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A RANDOMISED CONTROLLED TRIAL TO DETERMINE THE EFFECT OF INTENSITY OF THERAPY UPON LENGTH OF STAY IN A NEUROLOGICAL REHABILITATION SETTING

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A randomised single-blind controlled trial was designed to determine whether intensity of therapy (physiotherapy and occupational therapy) shortened length of stay for patients in a rehabilitation unit. Patients were under 65, primarily with stroke, but also with other conditions such as traumatic brain injury, and multiple sclerosis. The experimental group were timetabled to receive 67% more therapy in any given week, than the control group. After controlling for confounders and case mix (as expressed by type of therapy required) patients in the experimental group showed a significant 14-day reduction in length of stay ($<$0.01). Concurrently average length of stay was increased for both groups by 16 days due to delays in discharge.

Key words: cerebrovascular accident, brain injuries, length of stay, intensity, rehabilitation, treatment outcomes, delivery of health care, rehabilitation centres, physical therapy.

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INTRODUCTION

The consequences of sudden events such as stroke or traumatic brain injury can be devastating, leading to problems with everyday activities and limiting participation in society. Rehabilitation provides one of many interventions designed to alleviate these consequences. It is increasingly able to demonstrate its efficacy (1–4) and strives to improve its efficiency. Research into these issues faces formidable obstacles. Disorders such as stroke encompass a variety of impairments in various combinations such that the content and extent of treatment programmes will vary from patient to patient. A report on the effectiveness of rehabilitation argues that it is impossible to guarantee a uniform approach (5).

Variation in the consequences of disease, in the skill mix of those treating patients, and in the programmed time for treatment, make randomised controlled trials difficult, but not impossible to implement (6). Ideally therapy regimes should be compared with placebo i.e. no therapy, but this would be difficult to justify on ethical grounds. Instead, many have been concerned with the competing efficiency of different settings for rehabilitation, for example specialised stroke units compared to general medical wards (7, 8), or hospital versus home services (9, 10).

Other studies have examined the effect of intensity of therapy upon length of stay (11–13) or upon disability (14, 15). A measurable benefit related to intensity of rehabilitation was suggested in a meta-analysis (1). A systematic review of 9 controlled studies with 1051 patients identified a small and significant outcome for the intensive group ($p < 0.05$).

Table I. *Diagnosis of patients*

	Experimental *(left) (right) paralysis*	Control *(left) (right) paralysis*	Total	Sig.
Stroke	50 *(17) (29)*	50 *(15) (28)*	100	
TBI	12	14	26	0.084
Other	18 *(3) (1)*	17 *(1) (1)*	35	
Total	**80**	**81**	**161**	
Stroke	3 *(0) (2)*	9 *(1) (6)*	12	
TBI	1	2	2	0.641
Other	1 (0) (0)	4 *(1) (1)*	6	
Not included	**5**	**15**	**20**	
Stroke	47 *(17) (27)*	40 *(14) (22)*	87	
TBI	13	13	26	0.802
Other	15 *(3) (1)*	13 *(1) (0)*	28	
Included	**75**	**66**	**141**	

Sig. Chi square distributions. Stroke = left or right is side of paralysis. TBI = traumatic brain injury. 'Other' = a mixture of other neurological conditions such as MS.

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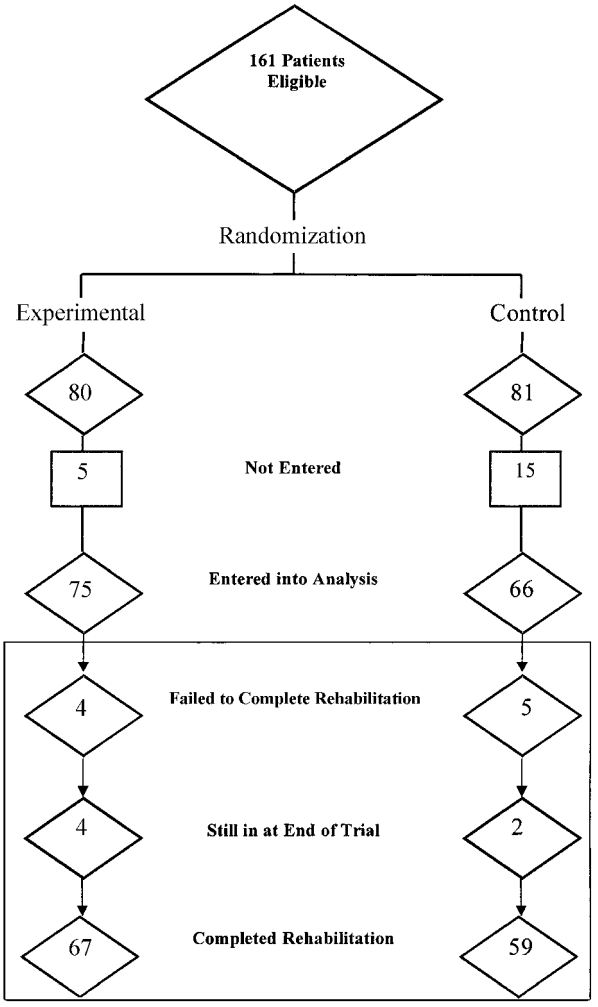

Fig. 1. Participant flow in trial.

In this article we describe a study to test the hypothesis that increasing amounts of physiotherapy and occupational therapy would shorten length of stay in a neurological rehabilitation setting. An additional hypothesis that patients would be discharged at similar levels of function was tested.

METHODS

Participants

The study was undertaken in a 19-bedded in-patient neurological rehabilitation unit for patients aged 16–65 years. Patients were recruited from 1995–1997 and all patients admitted to the rehabilitation unit were eligible for inclusion in the study. One hundred and sixty-one patients were eligible for recruitment into the trial. (See Fig. 1). Eighty patients were randomised to the experimental group and 81 to the control group.

The main diagnostic groups consisted of stroke, traumatic brain injury (TBI) and 'other' which consisted of a mixture of other neurological disorders such as multiple sclerosis (MS). Overall Stroke formed the largest diagnostic group with 50 in the experimental group and 50 in the control group (see Table I). The experimental had 12 patients with the diagnosis of TBI and the control groups had 14 patients. Within the 'other' diagnosis the experimental group had 18 cases and the control group 17 patients. There was no significant difference in diagnosis between the groups and although there were more patients with stroke-related right-sided weakness, this was not significant.

Treatment planning occurred a week in advance, enabling staff to plan the patients' treatment programme. Consequently randomisation occurred in the week preceding admission to the rehabilitation unit, prior to consent being given, as a result of this some patients were not included in the trial.

Five patients in the experimental group were not included in the trial, four of whom refused and consent could not be obtained from the fifth. Fifteen patients in the control group were not included, 8 refused, and consent could not be obtained in the remaining seven people.

Of those who were not included, in the experimental group the diagnosis consisted of three patients with a stroke, one a TBI and one 'other', in the control group the diagnosis consisted of 11 with a stroke, one TBI and three 'other'.

Consequently of the 141 analysed and entered into the trial eighty-seven patients had experienced a stroke, (47 experimental) (41 control) twenty-six patients TBI (12 each experimental and control) and the remaining twenty-eight in the 'other' diagnosis (16 experimental, 13 control).

Ethical approval was sought and granted from the ethics committee at the Leeds Teaching Hospitals. Written consent was obtained unless patients had severe communication difficulties, when relatives or carers acted as their proxy. If no consent could be obtained, patients were excluded from the trial and received normal levels of therapy.

Interventions

For the study, therapists identified how much therapy time they had available for treating patients for the following week. They removed 25% of the time available, and divided the remaining amounts equally between control and experimental groups. The 25% set aside was then added to the amount available for the experimental group for the following week. This allocation process meant that patients who were included in the experimental group were allocated 67% more therapy, in any given period, compared with those in the control group (i.e. 62.5% of the total time available, compared to 37.5%).

Table II. *Background characteristics of patients (75 experimental and 66 controls), entered into the trial*

	Experimental Median (IQR)	Control Median (IQR)	Total	*p*
Age (years)	52 (36–61)	54 (41–62)	53 (40–62)	0.347
Days since event	47 (24–75)	45 (28–81)	47 (26–78)	0.722
Admission Barthel	45 (32–61)	49 (28–78)	47 (31–72)	0.281
Change Barthel	20 (9–32)	14 (2–28)	17 (4–29)	0.055
Admission Mayo	28 (0–35)	19 (0–33)	22 (0–34)	0.215

p values are from Mann Whitney U test. (Age and days since event were not normally distributed). IQR is the inter quartile range of the scores 25th and 75th percentile. Days since event is the number of days since admission to hospital for event leading to the need for rehabilitation. Change in Barthel is the difference between admission and discharge scores.

Extra therapists were brought in for the trial but their services were available to all patients. All therapists treated a mix of control and intensive patients. Therapy input was recorded as quarter hour units, both as planned, and delivered. The discrepancy between the two arose because of factors such as patient or staff illness and the need for investigations. These factors were coded and recorded. The type of therapy given was also recorded, (physical, perceptual and cognitive, washing and dressing, daily living activities, group treatment, joint treatment and splinting).

Outcomes

Information was collected on demographic, clinical and potential confounding factors such as delays caused by waiting for adaptations to the home. An audit clerk collected this information from ward rounds and patients' notes. Extent of dependency was recorded using the Modified Barthel Index (16). The Barthel is an index of daily living activities, range 0–100 (0 totally dependent, 100 independent). The multi-disciplinary team (MDT) completed the Barthel Index at fortnightly ward meetings. Each profession took responsibility for recording scores for their patient on items that were relevant to their profession (e.g. walking by physiotherapists).

Perceptual and cognitive impairments were assessed using a short test of mental status (Mayo Scale—named after the clinic) (17). It is a measure of mental status that identifies abilities in several domains, e.g. orientation, arithmetic, construction and recall etc. (range 0–38, 0 = severe problems, 38 = no problems). The admitting junior doctor administered the test on admission. Length of stay was defined from date of admission to actual discharge date.

It was calculated that 160 patients, 80 per group, were needed to give the study a power of 80% to identify a mean difference of 15 days' stay (a reduction of 17% in the average length of stay) between groups with a significance level of <0.05.

Randomisation and blinding

Randomisation occurred when the admission date of the patient was known, in order to allow for the timetabling of therapy, usually undertaken a week in advance. Patients were randomised to experimental and control groups by the university epidemiological unit. Randomisations used successive blocks of 8 or 12. This prevented unequal group sizes, so that in a block of 8 for instance there would be 4 randomisations in the experimental group and 4 in the control group in any combination e.g. eeccecec or ccceecee. The blocks were of different sizes to prevent anticipation by staff on group randomisation. Runs of control or experimental randomisations were limited to four, to ensure intensive therapy could be delivered.

Therapists planning the timetable knew which group patients had been assigned to but patients and other team members were blinded to the patients' grouping.

Statistics

All patients who consented to inclusion in the trial were analysed on an intention to treat basis. Differences in baseline factors between groups were analysed using *t*-test, chi-square and Mann Whitney tests as appropriate (18). Age and days since event were not normally distributed and thus results are presented as the median and inter quartile range (IQR). 95% confidence intervals and <0.05 probability were used throughout.

The effect of increased therapy on length of stay was assessed by multiple regression analysis. Predictors of length of stay were identified and incorporated into a conceptual model based upon clinical experience (see Fig. 2).

This identified all the factors likely to influence the need for rehabilitation, and other factors likely to influence length of stay, irrespective of that need (i.e. confounders). Variables entered into the regression models were required to meet the basic assumptions for parametric analyses (19).

The distribution of each predictor was examined by the Kolmogorov Smirnov test (20). Predictors that were not normally distributed were transformed using square root transformations or dichotomisation into a dummy variable. All other assumptions underlying the use of regression models, for example, heteroscedasticity, were examined in detail (20, 21).

Supplementary analysis examined the levels of dependency at discharge. The discharge Barthel Index scores were transformed from ordinal scores to interval level measures by fit of the data to the Rasch Model (22, 23). The Rasch model is a uni-dimensional measurement model based on principles of fundamental measurement i.e. order and objectivity. If data fit the Rasch model, item difficulties are distributed along a metric measurement continuum. Patient ability is also calculated on the same continuum. We used the Rasch analysis software RUMM 2010 to fit data to the Rasch model (24). Transformation using this method results in a 'scale-free' person measurement and 'sample-free' item calibration (25). Construct validity is deemed inherent in that items are unidimensional as a requirement of the model and all items are considered to be measuring the same trait. The transformed scores (logits, an abbreviated term for log-odd units which is the natural log (base e) taken from the probability of success divided by the probability of failure (26) were then entered into multi-variate regression analysis.

RESULTS

The median age of the 141 patients who consented to be in the trial was 53 years, with a median 47 days since their event (Table II). There was no significant difference in age, or time since event between those who did and did not consent. There were no significant differences in the distribution of males and females, diagnostic groups, side of stroke between the experimental and control groups (Table I).

The median admission Barthel and Mayo scores were 47 and 22, respectively. There was no significant difference in any demographic or clinical baseline data between the experimental and control group. Both experimental and control groups showed an improvement in their Barthel Index scores.

Although there was a significant difference ($p < 0.05$) (Table III) in the amount of therapy received between the groups, that received by the intensive group was only approximately an hour and a quarter a day (5 days a week) of physiotherapy and occupational therapy, compared with just less than one hour for the controls.

Examination of the amounts of therapy received and amounts missed showed a significant difference ($p < 0.05$) between the control and experimental group, suggesting that the experimental group may not be tolerating the higher amounts of treatment. However, further analysis examined the missed treatment as a percentage of therapy received, there was no significant difference identified between the two groups, showing that patients tolerated the intensive therapy with no adverse effects.

One patient aged 16 years in the experimental group who had sustained a traumatic brain injury, manifested severe behaviour problems, refusing to co-operate in his treatment. The level of his treatment was reduced and a behaviour modification programme introduced. His behaviour improved and intensive therapy was reintroduced at a later date with no recurrence of his behavioural problems.

The mean length of stay for all the patients was 84.6 days (SD 53.34, CI 75–93), showing a slight positive skew. A multiple regression model that took into account confounders, which could not be controlled for in the design (community delays and missed treatment) showed the experimental group as having 5

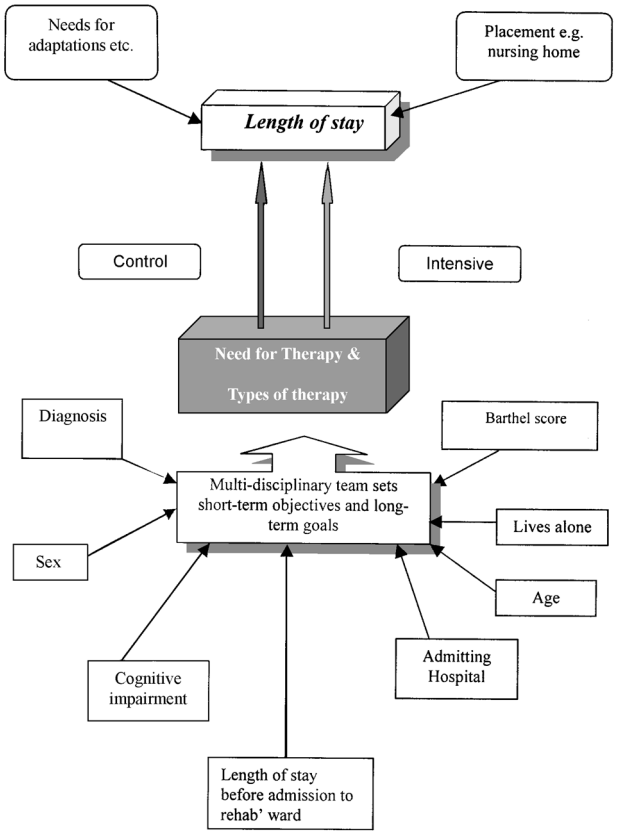

Fig. 2. Influences on the need for therapy and length of stay.

days shorter length of stay. This was not significant (Model A, Table IV). The adjusted R^2 for model A was 0.625.

A second multiple regression (model B) which added impairment mix, represented by the type and amount of therapy required, showed that the experimental group had a significant reduction of 14 days stay less than controls ($p < 0.001$), (Model B, Table V). The model continued to highlight the effects of confounders. An additional 16 days stay resulted from delays in discharge caused by external agencies, adjusted for impairment mix. In this model, the need for daily living treatment had the biggest effect on days stay (beta value 0.37). This regression model has an adjusted R^2 of 0.881 (Table V).

A further regression model (not shown) was used to ascertain whether or not patients discharged after intensive levels of therapy had reached a similar level of independence to those receiving standard treatment. Ordinal Barthel Index scores were transformed to interval level measures by fit to the Rasch model. Overall fit the Rasch model was good with a chi square of 27.93 ($p = 0.032$, Bonferroni corrected $p = 0.0013$). The item mean was −0.400 with a SD of 0.994 and the person's fit mean was −0.325 with a SD of 0.746, the person separation index was good at 0.954.

No significant difference in discharge Barthel scores was found between the experimental and control groups. The actual difference shows less than one Barthel Index score point difference between the groups. A regression model shows that the Rasch transformed admission Barthel score was the most significant predictor of discharge Barthel. Age was also a predictor of discharge scores with older patients having lower discharge scores.

DISCUSSION

Optimum therapy levels for inpatient rehabilitation are unclear, but many units outside the UK are required to provide much higher levels (often at least 3 hours a day) for accreditation as rehabilitation facilities (27). The enhanced level of rehabilitation given in this trial is rarely obtainable within the National Health Service, and even the basic level of therapy is unavailable to many patients. Even with a 67% increase in levels the intensive group still only received approximately one and a quarter hours of physiotherapy and occupational therapy each day. Patients were able to tolerate these higher levels of therapy. With these higher levels of therapy, and adjusting solely for confounders such as delays in discharge a non-significant reduction in stay of 5 days was observed. When impairment mix was taken into account, the reduction increased to a significant reduction of 14 days' stay for the experimental group.

Is this finding generalisable? As a randomised single-blind study, the randomisation was supposed to be able to deal with the effects of structural changes. However, in the current study, due to a temporary relocation of the neurosurgical service, the unit was required to admit some patients very early in their recovery when they had high dependency level. This increased the standard deviation of our primary outcome variable and thus reduced the power of the study. This emphasises the vulnerability of trial design in a real world setting. Also the need to randomise prior to admission to facilitate timetabling had the potential for introducing post randomisation withdrawal bias. However no significant difference in baseline characteristics was found between those who did and did not consent.

A number of issues arise from these findings. Both this study, and others have shown that it is possible to undertake a randomised controlled trial within a rehabilitation setting. Although it was not possible to blind all staff, patients and those taking the decision about discharge were blinded to level of therapy. The fact that both groups were discharged at similar Barthel levels suggests that there was no bias in discharge planning. An exit poll to determine if the patients were aware of their group randomisation might have been appropriate (28).

The disparate results emerging from the analysis with respect to factors entered into the regression model is a cause of considerable concern. Illness during rehabilitation, equipment needs, modifications to the home or the requirement for continuing care cannot be predicted on admission. Thus randomisation may not always even out potential confounders. However, Hennekens & Buring (29) suggest that confounders can be controlled for in the final analysis, as we have done.

The critical issue therefore for randomised controlled trials in rehabilitation is to identify all or as many as possible potential

Table III. ***Amounts of therapy received for the experimental group (n = 75) and the control group (n = 66) for the total period of hospital stay***

	Experimental Mean ***(SD)*** (95% CI)	Control Mean ***(SD)*** (95% CI)	***p***
Planned qtr hrs	126.4 ***(79.8)*** (108.04–144.75)	81.7 ***(54.3)*** (68.34–95.06)	0.0001
Received qtr hrs	118.3 ***(74.1)*** (101.24–135.35)	77.4 ***(51.4)*** (64.76–90.02)	0.0002
Missed qtr hrs	8.1 ***(8.5)*** (6.14–10.05)	4.3 ***(4.3)*** (3.20–5.31)	0.0007
Percentage missed	7.0 ***(8.2)*** (5.07–8.85)	5.2 ***(4.0)*** (4.21–6.19)	0.1167
Weekly amount hours PT and OT	6.4 ***(1.2)*** (6.15–6.71)	4.9 ***(1.0)*** (4.67–5.18)	0.0000

Planned qtr hrs: The amount of therapy in quarter hours patients should have received. Received qtr hrs: The amount actually received. Missed: The amounts missed because of illness, staff cancellation, the need for other procedures, e.g. CT scan. Percentage missed: Missed treatments as a percentage of the amount planned. Weekly amounts: The daily amounts received over a 5-day period for physiotherapy (PT) and occupational therapy (OT).

confounders at the outset. Furthermore, the failure of global baseline measures such as the Barthel index to identify the differences in need between groups raises questions about the analysis of rehabilitation outcomes that rely on such variables (30, 31). In a separate regression model (not shown) we were only able to account for 48% of the variation in therapy delivered, by including all the demographic and clinical baseline variables collected.

In the current study we used therapy time and task as a surrogate for the impairment mix, under the assumption that clinical assessment identified these complex needs and responded accordingly. A recent editorial stimulated by the findings of Green et al. (31) suggested that results cannot be generalizable when a mixture of treatments is tailored to fit the needs of the individual patients (30). In future trials the impairment/disability mix, and treatment mix, will need to be made explicit in the study design.

The assumption underlying this study was that bed days are the most expensive component of rehabilitation and that any reduction would be worthwhile. A recent study compared bed days between a Californian non-profit-making health organisation and the NHS and found hospital bed days are the most expensive component of any health care system (32).

In the current study delays caused by external agencies resulted in an extra 16 days stay (model B). If these were avoided considerable savings could be made and available bed space used more efficiently (33, 34). If combined with more intensive therapy, real gains in efficiency could be achieved.

Table IV. ***Coefficients of the regression model***

	Unstandardised B	Standardardised Coefficients Beta	Sig.	95% Confidence Interval for B	
				Lower bound	Upper bound
(Constant) (Model A)	17.69		0.002		28.94
Experimental group	**−5.43**	−0.051	0.354	−16.96	6.11
Community delays	32.40	0.279	0.000	19.44	45.36
Missed treatment*	27.70	0.659	0.000	22.79	32.61
(Constant) (Model B)	−0.254		0.952	−8.50	7.10
Experimental group	**−13.65**	−0.13	0.000	−20.35	−6.95
Community delays	16.44	0.14	0.000	8.65	24.22
Missed treatment*	11.13	0.26	0.000	7.64	14.62
Daily living code	0.32	0.37	0.000	0.26	0.39
Perceptual cognitive*	4.60	0.25	0.000	3.31	5.99
Washing/dressing*	4.63	0.24	0.000	3.16	5.96
No group treatment required	−10.03	−0.08	0.015	−18.12	−1.95

* Square root.
B = the value of the regression coefficient and the constant. Beta coefficients = the beta weight showing the change in the dependent variable expressed in standard deviation units that would be produced by a positive one standard deviation change in the independent variable. Sig. = tests the regression coefficient for significance of the *t* test (not shown). Confidence intervals for B = identifies the upper and lower boundaries for the population mean of B. This table identifies the dependent variable with the best predictive powers for the independent variable days stay.

Table V. *Model summary*

Model	R	R^2	Adjusted R^2	Change statistic				
				R^2 change	F change	DF1	DF2	Sig. F change
A	0.796	0.633	0.625	0.613	114.507	2	137	0.000
B	0.942	0.886	0.881	0.253	74.209	4	133	0.000

R^2 = positively biased estimate of the proportion of variance dependent variable accounted for by the regression model. Adjusted R^2 = correction for the bias and is therefore lower in value. R^2 change = changes in the model by adding variables. F change = changes in the F statistic by additional variables. DF = degrees of freedom 1, 2. Sig F change = change in the significance of the F statistic by adding variables.

This study confirms the results of other studies that have looked at the efficacy of rehabilitation treatment and settings, and specifically intensive therapy (1, 4, 5, 33). However, this study differs in the emphasis given to the effects of impairments/disability mix (as identified by the types of treatment received). A more sophisticated set of baseline measures is required to catalogue the mix of impairments and disabilities. This finer grading of information may also facilitate other randomisation techniques such as minimisation (35) where baseline variability could be systematically built into the procedure. However multivariate analysis would still be required to account for post-randomisation confounders.

In summary, enhanced levels of physiotherapy and occupational therapy (to a planned intensity of 67% above the standard) show results which vary according to the specification of the model used in the analysis. Adjusting for confounders, a slight non-significant trend in favour of the experimental group was observed. Accounting for impairment/disability mix, and the consequent response of therapy, a significant benefit to the experimental group was demonstrated.

Baseline measures failed to identify potential differences in the need for rehabilitation between groups. Serious consideration should therefore be given to more complex designs and analysis to determine the true effect of interventions to improve the efficiency of the rehabilitation process. Finally, without any staffing increases considerable savings could be made if discharge delays were reduced.

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