

## Does an early increased-intensity interdisciplinary upper limb therapy programme following acute stroke improve outcome?

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**Objective:** To determine whether an early increased-intensity upper limb therapy programme following acute stroke improves outcome.

**Design:** A randomized controlled trial.

**Setting:** A stroke unit which provides acute care and rehabilitation for all stroke admissions.

**Subjects:** One hundred and twenty-three patients who had had a stroke causing upper limb impairment within the previous 10 days.

**Intervention:** The intervention group received stroke unit care plus enhanced upper limb rehabilitation provided jointly by a physiotherapist and occupational therapist, commencing within 10 days of stroke, and available up to 30 minutes/day, five days/week for six weeks. The control group received stroke unit care.

**Main outcome measures:** The primary outcome measure was the Action Research Arm Test (ARAT) three months after stroke. Secondary outcome measures: Motricity Index; Frenchay Arm Test; upper limb pain; Barthel ADL Index; Nottingham E-ADL Scale; and costs to health and social services at three and six months after stroke.

**Results:** There were no differences in outcomes between the intervention and control groups three and six months after stroke. During the intervention period the intervention group received a median of 29 minutes of enhanced upper limb therapy per working day as inpatients. The total amount of inpatient physiotherapy and occupational therapy received by the intervention group was a median of 52 minutes per working day during the intervention

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period and 38 minutes per working day for the control group ( $p = 0.001$ ). There were no differences in service costs.

**Conclusions:** An early increased-intensity interdisciplinary upper limb therapy programme jointly provided by a physiotherapist and occupational therapist did not improve outcome after stroke. The actual difference in the amount of therapy received by intervention and control groups was less than planned due to a competitive therapy bias.

## Introduction

Upper limb impairment affects 85% of stroke patients, 55–75% still experience problems three to six months later.<sup>1,2</sup> Fifty per cent of stroke patients with initial upper limb impairment still have significant functional upper limb problems four years later.<sup>3</sup> In contrast, 80% of survivors are able to walk again.<sup>4</sup> Stroke patients often feel that insufficient attention has been paid to upper limb recovery<sup>5</sup> and that rehabilitation has prioritized lower limb therapy over upper limb activities.<sup>6,7</sup> Intensive therapy for the upper limb after stroke is associated with small but statistically significant improvements in neuromuscular and functional outcomes and may enhance the rate of recovery.<sup>8</sup> The literature is unclear about the effectiveness of specific upper limb rehabilitation strategies which include: increased intensity of physiotherapy; 'forced use' therapy; repetitive tasks; electrical stimulation and electromyographic biofeedback. A systematic review<sup>9</sup> identified four randomized controlled trials (RCTs) of enhanced upper limb rehabilitation<sup>10–13</sup> and concluded that there is insufficient evidence to draw conclusions about the effectiveness of exercise therapy on arm function following stroke.

As the majority of functional recovery occurs within the first six months after stroke and is most rapid in the first few weeks and if concepts of neuroplasticity are accepted then the maximum opportunity to improve recovery should be through early intervention.<sup>14</sup> Early intervention might also avoid learned non-use or abnormal movement patterns and reduce the incidence of post-stroke upper limb pain. We aimed to evaluate an early increased-intensity upper limb therapy programme which was provided jointly by an occupational therapist and physiotherapist.

## Methods

The study was a pragmatic single centre randomized controlled trial. Ethical approval was obtained and data were stored on accordance with the Data Protection Act.

All stroke patients admitted to our hospital are transferred to the stroke unit from the medical admissions unit within 48 hours. Stroke patients remain on the stroke unit throughout their in-patient stay. Stroke patients admitted between 1 March 1999 and 30 June 2001 were screened and invited to participate if they had had a new stroke within the previous 10 days resulting in upper limb impairment due to one or more of the following: weakness; sensory loss; ataxia; visuospatial impairment. All subjects gave written consent. Exclusion criteria were: not medically stable within 10 days; persistent impaired conscious level days 0–10 (Glasgow Coma Scale eye opening score  $\leq 4$ )<sup>15</sup>; significant communication difficulties (Sheffield Aphasia Screening Test cut-off scores: age <60 – 17; age 60–69 – 16; age 70+ – 15)<sup>16</sup>; significant cognitive problems (Abbreviated Mental Test score <6)<sup>17</sup>; severe handicap prior to stroke (pre-stroke Oxford Handicap Scale score >3)<sup>18</sup>; a diagnosis likely to interfere with rehabilitation; additional upper limb problems within the previous six months, e.g., frozen shoulder, fracture.

Randomization was carried out using an independent telephone computerized service. Patients were stratified according to their Frenchay Arm Test (scores 0–1 and scores 2–5).<sup>19</sup>

At the initial assessment the following data were collected: demographic details; stroke type and subtype<sup>20</sup>; handedness; pre-stroke Nottingham E-ADL Index<sup>21</sup>; upper limb motor impairment (Motricity Index<sup>22</sup>); visuospatial deficit (Star Cancellation Test<sup>23</sup>); arm ataxia (NIH Stroke Scale)<sup>24</sup>; Frenchay Arm Test<sup>19</sup>; Action

Research Arm Test (ARAT).<sup>25</sup> The planned intervention comprised:

- *Interdisciplinary treatment programme* consisting of joint therapy sessions which integrated our current stroke unit physiotherapy (Bobath based)<sup>26</sup> and occupational therapy practice combining a 'normal movement' approach within meaningful activity and task analysis.<sup>27</sup> The physiotherapist and occupational therapist worked together during each session.
- *Enhanced upper limb therapy time* commencing within 10 days of stroke. Participants received 30 minutes of rehabilitation jointly from the study physiotherapist and occupational therapist, five days a week for up to six weeks, in addition to their other rehabilitation needs. Participants discharged from hospital during the intervention period received enhanced therapy either as outpatients or in their own home. Patients who regained arm function within the intervention period were discharged from the enhanced therapy programme if they were able to score full marks on the ARAT.

Actual and planned therapy time (both face to face and nondirect contact) was recorded for both intervention and control groups.

The Barthel Index<sup>28</sup> was measured at seven days after stroke. Patients were assessed at three and six months after stroke by a researcher who was blinded to the randomization group. The primary outcome measure was the ARAT at three months after stroke.<sup>29</sup> Secondary outcome measures were: impairment – Motricity Index<sup>22</sup>; upper limb function – Frenchay Arm Test<sup>2</sup>; disability – Barthel Index,<sup>28</sup> Nottingham E-ADL,<sup>21</sup> reported upper limb pain (five-point severity scale and 0–10 numerical rating scale) at three and six months after stroke.

Costs to health and social services were measured over a six-month period. Data were collected from service records or patient self-report. For community resource use, subjects were asked to record the frequency of service receipt over the previous week or month at the three and six month assessment. Adjusting for the date of hospital discharge, estimation of total resource use was then made by multiplying weekly/monthly

resource use by time spent in the community. Services were valued at 2000/2001 prices using national unit cost estimates.<sup>30</sup>

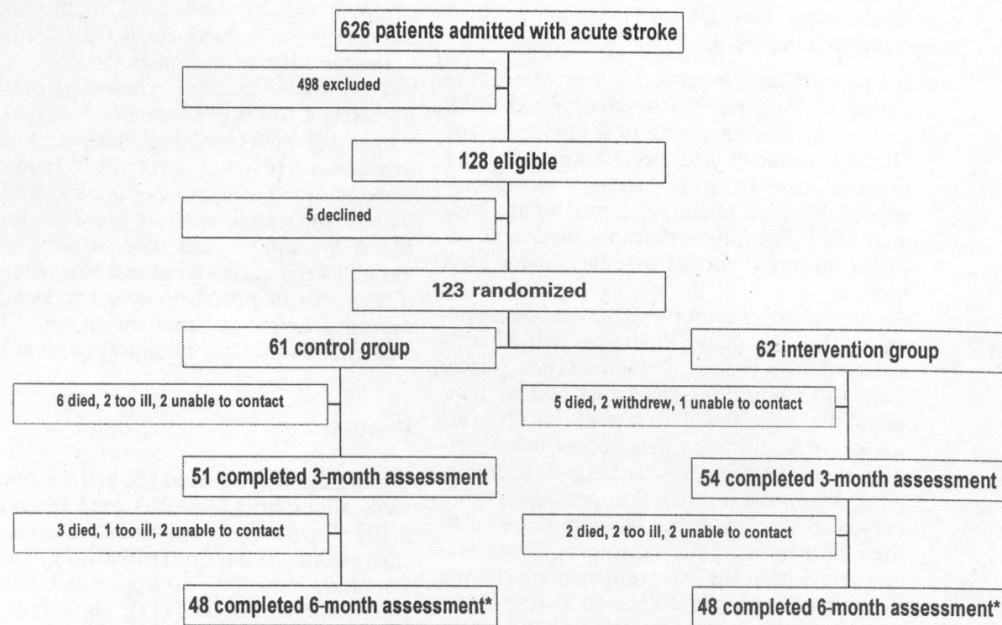
To achieve an 80% chance (power 0.8) of detecting a 10% difference between mean ARAT scores 144 subjects were needed. Allowing for attrition, we planned to recruit 160 subjects. Data were analysed using nonparametric methods. The main comparative analyses were made using the Mann-Whitney *U*-test. For ordered categorical variables the chi-squared test was used to detect differences in proportions, a two-sided 5% significance level was used throughout. The study was analysed on an 'intention to treat basis'.

## Results

During the study period 626 acute stroke patients were admitted; 123 (20%) were recruited to the study (Figure 1). The reasons for exclusion were: died within 10 days of stroke (62); lived outwith the study area (20); no upper limb deficit (130); significant dysphasia (111); significant handicap prior to stroke (62); other diagnoses likely to interfere with rehabilitation (32); not medically stable (24); admitted >10 days after stroke (19); cognitive impairment (13); discharged or transferred to another hospital within a few days of admission (18); admitted on two occasions (5); other reasons (2). Five eligible subjects declined to take part in the study.

Randomization groups were matched in terms of age, sex and pre-stroke function (Table 1). Subjects were randomized a median of five days after stroke. There was a higher proportion of total anterior circulation strokes in the control group (13 (21%) versus 8 (13%)) but this difference was not statistically significant. There were no differences in other markers of stroke severity or upper limb neurological deficit.

One hundred and five subjects completed the three-month assessment (Figure 1). Eleven (9%) died prior to the assessment, 3 (2%) were lost to follow-up, 4 (3%) withdrew or were too ill to be assessed. One patient in the intervention group had a further stroke and is included in the analysis. Sixteen (13%) died prior to the six-month assessment, 11 (9%) were lost to follow-up or were too ill to be assessed. Five patients in the



**Figure 1** Study profile. \*Three subjects in the control group did not complete the three-month assessment but completed the six-month assessment.

control group had a further stroke subsequent to the three-month assessment (all are included in the analysis). Death and attrition rates were similar for both groups.

Table 2 shows three- and six-month outcomes. The primary outcome measure was the ARAT at three months after stroke: the median ARAT for the intervention group was 53 compared with 54 for the control group (NS). No differences were found between groups in terms of upper limb impairment; upper limb pain; disability or handicap at three or six months after stroke.

As previous studies have found that subjects with severe initial upper and mild/moderate initial limb impairment differ in response to enhanced therapy we undertook this analysis. There were no differences in three-month outcomes between intervention and control groups for patients with either severe (ARAT = 0) or mild/moderate (ARAT > 0) initial upper limb impairment (Table 3).

Previous studies have also looked at differences between the initial and outcome assessment for upper limb impairment and function. We found no differences in the change in ARAT, Motricity Index, Frenchay Arm Test scores and Barthel Index between randomization groups (Table 4).

Intervention and control groups received similar frequencies of physiotherapy and occupational therapy (as measured in working days (WD)) during the preintervention, intervention or post-intervention periods (Table 5). Table 6 shows the number of patients who received joint and multidisciplinary therapy sessions from qualified therapists, therapy assistants and generic support workers. Table 6 also shows the median amount of therapy (minutes per working day) received during the intervention period. Generic support workers have basic training as therapy assistants and also provide social care. It was not possible to distinguish the time spent undertak-

**Table 1** Initial assessment

	Control (n = 61)	Intervention (n = 62)	p-value
Median age	75	74	0.980
Male	30 (49%)	28 (45%)	0.436
Days to randomization. Median [IQR]	5 [3-7]	5 [3-8]	0.449
Nottingham E-ADL Index (prestroke) Median [IQR]	17 [14-20]	19 [15-20]	0.685
Previous stroke	15 (25%)	11 (18%)	0.352
Side of weakness			
Right	26 (43%)	28 (45%)	0.777
Left	35 (57%)	34 (55%)	
Handedness			
Left	4 (7%)	4 (7%)	0.501
Right	54 (89%)	57 (92%)	
Ambidextrous	3 (5%)	1 (2%)	
Stroke subtype <sup>17</sup>			
Total anterior circulation stroke (TACS)	13 (21%)	8 (13%)	0.226
Partial anterior circulation stroke (PACS)	17 (28%)	17 (27%)	
Lacunar stroke (LACS)	29 (48%)	34 (55%)	
Posterior circulation stroke (POCS)	2 (3%)	3 (5%)	
Stroke type			
Infarct	57 (93%)	55 (89%)	0.509
Haemorrhage	4 (7%)	6 (10%)	
Not known	0	1 (1%)	
Barthel Index (7 days after stroke) Median [IQR]	9 [6-14]	8 [6-13]	0.698
Upper limb Motricity Index Median [IQR]	55 [14-77]	61 [15-81]	0.517
Frenchay Arm Test. Median [IQR]	0 [0-3]	0 [0-2]	0.813
Action Research Arm Test (ARAT) Median [IQR]	0 [0-45]	6 [0-41]	0.553
Cerebellar signs	8 (13%)	8 (13%)	0.972
Sensory symptoms	24 (39%)	19 (31%)	0.312
Score ≤51 on Star Cancellation Test	32 (53%)	23 (37%)	0.087

E-ADL, extended activities of daily living; IQR, interquartile range.

**Table 2** Three- and six-month outcomes

	3-month outcomes			6-month outcomes		
	Control (n = 51)	Intervention (n = 54)	p-value	Control (n = 48)	Intervention (n = 48)	p-value
Action Research Arm Test (ARAT)						
Median [IQR]	54 [1-57]	53 [20-57]	0.968	56 [25-57]	55 [14-57]	0.736
Upper limb Motricity Index						
Median [IQR]	78 [51-100]	85 [65-92]	0.969	77 [65-100]	83 [62-100]	0.668
Frenchay Arm Test						
Median [IQR]	4 [0-5]	4 [2-5]	0.715	4 [1-5]	5 [1-5]	0.679
Nottingham E-ADL						
Median [IQR]	8 [3-13]	8 [3-16]	0.941	8 [5-13]	10 [3.5-17]	0.169
Upper limb pain	27 (53%)	28 (52%)	0.911	27 (56%)	22 (46%)	0.307
Oxford Handicap Scale (OHS)						
0-2	20 (39%)	24 (44%)	0.532	22 (46%)	20 (42%)	0.681
3-5	31 (61%)	30 (56%)		26 (54%)	28 (58%)	
Barthel Index Median [IQR]	17 [10-19]	17 [8-19]	0.957	17 [14-18]	18 [11-20]	0.276

E-ADL, extended activities of daily living; IQR, interquartile range.

**Table 3** Three-month outcomes according to severity of initial upper limb impairment

	Initial ARAT = 0			Initial ARAT >0		
	Control (n = 28)	Intervention (n = 23)	p-value	Control (n = 23)	Intervention (n = 31)	p-value
Action Research Arm Test (ARAT)						
Median [IQR]	9 [0-53]	17 [0-53]	0.961	57 [55-57]	57 [51-57]	0.135
Upper limb Motricity Index						
Median [IQR]	61 [32-78]	67 [35-86]	0.747	100 [85-100]	85 [81-93]	0.053
Upper limb pain	17 (61%)	16 (70%)	0.510	10 (44%)	12 (39%)	0.724
Frenchay Arm Test						
Median [IQR]	1 [0-4]	1 [0-4]	0.927	5 [4-5]	5 [4-5]	0.330
Nottingham E-ADL						
Median [IQR]	6 [2-12]	4 [2-9]	0.382	11 [6-16]	11 [5-18]	0.953
Oxford Handicap Scale (OHS)						
0-2	6 (21%)	5 (22%)		14 (61%)	19 (61%)	
3-5	22 (79%)	18 (78%)	0.979	9 (39%)	12 (39%)	0.824
Barthel Index Median [IQR]	14 [9-17]	11 [6-18]	0.488	18 [16-20]	18 [14-20]	0.592

E-ADL, extended activities of daily living; IQR, interquartile range.

ing rehabilitation from the time spent on social care.

Patients in the intervention group received more combined therapy (29 minutes versus 4 minutes,  $p = 0.006$ ) and inpatient total therapy (52 minutes versus 38 minutes,  $p = 0.001$ ) than the control subjects. Although the intervention and control groups should have received similar amounts of therapy outwith joint upper limb therapy sessions, the control group received significantly more inpatient physiotherapy than the intervention group (21 versus 12 minutes per working day,  $p < 0.001$ ). The control group also received more occupational therapy as an inpatient (8 versus 6 minutes per working day,  $p = 0.03$ ) and as an outpatient ( $p = 0.03$ ). The total amount of inpatient physiotherapy and occupational therapy (including assistant time) received by the intervention group during the six-week intervention period was 52 minutes per working day for the intervention group and 38 minutes for the control group ( $p = 0.001$ ). There was no difference in the total amount of therapy received as an outpatient.

Not all patients in the intervention group were able to tolerate the extra therapy sessions. A total of 150 hours (2.5 hours per patient) were not given due to illness or patients declining during the intervention period.

There were no significant differences between groups in total health and social care costs within

the six months after stroke. Control group costs were a median of £5435 per patient compared with £5575 for the intervention group.

## Discussion

An early increased-intensity interdisciplinary upper limb therapy programme did not improve outcomes at three and six months after stroke. No differences in upper limb impairment; upper limb function; upper limb pain; or disability were seen between control and intervention groups.

### Clinical messages

- An early increased-intensity upper limb therapy programme provided jointly by a physiotherapist and occupational therapist following acute stroke did not improve outcome when compared to stroke unit care.
- Stroke unit care should be the 'gold standard' against which to compare stroke rehabilitation interventions.
- Randomized controlled trials of the intensity of therapy should be aware of the impact that competitive therapy bias can make on control group treatment.



**Table 5** Frequency of physiotherapy and occupational therapy received per subject: median number of working days (Wd) when therapy was received

	Control (n = 61)	Intervention (n = 62)	p-value
Length of stay (all subjects) (days)	31	37	0.524
Length of stay (survivors) (days)	30	37	0.449
Preintervention	4	4	0.552
Intervention period – inpatient	20	19	0.967
Intervention period – outpatient	10	11	0.350
Postintervention period until discharge from therapy	71	59	0.896

**Table 6** Actual amount of therapy received during the intervention period (median minutes per working day)

	Inpatient			Outpatient		
	Control (n = 61)	Intervention (n = 60)	p-value	Control (n = 33)	Intervention (n = 36)	p-value
Physiotherapist (unidisciplinary)	n = 60 21	n = 57 12	<0.001	n = 30 9	n = 29 8	0.29
Occupational therapist (unidisciplinary)	n = 47 8	n = 47 6	0.03	n = 20 5	n = 16 3	0.03
Joint sessions (from physiotherapist and occupational therapist)	n = 4 4	n = 59 29	0.006	n = 0 0	n = 20 10	0.001
Physiotherapy assistant	n = 46 4	n = 33 3	0.45	n = 7 16	n = 9 3	0.14
Occupational therapy assistant	n = 18 4	n = 14 7	0.48	n = 8 9	n = 6 2	0.005
Generic support worker	n = 14 8	n = 16 3	0.11	n = 20 82	n = 16 46	0.14
Total	38	52	0.001	56	25	0.13
Total excluding GSW	35	50	<0.001	22	18	0.71

GSW, generic support worker.

Median (mean) minutes/working day/subject who received joint sessions.

Enhanced upper limb therapy did not result in reduced length of inpatient stay or less input from health or social services following discharge.

We were keen to include a heterogeneous group of patients who were representative of patients on a stroke rehabilitation ward yet despite broad eligibility criteria only 20% of patients admitted with stroke participated in the study. Other UK studies of early intensive upper limb therapy have recruited a similar proportion.<sup>11,12</sup> Sunderland *et al.* found that those with mild/moderate but not severe impairment benefited from enhanced upper limb rehabilitation,<sup>12</sup>

while Feys *et al.* showed that those with severe initial impairment benefited most.<sup>13</sup> It is therefore appropriate to include patients with all levels of upper limb impairment in trials of this kind unless the intervention requires the participant to be able to attempt specific tasks, such as repetitive movement or forced use.

Early intervention offers the maximal opportunity to influence recovery. The ideal time to begin an intervention of this nature is unclear so the 10-day recruitment window was a pragmatic decision. There is an argument for including only patients who can tolerate extra therapy in reha-

bilitation trials. As 'able to tolerate' is difficult to define and the patient's condition can fluctuate in the first few weeks after stroke we did not use this as an eligibility criterion. Not all rehabilitation involves active participation and early 'passive' therapy which addresses positioning, tone or neglect might improve outcome or prevent future problems. However, 29 (47%) patients in the intervention group and 13 (21%) patients in the control group did not receive at least one planned therapy session during the intervention period. This was usually due to fatigue, poor concentration or they were too unwell. This compares with 20%<sup>11</sup> in the intervention group of a study which recruited 22% of stroke admissions between one and five weeks after stroke and 14%<sup>10</sup> in another which recruited 3% of stroke admissions within 14 days of stroke.

As upper limb re-education is a feature of both occupational therapy and physiotherapy, we felt that joint therapy sessions would produce 'added value'. The provision of the intervention by a single physiotherapist and a single occupational therapist is a limitation of the study and reduces the generalizability of the results. The intensity of the intervention was based upon what was practical and could be implemented in practice in the UK. At the time of this study a median of 0.8 (interquartile range (IQR) 0.2–1.4) physiotherapy sessions (one session = half a day) and 0.6 (IQR 0.2–1) occupational therapy sessions per week from trained therapists were available per patient on stroke rehabilitation units in the UK.<sup>31</sup> If all available time was used in direct patient contact, this equates to 2.8 hours per week per patient for physiotherapy and 2.1 hours per week for occupational therapy. Although much higher levels of therapy are available in stroke units and rehabilitation units elsewhere, the stroke units evaluated by the Stroke Unit Trialists Collaboration provided 1–2 physiotherapy sessions per bed per week and 0.9–1.3 occupational therapy sessions per bed per week.<sup>32</sup>

The amount of extra therapy provided was similar to other studies of enhanced therapy<sup>9</sup> but it was considerably less than studies of repetitive tasks and 'forced use' of the affected arm where treatment was provided for at least 6 hours per day.<sup>33–35</sup> We aimed for those in the intervention group to receive 2.5 hours per week extra

therapy specifically for the upper limb but it may be that the amount of treatment received by intervention and control groups was not sufficiently different to affect outcome and that a more intensive programme is required.

The 'gold standard' for any inpatient stroke rehabilitation trial is stroke unit care. All participants in this study were treated on a stroke unit. Fifty-five per cent of patients in the trial by Lincoln *et al.* received stroke unit care<sup>11</sup> but the proportion in other studies is not stated.<sup>10,12,13</sup>

It is important to try to describe and measure not only the intervention but the 'standard' therapy received in complex intervention trials but there is no widely accepted method because of the eclectic nature of rehabilitation.<sup>36</sup> Prior to the study we did discuss developing a treatment manual and treatment protocols but variation in neurological impairment following stroke makes it difficult to ascribe standard quantities and components of therapy and therapy content is heavily influenced by the educational background of the individual therapists. Standardization of therapy may be possible in future research as three relatively small studies have reported improvement in upper limb function using a neurodevelopment approach which requires a skill to be relearned through practising in a varied context.<sup>33–35</sup>

Accurate recording of the actual amount of treatment received by intervention and control groups is essential to understanding intervention trials. However, this practice is currently not universal. The prime weakness of this study is that although the intervention group did receive joint treatment sessions as planned, the control group received more unidisciplinary rehabilitation and more therapy assistant time. This represents a 'competitive therapy' bias. Stroke unit therapists were not blinded to the randomization group so perhaps felt that those in the control group were disadvantaged and so prioritized these patients. Treatment for both intervention and control patients was undertaken within the stroke unit, so to avoid this bias perhaps subjects in both groups should have left the ward for active or sham treatment sessions. However, in practice this would have been difficult to achieve, particularly for patients with significant disability. Although this may have affected our results, it

should be noted that we were able to identify the competitive therapy bias by recording the actual treatment received by both groups. The design of future studies needs to take into account this potential source of bias.

It has been argued that outcome measures such as the ARAT are unsuitable to evaluate the effectiveness of different approaches to stroke rehabilitation, as they do not relate to the conceptual framework of the therapy applied.<sup>37</sup> While we recognize that the ARAT has some limitations, it is a measure of upper limb function, which is an important outcome for patients.

On completion of the study we reviewed the statistical power and can confirm that the study does have adequate statistical power. The ARAT at three months after stroke was available for 105 subjects (73% predicted) which gives a study power of 0.7 based on our initial calculations. However, the ARAT standard deviation used for the initial power calculation was considerably larger than was found in the study subjects. Using the actual figure a retrospective examination of the power has shown that 105 subjects would have a power of 0.97 of detecting the 10% ARAT difference.

The maximum ARAT score is 57. At three months after stroke the median ARAT score for the intervention group was 53 and 54 for the control group, indicating considerable functional recovery. The median values are considerably higher than was seen at six months after stroke in the study by Lincoln *et al.* (control group = 19; assistant physiotherapist = 23; qualified physiotherapist = 3)<sup>11</sup> and three months after stroke in the study by Kwakkel *et al.* (control = 0; arm training = 3)<sup>10</sup> despite all three studies having similar baseline values. The reasons for these differences are unclear but perhaps could be explained by the fact that all patients in our study received stroke unit care from early in their inpatient stay. It may therefore be difficult to improve upon outcomes which are already good by giving more therapy.

Previous reviews suggest that current evidence about enhanced upper limb therapy following stroke is inconclusive.<sup>8,9,38-40</sup> Our study did not find that patients who received a more intensive upper limb therapy regime provided jointly by a physiotherapist and occupational therapist had

better outcomes. Unlike most previous studies we have compared enhanced therapy with current best practice (i.e., stroke unit care) and perhaps this in part explains why we have not demonstrated a difference. Further research is needed to identify predictors of upper limb recovery within a stroke unit setting and to identify effective interventions to improve upper limb function. There is also a need to develop tools to describe and measure components of therapy for use in trials in stroke rehabilitation.

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