had a clinical diagnosis of stroke within the previous six weeks and were able to tolerate and benefit from mobility rehabilitation (see Table 1 for exclusion criteria).

We aimed to recruit 100 patients, giving the trial an 80% power (at 5% level) to detect a seven-day reduction in time taken to recover independent walking.

After giving informed consent, patients were randomly assigned (by a remote, independent centre offering a telephone randomization service) to one of two groups: (a) conventional inpatient stroke services including conventional physiotherapy input (30–40 minutes direct physiotherapy contact per day, five days per week), or (b) conventional stroke services plus additional physiotherapy input (aiming to approximately double the total daily physiotherapy time to 60–80 minutes per day, five days per week). Randomization was stratified by study site, age (above or

Table 1 Reasons for exclusion from study

Exclusion (categories not mutually exclusive)	Number of patients
Communication impairment	237
Previous history of stroke	171
Cognitive impairment (AMT ≤8)	169
No sitting balance	101
Pre-stroke Rankin >2	39
Dementia	26
Unconfirmed stroke	24
Carcinoma	24
Arthritis limiting ADL	23
Unstable angina (limits exercise)	21
COPD limiting exercise	16
Major surgery (3 months)	14
Poorly controlled diabetes	13
Recent MI (3 months)	10
PVD limiting exercise	6
Total exclusions	625

AMT, Abbreviated Mental Test score; ADL, activities of daily living; COPD, chronic obstructive pulmonary disease; MI, myocardial infarction; PVD, peripheral vascular disease.

below 75 years), and level of severity (Barthel Index (BI)[16] (0–9 or 10–20)) at recruitment.

The three chosen centres were felt to be representative of physiotherapy approaches in normal UK practice.[5,17] We considered it impossible to designate in advance a standard treatment for all patients but outline treatment schedules were discussed (based on Edwards *et al.*[18]) by the trial management group to ensure consistency of treatment categories. A standard format for recording the type, amount and focus of treatment was developed and piloted. Treatment was broadly based on the 'Normal Movement' (Bobath) approach. Specific functional objectives included the establishment of independent dynamic sitting balance, standing balance, upper limb function and walking, and other functional mobility tasks. The additional therapy time was provided to the augmented group by the usual therapy staff. Two half-time study therapists were employed to provide 'back fill' time support for physiotherapists delivering the extra therapy while a third half-time therapist carried out blinded assessments of outcome. There was no difference in staff grade or type (skill mix) between the two groups.

Patients in both groups had the normal access to all other interventions (e.g., nursing, occupational therapy) in hospital and after discharge in the community.

Outcomes

The primary outcome measures were the achievement of key mobility milestones as either discrete events[19,20] or a compound Rivermead Mobility Index (RMI) score.[21] The outcome measures were assessed as follows:

1) Record the type and amount of treatment (see above).
2) Patient activity – We measured patient activity using an automated system developed for our purpose by the University of Strathclyde Bioengineering Unit. It was applied to the patients on a single occasion three weeks after randomization and worn by them from early morning to late evening. It provided a continuous record of the proportion of the time spent in an 'upright position' (standing or walking) and the number of transitions per hour between 'non upright' (sitting or lying) and 'upright'. From early morning to late afternoon it was assumed that activity was influenced by the amount of therapy input. However in the evening activity may depend on the patient's ability, motivation, nursing staff assistance and ward routines.
3) Recovery of impairment – We assessed the Trunk Control Test[16] and Motricity Index[16] at week 4 then at three and six months. We scored the Motricity Index out of 200 (high score = maximum ability); normally the arm and leg scores are averaged to obtain a score out of 100.
4) Recovery of walking – The achievement of mobility milestones,[19,20] Rivermead Mobility Index (RMI)[21] and walking speed was recorded weekly in hospital, then at three and six months.
5) Activities of daily living (ADL) and quality of life – We recorded the Barthel Index[16] and Nottingham Extended ADL[16] score at four weeks, three months and six months post randomization plus the EuroQol[22] at baseline and six months.
6) Discharge home – We recorded the patients' length of stay in hospital, as well as reasons that might have delayed discharge.
7) Complications – We recorded the presence or absence of various complications (including falls, pain, shoulder pain, and fatigue) at weekly intervals, plus at three- and six-month follow-up.

The Robertson Centre for Biostatistics at the University of Glasgow managed all the data and carried out the analyses. The Bioengineering Unit at the University of Strathclyde analysed and interpreted data gathered from the activity monitor using custom-written software.

Statistical analyses were performed using SAS for Windows (version 8.2). Comparisons were made between the standard and augmented physiotherapy groups using two-sample t-tests with corresponding 95% confidence intervals (CI) for the Motricity Index, Rivermead Mobility Index, the activity of daily living measures (Barthel Index and Nottingham Extended ADL) and the EuroQol calculated. The Mann–Whitney test was used to

compare average walking speeds between the two groups and was also used to analyse data from the activity monitor. Time to achieving each milestone was examined using the log-rank statistic. Patients who did not achieve the milestone were censored at either their death, end of study, or withdrawal. Results are reported as number (%) of participants achieving milestones for each physiotherapy group, and hazard ratios (% CI) and p-values. All analyses were according to the intention-to-treat principle, using all available data for each measurement at the appropriate visit. We did not use imputation or any 'last observation carried forward' methods to deal with the problem of missing data. No formal adjustment has been made for multiple comparisons.

Results

Between July 1999 and February 2001 we screened 708 patients admitted to the three stroke rehabilitation units (Figure 1), from which we recruited 70 (10%). Reasons for exclusion are listed in Table 1. Patients were recruited 25 days (range 6–71 days) after their stroke. Thirty-five patients were randomized to each arm of the study. Two patients died and none withdrew during the study period. Follow-up was very satisfactory with only 14/280 (5%) of assessments being missed; 6 – patient unwell, 4 – patient dead, 3 – patient declined; 1 – patient missing (Figure 1).

The mean (95% CI) number of physiotherapy sessions per patient was greater in the augmented

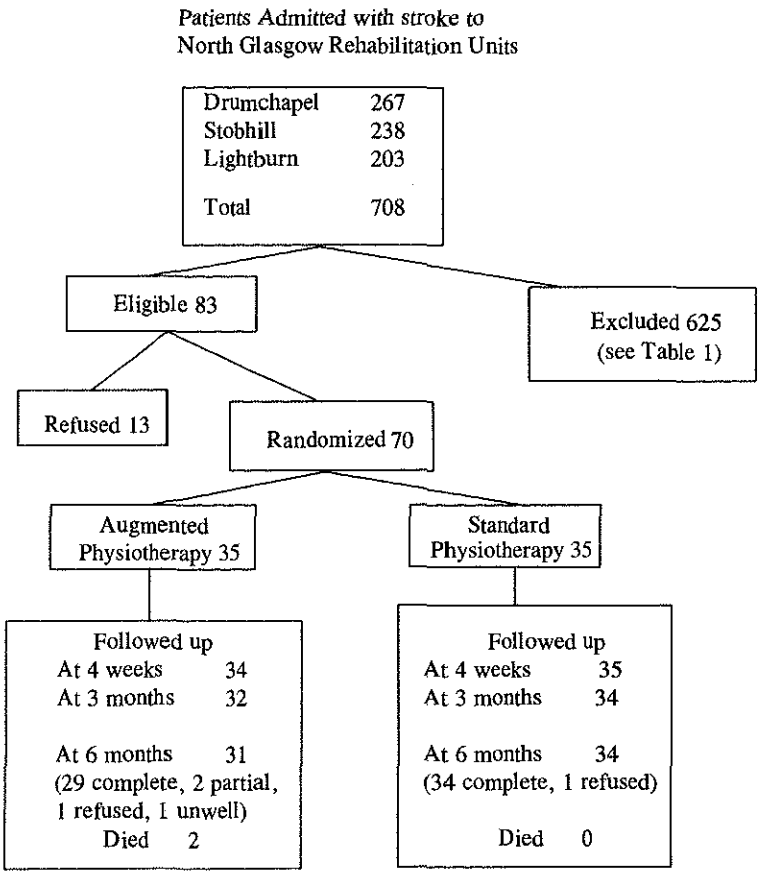

Figure 1 GAPS study recruitment and randomization.

Table 2 Baseline characteristics

	Augmented physiotherapy ($n=35$)	Standard physiotherapy ($n=35$)
Age	68 (11)	67 (10)
Sex – female	11 (31)	18 (51)
Pre-stroke dependency (Rankin score)		
0	18 (51)	17 (49)
1	10 (29)	14 (40)
2	7 (20)	4 (11)
Days after hospital admission	22 (14)	25 (18)
Days to transfer to rehabilitation unit	13 (11)	15 (14)
Stroke classification		
Right hemisphere stroke	15 (46)	15 (43)
Total anterior circulation infarct	6 (17)	7 (21)
Partial anterior circulation infarct	15 (43)	18 (50)
Lacunar infarct	10 (29)	8 (24)
Posterior circulation infarct	2 (6)	1 (3)
Other	2 (6)	1 (3)
Barthel Index (mean, SD)	11.8 (3.3)	10.3 (3.1)
Trunk Control Test (mean, SD)	72 (23)	68 (24)
Motricity Index (mean, SD)	110 (43)	100 (43)

Values are expressed as the mean (SD) for continuous measures and number (%) for categorical measures.

therapy (43; 35–51) than the standard therapy group (32; 24–40). This equated to an average number of physiotherapy treatment hours in the augmented therapy group (34 hours total; 10 hours on upper limb work; 9 hours on lower limb; 15 hours other work) which was greater than that of the standard therapy group (21 hours total; 5 hours on upper limb; 5 hours on lower limb; 11 hours other work). The average number of treatment hours per weekday differed by 0.45 hours (i.e., 62 versus 35 minutes).

The baseline characteristics of the subjects are shown in Table 2. The standard and augmented groups were broadly similar at baseline although the Barthel Index tended to be higher for patients in the augmented group.

Activity monitoring data were available for a representative subgroup of 41 (58%) patients (22 augmented therapy; 19 standard therapy). These were analysed in terms of the patient's average number of transitions to the upright position per hour. The mean (SD) for the augmented group was significantly greater than the standard group (2.6 ± 1.2 per hour versus 1.7 ± 1.3; $p=0.007$).

The mean proportion (%) of time spent standing or walking was greater in the augmented group (8.0% versus 4.8%; $p=0.002$).

When we analysed activity over different periods of the day we found the augmented group were more active (more transitions and a greater average proportion of their time spent standing or walking) during the day (up to 4.30 pm). There was no significant difference in activity between the groups in the period after 4.30 pm, indicating that the additional physiotherapy contact resulted in greater mobility-related activity for the augmented group patients.

Results for the Motricity Index are shown in Table 3. There were no statistically significant differences between the two groups.

The results of the time-to-event analysis for the mobility milestones are shown in Table 4. In both groups the majority of subjects achieved all three milestones within six months. The rate was higher

Table 3 Motricity Index (MI) score

	Augmented physiotherapy		Standard physiotherapy		Mean difference (95% CI)	*p*-value
	n	Mean (SD)	*n*	Mean (SD)		
Baseline	35	110 (43)	35	100 (43)		
Four weeks	33	119 (46)	34	111 (45)	8 (−15, 30)	0.49
Three months	32	130 (44)	33	120 (42)	10 (−12, 31)	0.37
Six months	30	124 (42)	34	121 (51)	3 (−21, 26)	0.82
Change at six months from baseline	30	20 (20)	34	23 (27)	−3 (−15, 10)	0.67

Data are presented as the mean (SD) and mean difference.

Table 4 Comparison of time to achieve 'mobility milestones'

Milestone	Augmented physiotherapy ($n=35$)	Standard physiotherapy ($n=35$)	Hazard ratio (95% CI)	p-value (log-rank)
Standing	34 (97.1)	35 (100.0)	1.34 (0.81, 2.23)	0.25
10 paces	32 (91.4)	31 (88.9)	1.39 (0.84, 2.30)	0.20
10 metres	33 (94.3)	32 (91.4)	1.48 (0.90, 2.43)	0.12

Results are expressed as the number (%) who achieved mobility milestones during the study plus the relative probability of achieving a milestone at any time point (hazard ratio).

among the augmented therapy group which did not achieve statistical significance.

The best recorded 10-metre walking speed (m/s) at any study visit did not differ significantly between the two groups (the median preferred walking speed in the augmented group was 0.63 m/s versus 0.53 m/s in the standard group; median difference 0.04; 95% CI −0.16 to 0.23; $p=0.70$).

The Rivermead Mobility Index scores for the two groups of patients are presented in Table 5. The largest difference in scores (augmented = 9.7 and standard = 8.1; $p=0.068$) between the two groups was at three months.

There were no statistically significant differences between the two groups in the Barthel ADL Index (Table 6).

There were also no statistically significant differences between the augmented and standard group in the Nottingham Extended ADL scores at three months and six months (Table 7).

The EuroQol visual analogue scale was used as an indicator of health-related quality of life (Table 8). The mean scores of the two groups were similar at baseline but at six months the augmented group tended to have a higher score. The change in score over the six months was 10 for the augmented group and −2 for the standard group (mean difference 12; −3 to 26; $p=0.11$) (Table 8).

The mean (range) length of stay from randomization for the augmented group was 45 (4–123) days and 54 (8–180) days for standard group ($p=0.29$). Twelve (17.1%) patients were considered to have had their discharge delayed for some reason (e.g., awaiting social work intervention) but with no significant difference between groups.

Data were collected on complications. There was no significant difference in the proportion of patients reporting any complication (augmented 83% versus standard 78%) nor in the frequency of individual complications. There were no serious adverse events during the trial.

Discussion

This trial was one of the first to evaluate the impact of an increased intensity of physiotherapy on the recovery of mobility after stroke. We did not demonstrate any statistically significant impact on

Table 5 Rivermead Mobility Index (RMI) score

	Augmented physiotherapy		Standard physiotherapy		Mean difference (95% CI)	p-value
	n	Mean (SD)	n	Mean (SD)		
One week	4	5.2 (2.4)	34	4.6 (2.6)	0.6 (−0.6, 1.9)	0.32
Four weeks	3	7.4 (3.3)	34	7.0 (3.5)	0.4 (−1.2, 2.1)	0.61
Three months	32	9.7 (3.3)	34	8.1 (3.6)	1.6 (−0.1, 3.3)	0.068
Six months	30	10.2 (3.1)	34	9.1 (4.0)	1.1 (−0.7, 3.0)	0.21
Change from week one to three months	32	4.7 (2.8)	33	3.5 (2.8)	1.1 (−0.2, 2.5)	0.10
Change from week one to six months	30	5.1 (2.7)	33	4.4 (3.2)	0.6 (−0.9, 2.1)	0.41

Data are presented as the mean (SD) and mean difference.

Table 6 Barthel Index (BI) score

	Augmented physiotherapy		Standard physiotherapy		Mean difference (95% CI)	*p*-value
	n	Mean (SD)	*n*	Mean (SD)		
Baseline	35	11.8 (3.3)	35	10.3 (3.1)		
Four weeks	33	14.6 (3.4)	34	14.1 (3.7)	0.5 (−1.2 2.2)	0.55
Three months	32	16.6 (2.8)	33	16.1 (3.3)	0.7 (−0.9, 2.2)	0.39
Six months	31	16.9 (2.7)	34	16.2 (4.2)	0.7 (−1.1, 2.3)	0.45
Change at six months from baseline	31	5.1 (3.7)	34	5.9 (4.1)	−0.9 (−2.8, 2.8)	0.37

Data are presented as the mean (SD) and mean difference.

Table 7 Nottingham Extended Activities of Daily Living Index score

	Standard physiotherapy Mean (SD)	Augmented physiotherapy Mean (SD)	Mean difference (95% CI)	*p*-value
Three months	22.2 (11.0) $n=34$	27.6 (12.8) $n=32$	−4.0 (−9.9, 2.0)	0.19
Six months	26.2 (13.1) $n=34$	29.1 (11.5) $n=30$	−1.5 (−7.7, 4.6)	0.54

a range of clinical outcomes. It is possible that increasing the intensity of this form of physiotherapy with this type of patient has no effect on the outcomes we measured. Alternatively, we may have failed to demonstrate a true effect through a false negative (type II) error. First, our trial was relatively underpowered to detect modest changes in outcome. Our pilot feasibility studies overestimated the numbers of eligible patients that would be admitted to our rehabilitation wards with stroke, although this was partly compensated by the fact that our drop-out rate was low.

Secondly, we were constrained by limited resources to provide the augmented treatment. Eligible patients were not admitted in a regular manner and a few had to be excluded because we were unable to guarantee that we could provide the augmented physiotherapy input if they were randomized to the intervention arm of the trial. Thirdly, it proved difficult to deliver a doubling of physiotherapy treatment. However we did manage to provide a ratio of about 1.6:1 overall with a higher ratio of input focussing specifically on upper and lower limb activities. Our electronic activity monitoring independently confirmed a higher level of daytime activity in the augmented therapy group.

Despite these potential limitations we believe our trial makes an important contribution to this topic. The trial met several quality criteria including central (concealed) randomization, blinding of standardized outcome assessments, completeness of follow-up and the use of an intention-to-treat analysis. Our physiotherapy intervention seems to reflect normal physiotherapy practice (at least in the UK), involving a broad spectrum of interven-

Table 8 Quality of life (visual analogue scale from EuroQol)

	Standard physiotherapy Mean (SD)	Augmented physiotherapy Mean (SD)	Mean difference (95% CI)	*p*-value
Baseline	52.4 (18.9) $n=29$	53.7 (18.2) $n=32$		
Six months	51.8 (23.5) $n=32$	62.3 (24.6) $n=29$	−10.5 (−22.8, 1.8)	0.09
Change	−2.0 (20.8) $n=26$	9.78 (30.8) $n=27$	−11.7 (−26.3, 2.8)	0.11

Clinical messages

- Methodologically sound trials of rehabilitation interventions are feasible.
- A modest augmented physiotherapy programme resulted in patients having more direct physiotherapy time and being more active.
- The inability to show statistically significant changes in outcome measures could indicate either that this intervention is ineffective or that our study could not detect modest changes.

tions, delivered by a variety of clinicians representative of clinical practice.[17] Our patients were treated by a range of senior and junior qualified physiotherapists, occasionally by physiotherapy undergraduate students and assistants (both under supervision).

In conclusion, patients allocated to receive a higher intensity of this form of physiotherapy in rehabilitation wards did receive more direct physiotherapy contact time and showed increased activity levels. However the intervention did not produce statistically significant changes in measures of mobility, activities of daily living, patient quality of life or length of hospital stay. In view of the difficulty in conducting adequately powered trials in this area, we plan to include our results in a meta-analysis of all augmented physiotherapy trials.

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