

The effects of increased rehabilitation therapy after brain injury: results of a prospective controlled trial

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Objective: The objective was to investigate the effect of increased intensity of rehabilitation therapy provided to brain-injured subjects on the rate at which independence was regained and the duration of hospital admission.

Design: A two-centre, prospective, controlled study with random allocation to groups.

Setting: Two district general hospitals on the south coast of England.

Subjects: Fifty-six people with moderate and severe head injury consecutively admitted to Southampton and Poole hospitals between June 1995 and September 1997.

Interventions: Increased intensity of rehabilitation therapy input without change in content.

Results: Subjects receiving more intensive therapy made more rapid progress and were discharged home sooner. The different intensities of therapy employed in this study showed no evidence of a 'ceiling' effect and the 'intervention group' made significantly more rapid progress on tests of dependency during the period of admission. A clear response to increased therapy input was seen in one of the centres with more rapid functional improvement and a shorter length of hospital stay. This centre already had more therapy and better community facilities. No such benefits were seen at the other centre where the intervention group had a longer hospital stay than the routine group.

Conclusion: Increasing the hours per week of therapy given to adults recovering from brain injury in hospital can accelerate the rate of recovery of personal independence and result in their being discharged from hospital sooner. Increased rehabilitation therapy after brain injury is associated with enhanced functional recovery and shorter hospital stay if provided in the context of an integrated service that can provide ongoing community support. There is no evidence of any ceiling effect of therapeutic intensity beyond which no further response is observed.

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Introduction

Rehabilitation after brain injury is time-consuming and costly. Formal rehabilitation may not begin for a considerable time after injury, either because of a belief that subjects have to reach a specific level of responsiveness to benefit or because demand exceeds the beds available and subjects therefore have to wait for a place on a specialist rehabilitation unit. Little is known about either the optimum intensity of treatment or about the optimum timing of its delivery. Although anecdotally there is a belief that greater amounts of therapy lead to better outcome, there is little empirical evidence to support this notion.

There have been few systematic attempts to evaluate the effect of altering the timing or amount of rehabilitation therapies delivered to people recovering after brain injury. Cope and Hall¹ studied two patient groups matched for age, length of coma, level of disability, CT scan findings and neurosurgical intervention. Subjects were divided retrospectively into groups who started rehabilitation either sooner or later than 35 days after injury. The group who started rehabilitation sooner left hospital significantly earlier after their injury. Hall and Wright² studied prospectively two groups of patients, matched for age, coma, level of disability, CT scan results and neurosurgical intervention. Early transfer to a specialist rehabilitation unit was found to be associated with a shorter duration of inpatient stay. MacKay *et al.*³ examined a group of 38 subjects half of whom received some rehabilitation input prior to admission to a specialist rehabilitation unit. The 'control' group was matched for severity of injury and received *ad hoc* treatment. Interventions were according to needs and included provision of family information and co-ordination of rehabilitation teams. The results suggested that the treatment group spent less time in coma and, on average, 30% less time as inpatients in total. There were significant differences between the groups with regard to level of independence and motor, cognitive and perceptual skills, both on admission to and discharge from rehabilitation. Even taking this imbalance into account, the conclusions were that a greater percentage of subjects returned home in a shorter

period of time when rehabilitation had begun earlier. However, in all of these studies the timing of intervention rather than the intensity was manipulated.

Clearly, aspects other than actual intensity of intervention such as age can also affect outcome and need to be controlled for. Vollmer *et al.*⁴ concluded that less severe injuries may result in a worse outcome in older people than in younger people but suggested that this may be a result of interaction effects between the head injury and other medical conditions rather than any effects of age *per se* on the process of recovery. Pennings *et al.*⁵ concluded that elderly patients had higher mortality, worse functional recovery and consumed more resources than younger patients with similar injury.

The effects of differing intensities of rehabilitation have not been tested formally in a prospective study with brain-injured patients. The aim of this study was to evaluate the effect of providing a greater intensity of therapeutic input to a group of brain-injured patients compared with a control group and evaluating the impact of this increase on outcome in terms of functional independence and length of stay.

Method

This was a two-centre prospective controlled study with random allocation to intervention or routine treatment groups. Ethical Committee approval was granted in both centres and written consent of next of kin was obtained. Subjects were free to withdraw from the trial at any stage if they, or their relatives, requested this.

Subjects

Subjects were recruited from two general hospitals on the south coast of England – Poole Hospital and Southampton General Hospital. The criteria for entry to the study were as follows:

- 1) Acquired brain injury – severity of injury was assessed as follows: severe brain injury – Glasgow Coma Scale (GCS)⁶ score after resuscitation of 3–8 and moderate brain injury – GCS of 9–12 respectively.
- 2) Age 16–70 years.

- 3) No history of neurological illness, significant mental illness, learning disability or previous CNS trauma, including stroke or head injury.

All patients meeting the criteria were eligible for entry to the study. In some cases patients were not admitted to the rehabilitation ward but were resident and treated on a general medical or surgical ward for the duration of their admission. These cases were seen by the researchers and the general ward team if randomized to the intervention group but by the general ward team only if randomized to the routine group.

Randomization

The Research Unit Experimental Officer (MEB), who was otherwise uninvolved in the research, implemented the randomization using a computer package. Age, centre and severity of injury, judged on the basis of the GCS, were used to stratify the allocation. In order to match groups as equally as possible, random permuted blocks within strata were used.⁷ Allocation was prepared using the following parameters:

- 1) Age – 45 years and under, and 46 years and over.
- 2) GCS – those scoring 8 or less and those scoring between 9 and 12.

Of the subjects with GCS of 8 or less, 25% were randomized to intensive treatment on recruitment and 75% to routine treatment. When the GCS scores of the subjects on routine treatment reached 12, they were re-randomized so that a further 25% of the total were allocated to the intervention group while the rest remained in the control group, resulting in 50% being allocated to each group. The rationale for this was first that there is evidence that younger people make better recovery from head injury.^{4,5} Second, a previous study⁸ had found that more severely injured subjects (those who remained in coma for between 6 hours and one week) showed considerable variability in their subsequent rates of recovery. Therefore, in order to ensure an optimal balance of severity between the routine group and the intervention group randomization took place in two stages (Figure 1).

This resulted in a complex system of allocation that was held on computer and was accessible only to the experimental officer in charge of ran-

domization. Subjects were recruited by the researchers based at each centre who telephoned details of injury severity, centre and age to the experimental officer who then gave the treatment allocation. Outcome measurement at discharge and one year after injury was done by a masked assessor and the codes were only broken when all one year assessments were complete.

Provision of extra therapy

Additional treatment was provided to subjects in the intervention subgroups by an additional experienced health care professional, one of whom was based at each centre. In Southampton, this was an occupational therapist (OT) (DH) with eight years' experience and, in Poole, a rehabilitation nurse (RN) (JC) with 10 years' experience. Intensive treatment consisted of the routine treatment from the multidisciplinary team supplemented by treatment from the additional staff member as requested by the team. By prior agreement no routine treatment was withdrawn from the intervention group – in other words the input from ward staff was unchanged for all patients irrespective of their group. The implementation of this undertaking was checked by careful recording of the nature, purpose, duration and provenance of all the treatment received by both groups of patients as described below.

Provision of routine therapy

The multidisciplinary team at each centre provided routine therapy. However, the staffing levels of nursing staff and therapists differed between the units and are shown in Table 1. This imbalance meant that the mean weekly amount of routine therapy provided to both subgroups in Poole was significantly greater than in Southampton. Further details are given in the results.

Procedure

The objectives of treatment for each subject and therefore the problems addressed by the researchers were determined by the multidisciplinary team at each centre who requested additional input from the researchers as appropriate to the particular subjects in the intervention group. Both the additional members of staff were highly experienced clinicians. The research therapists in both centres worked across the spectrum

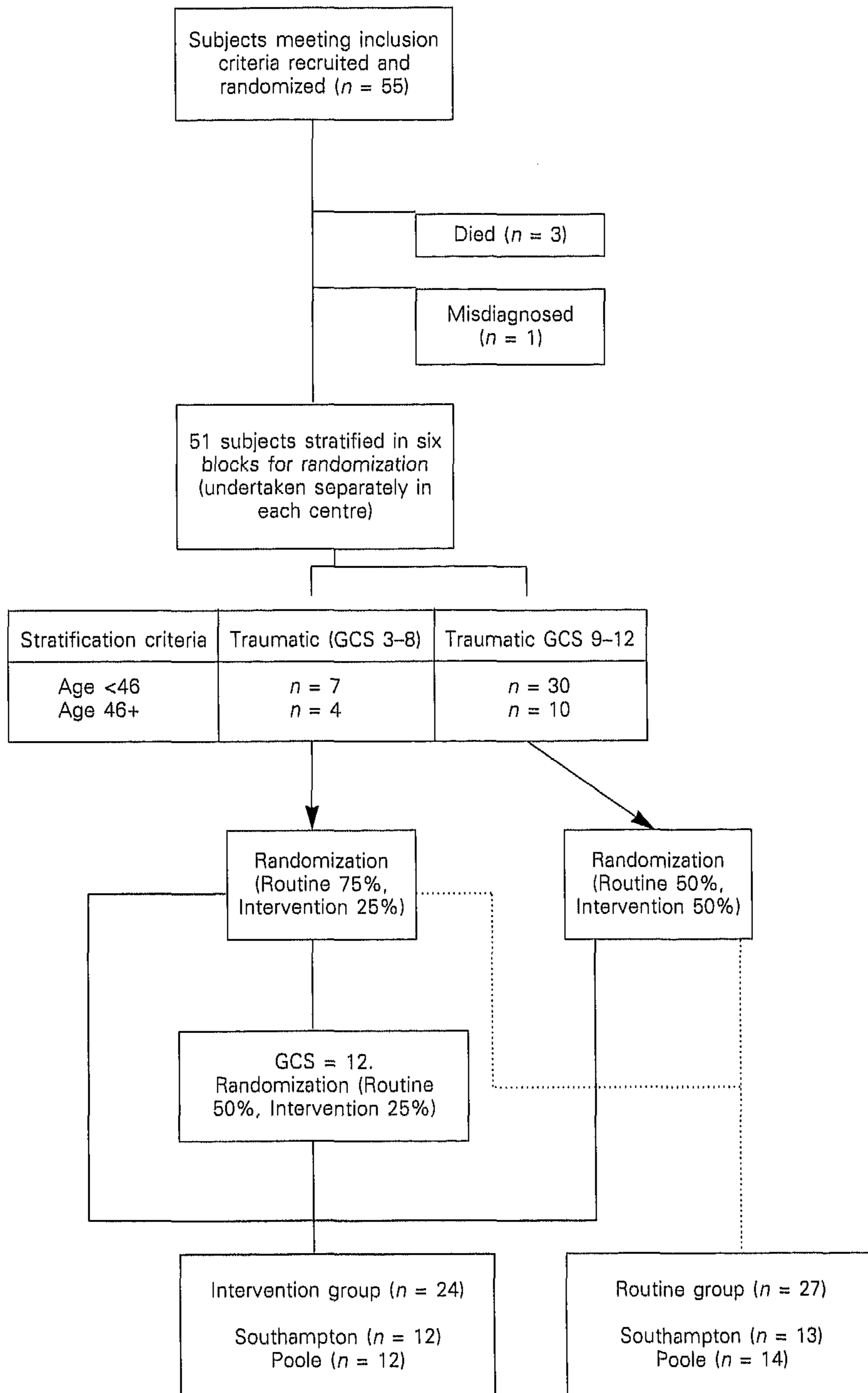


Figure 1 Randomization procedure.

Table 1 Staffing levels at participating centres at the time of the study

Staff	Southampton	Poole ^a
Medical	0.6 Consultant 0.5 Registrar House officer	1.0 Consultant - -
Therapy	Physiotherapy - 2 full time PT helper - 1 part time OT - 1 full time OT helper - 1 part time SALT - 1 part time Psychology - 1 clinical psychologist part time Occasional input from a range of social workers	Physiotherapy - 3 full time PT helper - 1 full time OT - 2 full time OT helper - 1 full time SALT - 2 full time Psychology - 1 clinical psychologist and two assistant psychologists full time 1 social worker full time
Nursing	10 trained nurses full time 2 trained nurses part time 4 nursing assistants full time 1 nursing assistant part time	13 trained nurses full time 9 trained nurses part time 8 nursing assistants full time 2 nursing assistants part time
Rehabilitation beds	14 in specially adapted unit	5 neurorehabilitation beds and 15 other beds (neurology and dermatology) in the same ward ^{a,b}

^aIn Poole, the brain-injury team provide a rehabilitation service to outliers in general beds and also provide the outpatient rehabilitation service to the brain-injured patients.

^bThe nursing staff work with all patients on the ward. The other staff on the brain-injury team work with rehabilitation patients only.

PT, physiotherapist; OT, occupational therapist; SALT, speech and language therapist.

of rehabilitation disciplines providing programmes suggested and agreed to by the team. The intention was that the additional therapy received by the intervention group should differ only in intensity (i.e. hours per week) from that received by the control group. However, it was also agreed that the nature and range of objectives potentially addressed by the whole team would be similar for both the intervention and control group. A summary of the interventions provided by the researchers is shown in Table 2.

Evaluation

Duration of coma was assessed using the Glasgow Scale.⁶ A patient was defined as being in coma if he or she had a score of 8 or less on the GCS and out of coma if the GCS was 9 or more.⁶ Duration of post-traumatic amnesia (PTA) was assessed using the Modified Westmead PTA test.⁹ Detailed timetables of all treatments delivered to both routine and intervention groups were kept. The duration of face-to-face therapy

delivered to each subject by the team for both groups and by the researcher for those in the intervention group was recorded daily in minutes by the research therapists. Face-to-face intervention by the team was categorized according to the discipline that delivered it and the interventions provided by the researchers were categorized according to the discipline of the team member who requested that the researcher provide it. For example, if an OT requested that the researcher carry out an orientation programme with the subject this was recorded as an OT intervention, although in terms of the content it covered, could be equally have been categorized as a psychological intervention. Detailed records of the treatment objectives in each case were also kept.

Subjects' progress was monitored using the Functional Independence Measure and Functional Assessment Measure (FIM+FAM).^{10,11} The FIM+FAM is a 30-item scale of dependency (FIM = 18 items; FAM = 12 items). It focuses on activities of daily living (ADL) (self-care, sphinc-

Table 2 Examples of interventions provided by researchers

Interventions	Examples
Cognitive	Assessment of cognitive function Functional cognition, e.g. planning and executing tasks, route planning, managing money Memory programmes Attention training
Motor	Stretching and range of movement prior to physiotherapy Passive movements Positioning Stamina and fitness exercises Transferring practice
Communication	General conversation Reading and writing practice Practising speech exercises Practice in the community – asking for something in shops, asking for directions, etc.
Self-care	Washing and dressing practice Transfer practice
Social	Taking patients outside the hospital Assessing safety in the community, e.g. crossing road, using public transport
Community integration	Home visits Work assessments
Behavioural	Designing and participating in running behaviour programmes Recording behaviours using ABC chart
Family support	Talking to and providing information to relatives Liaison with other agencies Allowing relatives to 'let off steam' Communication between staff and relatives where necessary
Feeding	Supervision when patient had swallowing difficulty Supervision of meals when patients needed to be prompted to eat Referral for provision of aids where necessary
Other	Liaison with outside agencies, e.g. Headway Contributing to staff training and development

ter control, mobility and transfers) but also includes assessment of functional communication, cognitive and psychosocial performance. Subjects are assessed on a seven-point scale ranging from 'Dependence' to 'Independence'. Assessment is on the basis of what patients actually do (performance) rather than what they are capable of doing (capacity).

Data analysis

Data analysis concentrated on identification of differences between the intervention group and the routine group. Because the groups were

small, data were ordinal and could not be considered to be normally distributed, nonparametric tests, which make no assumptions regarding the distribution of the data, were used. As the overall amount of therapy provided was greater in Poole, data analysis included a four-way comparison between subgroups (Kruskal-Wallis) and within centres with *post hoc* Mann Whitney tests to identify where differences lay (where appropriate). As the number of statistical comparisons carried out was large, with two way and four-way comparisons, a modified Bonferroni correction for multiple groups was applied.¹² To calculate

this, the nominal alpha (0.05) is multiplied by the degrees of freedom (3) and divided by the total number of comparisons (70). The level of statistical significance applied to these results was thus 0.0021.

Results

The sample comprised 56 subjects with severe and moderate head injury, who were consecutive admissions to Southampton and Poole hospitals. Ages ranged from 16 to 67 years ($\bar{X} = 36.7$ (SD 15.2) years). The duration of coma ranged from 1 to 54 days ($\bar{X} = 12$ days, SD 13). The duration of post-traumatic amnesia (PTA) which was measured prospectively, ranged from 5 to 299 days ($\bar{X} = 56$, SD 58). Three subjects died following recruitment and randomization and two subjects were excluded after recruitment and randomization, one because the original diagnosis of encephalitis was changed to multiple sclerosis and the other because the cause of injury was found to be a stroke. This resulted in a study sample of 51 subjects. Consent was refused for two subjects who were eligible for inclusion.

Randomization

As the majority of severely head-injured subjects were electively sedated and ventilated, few subjects were recruited when their GCS was less than 8. Demographic and injury severity details of the sample presented within subgroups in centres are presented in Table 3.

Group allocations and matching between centres and between groups

Centres

The Poole subjects differed from the Southampton subjects in the total duration of hospital admission (Poole $\bar{X} = 96$, SD 80; Southampton $\bar{X} = 158$, SD 101, $U = 173$, $Z = -2.694$, $p = 0.004$). There were no significant differences either between the centres with regard to age or severity of injury as indicated by initial GCS, GCS after resuscitation, duration of coma (i.e. GCS <9) or duration of PTA. However, there was a difference between the centres in FIM+FAM scores on admission relating to sphincter control ($U = 184$, $Z = -2.347$, $p = 0.03$)

and discharge sphincter control ($U = 105$, $Z = -3.47$, $p = 0.003$) and transfers ($U = 109$, $Z = -3.41$, $p = 0.05$) with subjects in Poole being more dependent. When the modified Bonferroni correction is applied to these results however, the differences cease to reach significance. Details of median scores and interquartile ranges for all domains are in Table 4.

Subgroups within centres

Subjects' levels of independence on admission to the trial and on discharge were examined using Mann-Whitney U -tests. There were no significant differences between the intervention group and the routine group with regard to any of the demographic variables on admission to the trial. The Poole subjects in both subgroups were more dependent in relation to sphincter control on admission than the Southampton intensive subgroup and more dependent on discharge from hospital than either of the Southampton subgroups. On all other domains of the FIM+FAM the groups did not differ significantly. Full details of median scores, interquartile ranges and p -values are given in Table 5.

Routine therapy provision

The median total duration of routine therapy provided did not differ significantly between the centres but was delivered over a shorter time frame in Poole, where more therapy per day was delivered. Analysis using Kruskal-Wallis tests with *post-hoc* Mann-Whitney tests showed that both the routine and intervention subgroups in Poole (\bar{X} routine therapy Poole 580 minutes per week, SD 211, median 639) received significantly more weekly input than those in Southampton (\bar{X} routine therapy Southampton 402 minutes per week, SD 208, median 424) ($\chi^2 = 11.36$, df 3, $p = 0.0099$). These differences between the groups (i.e. intervention and control) and the centres (i.e. Poole and Southampton) are considered further in the later analysis.

Duration of admission

There were significant differences between the two centres with regard to duration of admission. Subjects in Poole were discharged a median of 62 days earlier than in Southampton (median stay: Southampton 131 days, IQ range 25, 240; Poole

79 days, IQ range 25, 144; $U = 173$, $Z = -2.864$, $p = 0.004$) (Figure 2).

Further analysis within subgroups and between centres, using a Kruskal-Wallis test with *post-hoc* Mann-Whitney, showed that subjects in the

intervention subgroup in Southampton remained in hospital significantly longer than any of the other subgroups ($p = 0.001$) (Figure 3).

With regard to differences between the total intervention group and routine group, there was

Table 3 Description of groups: mean (standard deviation (SD)), median and ranges of demographic data in the two centres

		Southampton		Poole		<i>p</i> -value
		Intensive	Routine	Intensive	Routine	
Age at injury (years)	X (SD)	34.2 (14.6)	36.2 (13.9)	37 (18.2)	39 (15.9)	ns
	Median	32	34.5	32	34	
	Min-max	16-59	17-59	17-67	21-65	
Time in general ward (days)	X (SD)	48.7 (61.6)	49.2 (73.7)	32 (24.1)	19.9 (16.2)	ns
	Median	35	25	30	14	
	Min-max	0-244	0-294	5-68	0-49	
Total delay to admission to rehabilitation unit (days)	X (SD)	55.5 (72.2)	51.7 (81.6)	37.5 (21.3)	24 (15.8)	ns
	Median	48.5	39.5	34	24	
	Min-max	1-244	0-294	10-69	0-55	
Time in rehabilitation unit (days) ^a	X (SD)	125 (85.7)	54.9 (71.2)	44 (61.4)	75 (83.4)	0.03
	Median	102	24.5	30	42	
	Min-max	0-288	0-218	(0-172)	0-275	
Total length of hospital admission (days) ^b	X (SD)	187 (96.9)	123.5 (101.4)	64 (51.8)	95 (88.9)	0.006
	Median	197	71.5	44	77	
	Min-max	37-357	27-342	13-182	4-311	
GCS on admission	X (SD)	-	-	-	-	ns
	Median	5	6	4.5	5	
	Min-max	3-13	3-13	(3-15)	(3-14)	
GCS after resuscitation	X (SD)	-	-	-	-	ns
	Median	8	8	13	11	
	Min-max	3-15	7-15	7-15	7-15	
Coma (days)	X (SD)	16 (21.4)	7.5 (5.3)	15.6 (15.3)	10.4 (9.1)	ns
	Median	6.5	7.5	14	8	
	Min-max	1-54	1-15	1-46	(1-30)	
PTA (days)	X (SD)	64 (105.1)	61.2 (48.1)	46 (42.3)	55 (43.9)	ns
	Median	28	39	24	48	
	Min-max	5-299	13-141	10-120	(5-126)	

^a*Post-hoc* Mann-Whitney tests showed differences between the Southampton Intensive group and the Southampton Routine group ($p = 0.02$) and between the Southampton Intensive group and the Poole Intensive group ($p = 0.009$)*.

^b*Post-hoc* Mann-Whitney tests showed statistically significant differences between the Southampton Intensive group and the Poole Intensive group ($p = 0.001$)* and between the Southampton Intensive and Poole Routine group ($p = 0.01$). There were no statistically significant differences between the total intensive and control groups on any of these parameters.

Delay times are measured from the time of injury or first admission to hospital.

*Statistically significant with modified Bonferroni correction.

GCS, Glasgow Coma Scale; PTA, post-traumatic amnesia.

Table 4 Admission and discharge FIM+FAM scores for Southampton and Poole groups (medians and interquartile ranges)

Domain	Southampton	Poole	Z	Significance
Self-care				
Admission	23 (12,45)	13 (7,39)	-2.018	ns
Discharge	47 (41,49)	44 (44,49)	-1.375	ns
Sphincter				
Admission	13 (14,28)	6 (2,14)	-2.456	0.03
Discharge	28 (14,28)	14 (10,14)	-3.332	0.003
Transfers				
Admission	13.5 (6, 25)	5.5 (4,20,25)	-2.201	0.05
Discharge	26 (23,28)	27 (14,28)	-0.394	ns
Locomotion				
Admission	4 (3,15)	3 (3,11.5)	-1.730	ns
Discharge	17 (14.5,19)	18 (11,21)	-0.142	ns
Communication				
Admission	24.5 (9.75,33)	17.5 (7.25,29)	-1.575	ns
Discharge	20 (23,33)	29 (20,33)	-0.733	ns
Psychosocial				
Admission	13.5 (4,25)	7.5 (4,15.5)	-2.356	ns
Discharge	20 (16,24)	21 (8,23)	-0.461	0.04
Cognitive function				
Admission	15 (15,30)	7 (5,19.75)	-1.762	ns
Discharge	25 (18,33)	27 (16,31)	-0.649	ns

Table 5 Median and interquartile ranges of FIM+FAM scores on admission and discharge for the groups and centres and probability of statistically significant differences

Domain	Southampton		Poole		Significance
	Intensive	Routine	Intensive	Routine	
Self-care					
Admission	22 (8,39)	36 (19,45)	7.5 (7,25)	24 (9,41)	ns
Discharge	47 (41,49)	47 (41,49)	46 (41,49)	42 (23,49)	ns
Sphincter					
Admission	5 (4,19)	14 (8,28)	3 (2,12)	6.5 (4,14)	0.03
Discharge	21 (14,28)	28 (13,28)	14 (14,14)	11 (4.5,14)	0.003
Transfers					
Admission	6 (5.5,28)	19 (8,25)	4 (4,13.75)	9.5 (4,25)	ns
Discharge	27 (23,28)	26 (22,28)	28 (24,28)	23 (11.5,28)	ns
Locomotion					
Admission	4 (3,17)	5 (3,13)	3 (3,4)	3 (3,13)	ns
Discharge	17 (12,19)	17 (15, 19)	21 (14,21)	14 (6,20.2)	ns
Communication					
Admission	18 (7,31)	27 (16,33)	14 (6.5,26.5)	20 (7,29)	ns
Discharge	30 (21,34)	29 (26,32)	29 (28,33)	26 (14.5,33)	ns
Psychosocial					
Admission	8 (4,26)	17 (11,24)	7.5 (4,12)	8 (4,19.75)	ns
Discharge	17 (15, 25)	20 (17,24)	22 (18,23)	15 (6.5, 23)	ns
Cognitive function					
Admission	6 (5,32)	18 (9,27)	5.5 (5,17.5)	8.5 (5.5, 24.5)	ns
Discharge	34 (11,32)	25 (20,34)	28 (16,31)	26 (9.5,29.5)	ns

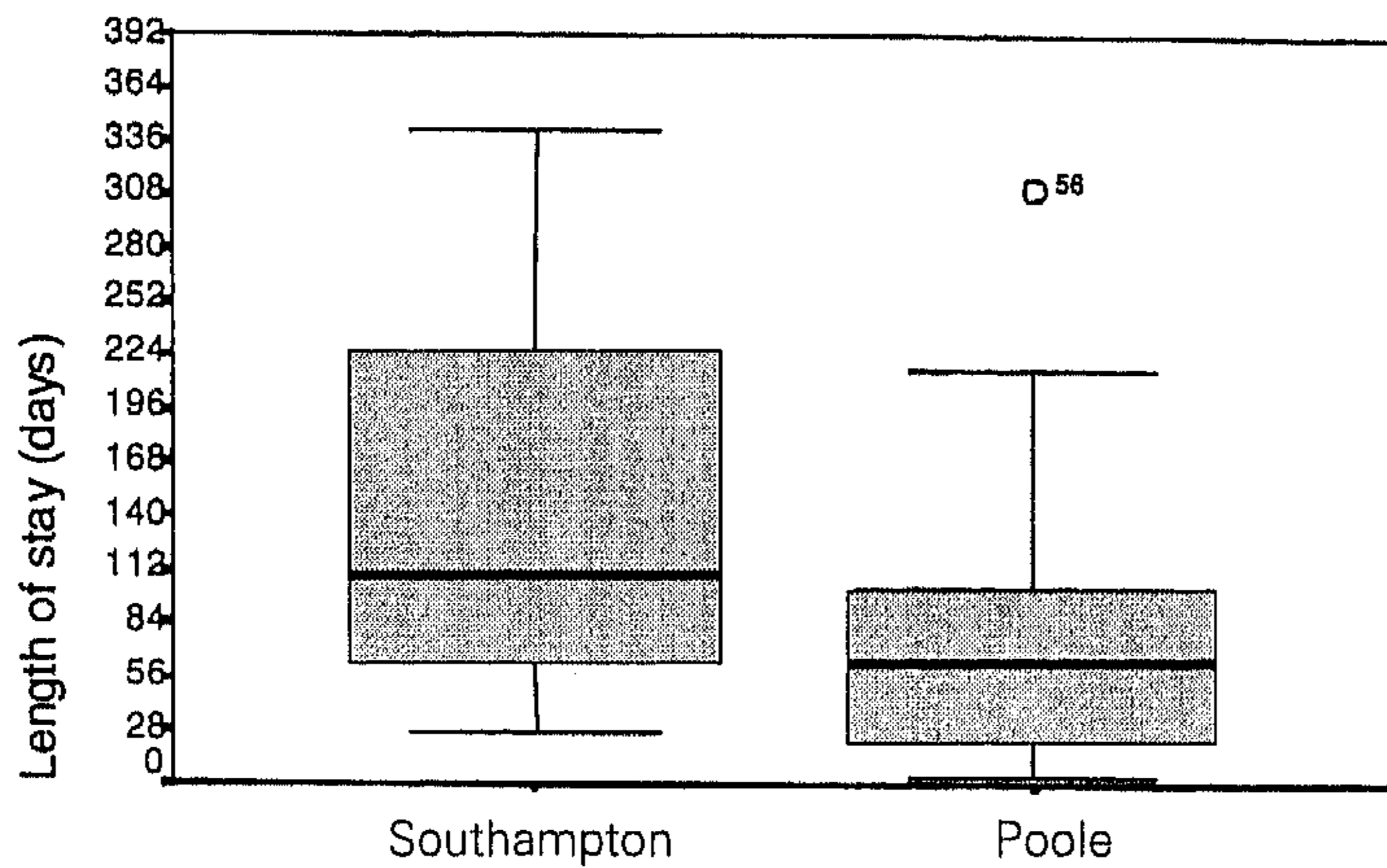


Figure 2 Length of stay in centres.

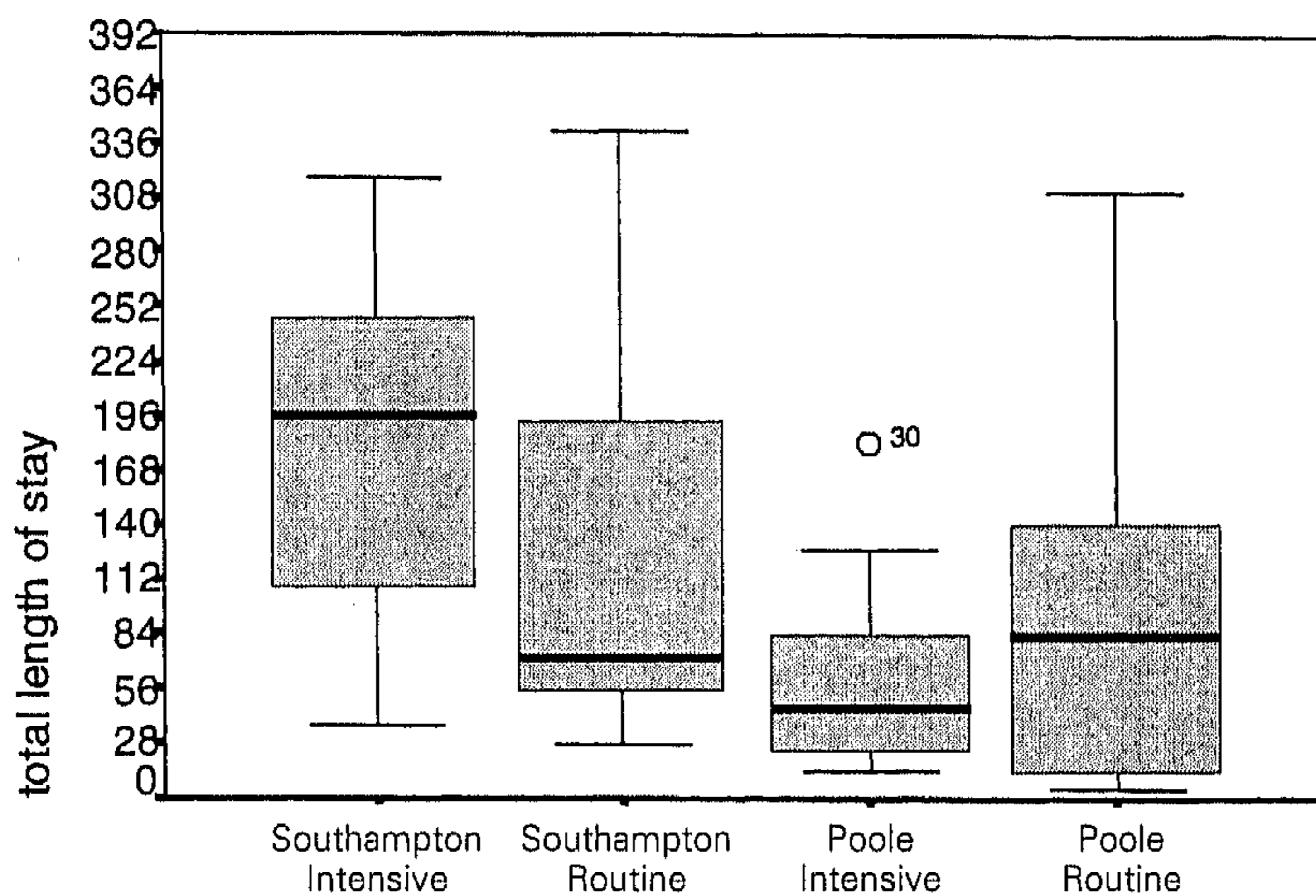


Figure 3 Length of stay within groups and centres.

no significant difference in overall duration of stay ($U = 305$, $Z = -0.569$, ns). This somewhat unexpected finding can be explained by the long period of admission for the intervention subgroup in Southampton (see Figure 2).

Level of function

On admission to the trial, subjects in the intervention group were more dependent in self-care ($U = 204$, $Z = -1.950$, $p = 0.05$) and sphincter con-

trol ($U = 206$, $Z = -1.910$, $p = 0.05$). On discharge, there were no differences between the groups. This was not surprising in that it is to be expected that subjects would have to reach a certain level of independence before discharge from hospital can take place (Table 6).

Of more interest was whether patients in the intervention group achieved this level of independence more quickly or made more rapid progress than the subjects in the control group.

Table 6 Admission and discharge FIM+FAM scores and interquartile ranges for intervention and routine groups (medians and interquartile ranges)

Domain	Intervention	Routine	Z	Significance
Self-care				
Admission	13 (7,28)	32 (12.5,14)	-1.777	0.03
Discharge	46 (41,49)	45 (33, 49)	-0.637	ns
Sphincter				
Admission	4 (3,14)	14 (5.5, 16)	-1.689	0.04
Discharge	14 (7,28)	14 (7.75,28)	-1.515	ns
Transfers				
Admission	6 (4,18)	13 (5,25)	-1.056	ns
Discharge	28 (24,28)	26 (13,28)	-1.500	ns
Locomotion				
Admission	3 (3,8)	4 (3,13)	-0.930	ns
Discharge	17.5 (13.75, 21)	15.5 (10.25, 19)	-1.539	ns
Communication				
Admission	18 (7,29)	27 (9,31)	-0.832	ns
Discharge	29.5 (23.75, 33)	28 (19,32)	-0.810	ns
Psychosocial				
Admission	8 (4,18)	14 (5.5,21)	-0.934	ns
Discharge	21.5 (15, 23.5)	19 (12.5, 23.5)	-0.850	ns
Cognitive function				
Admission	6 (5,24)	17 (7,25)	-1.018	ns
Discharge	26 (16,32)	26 (15.5,31)	-0.692	ns

In order to evaluate this, the change in scores between admission and discharge was calculated and differences tested using nonparametric analysis, which ranks the data and makes no assumptions about distribution. Results are shown in Table 7.

In all domains of the FIM+FAM the median change made by the intervention group was greater than that made by the routine group. Given that the subjects did not differ significantly on admission to the trial on these parameters, this suggests that the intervention group progressed more rapidly. However, if this is the case,

it is surprising that this accelerated progress was not reflected in an earlier discharge for the intervention group.

Comparison between groups within and between centres

Despite the fact that every effort had been made to match the groups equally, it was felt that the greater provision of routine therapy in Poole had an effect on rate of skill acquisition or reacquisition. Consequently, a within-subgroup between-centre analysis was also carried out. A four-way analysis was undertaken using Kruskal-

Table 7 Median increase in FIM+FAM scores and interquartile ranges during admission between intervention and routine group

Domain	Intervention	Routine	Z	Significance
Difference in self-care	30 (25,38)	12 (0,18)	-3.602	<0.001
Difference in continence	12 (1,17)	0 (0,7)	-3.319	0.001
Difference in transfers	18 (13,23)	5 (0,9)	-3.005	0.002
Difference in locomotion	14 (8.5,17)	4 (2,14)	-2.692	0.008
Difference in communication	12 (4.5,22.5)	4 (2,8)	-2.436	0.01
Difference in psychosocial	12 (5.5,17.5)	2 (1,4)	-2.426	<0.001
Difference in cognition	16 (5,23.5)	6 (2,10)	-2.732	0.008

Wallis tests with *post-hoc* Mann-Whitney tests where appropriate. The greatest differences were in the domains of self-care, transfers, locomotion and psychosocial functioning and sphincter control in which subjects in the intervention subgroups made significantly more progress. Details are in Table 8.

Post-hoc Mann-Whitney tests were then carried out to establish where the differences lay. There were no statistically significant differences between the centres but the differences between the subgroups within the centres were significant (Table 9).

Discussion

The principal aim of this study was to evaluate the effect of an increased intensity of rehabilitation therapy after traumatic brain injury. Despite extensive searching, few studies comparing intensities of treatment with head-injured patients have been found. Amongst the reasons for this may be the difficulties of carrying out such a study. In order to recruit enough subjects, two centres, one of which had considerably better staffing levels and could routinely provide more

Clinical messages
<ul style="list-style-type: none"> • Increasing intensity of treatment can facilitate more rapid acquisition of independence and reduce length of stay. • No 'ceiling' effect of intensity of treatment was observed. • Experienced rehabilitation professionals can address a variety of rehabilitation objectives that cross established discipline boundaries.

intensive rehabilitation than the other, were used. This created problems in terms of the different resources and illustrates the difficulties of random allocation in a trial of rehabilitation even when every attempt to stratify for the relevant variables was made. The study also illustrates the particular difficulty of randomization in the early stages after injury or insult.

In considering the results of our study, a number of limitations must be taken into account. First, although the groups were well matched on the parameters of severity of injury used for randomization and stratification, one of the sub-

Table 8 Median increase in FIM+FAM scores and interquartile ranges during admission

Domain	Southampton		Poole		Significance
	Intensive	Routine	Intensive	Routine	
Difference in self-care	29 (23,26)	13 (2.5,19)	33 (23,40)	7.5 (0,18)	0.003
Difference in continence	12 (3,23)	0 (0,8.5)	12 (1,12)	0 (0,2)	0.007
Difference in transfers	17 (9,22)	7 (1,14)	20 (13,24)	4 (0,12.25)	0.01
Difference in locomotion	11 (5,14)	10 (2,15)	17 (11,18)	3 (1.5,8.5)	0.003
Difference in communication	9.5 (5,9.5)	3 (1.5,12.5)	12 (7,18)	4 (1.5,8)	ns
Difference in psychosocial	11.5 (1.75,14)	3 (0.5,7)	12 (7,18)	2 (0.75,4)	0.003
Difference in cognition	11 (3.75,21)	7 (2.5,14.5)	20 (7,25)	5 (0,7.75)	0.03

Table 9 Median increase in FIM+FAM scores and interquartile ranges during admission in centres

Domain	Southampton	Poole	Z	Significance
Difference in self-care	20 (12,34)	23 (7,35)	-0.108	ns
Difference in continence	6 (0,17)	1 (1,12)	-0.818	ns
Difference in transfers	13 (2,21)	13 (13,23)	-0.829	ns
Difference in locomotion	10 (4,14)	10 (3,17)	-0.666	ns
Difference in communication	6 (2,16)	8 (3,13)	-0.312	ns
Difference in psychosocial	4 (1,12)	7 (1.5,14)	-0.340	ns
Difference in cognition	10 (3,16)	7 (3,20)	-0.204	ns

groups that emerged (Southampton intensive subgroup) appeared to include a disproportionate number of the most severely injured subjects. An unanticipated difficulty with randomization was the unanticipated numbers of subjects who were electively sedated and ventilated, reducing the numbers recruited with low GCS scores. Second, the FIM+FAM has drawbacks when used to assess the outcome of rehabilitation because its relevance is restricted to therapy aimed at reducing dependency on other people in daily activities. The inputs provided both by the multidisciplinary team and by the research therapists in some cases related to many of the domains and in others to none of them. Therefore it is probable that the total effect of the intervention may not have been well captured by the FIM+FAM. Third was the issue of carrying out a study in which the provision of routine therapy differed between the two centres. Subjects in one centre had considerably more routine intervention than in the other but the sizes of the groups and the subgroups meant that the overall effect of this could not be quantified.

In each centre the intervention subgroups showed significantly greater functional improvement compared with the routine subgroups. The baseline FIM+FAM for self-care, transfers, sphincter control and cognitive function was lower for the intervention than for the routine subgroups, suggesting that the opportunity for changes in these was greater in the intervention subgroups. The baseline FIM+FAM for patients in the intervention group was lower, particularly in the domains of self-care, transfers, sphincter control and cognitive function. The greater functional change in the intervention group could therefore be because there was more scope for improvement to a level of function needed for discharge. However, in Poole, this was achieved in a shorter time than it took the routine group to improve less, suggesting a real effect of intervention in that centre.

Subjects who received more intensive therapy at Poole were discharged home sooner after their injury or illness. It was our impression that subjects in Poole were discharged from hospital with lower independence scores (i.e. lower FIM+FAM scores) but this difference was not statistically significant. Poole has better resourced commu-

nity services, including an outreach brain injury rehabilitation team and dedicated social work support, which may have facilitated this. However, no quantifiable data on this difference in resources were collected.

Adding an extra member to a rehabilitation team, particularly when that individual has an interdisciplinary remit, required careful planning. Both additional staff members were professionally qualified, highly experienced in the rehabilitation of people with neurological disabilities and used to working as members of a team, which undoubtedly contributed to their success in fulfilling an interdisciplinary role. The introduction of the additional staff members to the teams was carefully managed and some understandable anxieties in team members needed careful attention. The additional staff member in Poole had an equally beneficial effect, as in Southampton, despite the greater routine input in Poole. There was no evidence that the 'ceiling' of effectiveness had been reached, raising the question of whether yet more intensive programmes would further accelerate the process of skill acquisition and independence and allow discharge from hospital even sooner.

These results do support the widely held view that increased intervention facilitates more rapid improvement after severe brain injuries and diffuse brain damage. The gains in throughput shown here and in the literature¹⁻³ are greater than the gains reported to be achieved by increasing resources to community teams with other patient groups.^{13,14} A further consideration is that intensive inpatient rehabilitation has the potential to lower the incidence both of physical deformities (such as contracture) and of early behavioural disorders, thus reducing the need for community teams to spend time on correcting avoidable deficits acquired while in hospital. It seems likely that both specialist inpatient rehabilitation and subsequent active rehabilitation in the community are necessary for optimal results to be achieved.

The overall relationship between intensity of therapy and rate of progress is unlikely, for obvious reasons, to be linear or to be the same for each subject. While it is clear that intensities of therapy in Poole were more appropriate for the needs of the subjects with brain injury than they

were in Southampton, there is not yet sufficient evidence to specify the most cost-effective intensity of therapy for this client group. Careful studies replicated in different centres are needed to establish this in current National Health Service (NHS) environments.

Conclusions

The results of the study have demonstrated that:

- 1) Subjects receiving more intensive therapy after acute brain injury made more rapid progress.
- 2) Subjects who made more rapid progress could be discharged home sooner.
- 3) Different intensities of therapy employed in this study showed no evidence of a 'ceiling' effect.
- 4) More studies are needed to establish the most cost-effective intensity of inpatient therapy in this client group.

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