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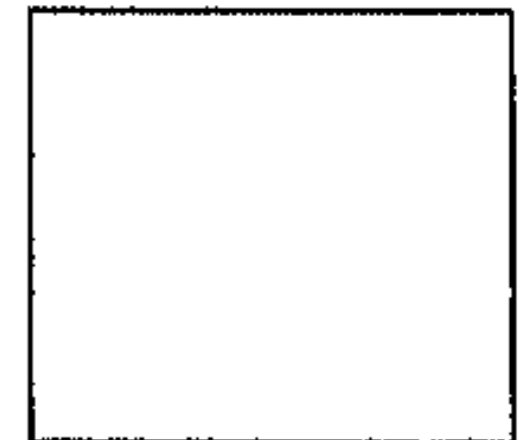
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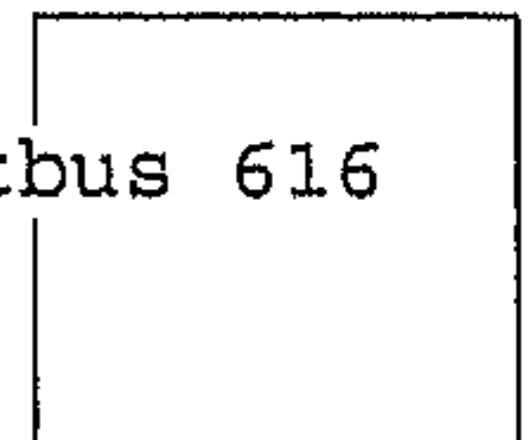


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## A study to assess the effect of nursing interventions at the weekend for people with stroke

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**Objective:** To examine whether additional therapy provided by nurses at the weekend improved the physical outcome for people with stroke on a stroke rehabilitation unit.

**Design:** A single blind randomized controlled trial.

**Setting:** A 16-bed stroke rehabilitation unit in the north of England.

**Subjects:** Forty-one people with stroke were randomized by means of minimization to intervention and control groups.

**Interventions:** The intervention group received additional exercise at the weekend provided by the nursing staff and the control group received their usual care. Both groups received usual care during weekdays.

**Main outcome measures:** The Motor Assessment Scale (MAS), the Barthel Index (BI) and length of stay in hospital.

**Results:** No significant differences were found between the groups in terms of MAS and BI at discharge but there was a borderline significant difference between the groups on unconditional testing in terms of length of stay in hospital and on the stroke unit ( $p = 0.05$  and  $p = 0.07$  respectively). However, these findings were in favour of the control group. On conditional testing (adjusting for BI on admission and age) these differences disappeared ( $p = 0.14$  and  $p = 0.15$ ) for length of stay in hospital and on the stroke unit respectively.

**Conclusions:** The present study indicates that an increase in one-to-one input by nurses for people with stroke did not lead to a measurable difference in outcome in this small study.

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## **Introduction**

Systematic reviews<sup>1</sup> and randomized trials<sup>2-4</sup> have demonstrated that, in general, intensified physiotherapy for stroke has a positive effect.

Comparisons between stroke units and acute medical wards<sup>5-9</sup> have demonstrated the former to be more effective in providing improved outcome in terms of mortality and physical outcome.<sup>9-13</sup> It has been hypothesized that a key ingredient contributing to the benefits of stroke unit care is the provision of skilled and knowledgeable nurses.<sup>13,14</sup>

Several studies<sup>15-20</sup> have investigated the effect of nurse education programmes. Although they have demonstrated improvements in nurse behaviour and understanding, none have shown this to filter through to provide improved patient outcomes.

Despite the ostensible importance of nurses to the rehabilitation process, no specific and unique nursing role has yet been identified in stroke rehabilitation<sup>21-25</sup> although Kirkevold's Unified Theoretical Perspective<sup>26</sup> provides a useful framework for nursing activity. One of the four functions described within the Unified Theoretical Perspective is the integrative role of the nurse, which is essentially the means by which nurses help patients to integrate newly learned activities from formal therapy sessions into practical activities, such as getting out of bed and getting dressed.

Subsumed within the integrative function is the 'carry-on' role<sup>25</sup> where nurses are presumed to act as stand-in therapists,<sup>18</sup> especially during their absence at weekends and out of the hours within which therapists traditionally work (Monday-Friday, 8.30 am-4.30 pm). This constitutes circumstantial overlap<sup>27</sup> where one group of workers takes over the role of another simply because of the latter's absence. One substantial period of circumstantial overlap occurs at the weekend.

Only two papers could be identified that considered interventions for stroke at the weekend. Both studies were conducted in the United States. Rapoport and Judd van Eerd<sup>28</sup> in their controlled clinical trial demonstrated that people with stroke spent less time in hospital when a seven-day therapy service was provided, compared with the usual five-day service. However, Ruff and colleagues<sup>29</sup> in their quasi-experimental study showed

patients receiving seven-day therapy had no more gains compared with those receiving a six-day service.

It remains unclear whether physical exercises provided on a seven-day basis will benefit people with stroke in terms of magnitude and rate of recovery.

This present study sought to investigate the effect of an intensification of treatment for people with stroke resident on a stroke unit, provided by nursing staff at the weekend.

## **Method**

All staff on a 16-bed stroke rehabilitation unit in the north of England were provided with an education programme. This aimed to provide a basis for the understanding of normal movement, develop new skills in handling and moving patients and to translate these skills into the work environment. It also sought to introduce the problem-solving approach<sup>30</sup> and to highlight its possible use in addressing individual patients' needs regarding handling and moving. The education package provided a classroom-based training programme and a work-based placement. Appendix 1 gives an outline of the programme.

The classroom-based programme was run repeatedly over one month in order to include as many staff as possible. The focus of the work-based education was to enhance the ability of the nursing staff to develop their 'carry-on' role<sup>25</sup> in their clinical context. A senior I physiotherapist (TW) worked alongside the nursing staff during the course of their normal work on the stroke unit, mirroring nursing shift patterns for the duration of the placement. This was so that he was available at all times to work with any of the nursing team and to experience the spectrum of the nurses' working day including night duty. The physiotherapist was solely an educational resource during the clinical placement and therefore had no clinical caseload. All 17 (12 day and 5 night duty) nurses were expected to utilize the physiotherapist during his period of work but no minimum time requirement was set for this.

The rehabilitation unit received patients from the acute medical setting with a typical time to

transfer of approximately four weeks. Patients admitted into the unit between 6 November 2000 and 26 October 2001 were eligible for entry onto the observer (single) blind randomized controlled trial.

Exclusion criteria included: medical instability (as determined by the ward physician) imminent transfer to another unit, dementia, refusal to give consent or severe comprehension problems.

A speech and language therapist (SaLT) assessed dyphasic patients' appropriateness for inclusion in the study. Those assessed as having insufficient comprehension to give informed consent or follow simple instructions (according to the clinical judgement of the SaLT) were excluded from the study. All other patients with speech problems were included in the study.

Minimization<sup>31-33</sup> was chosen as the method of randomization using the MINIM computer software program.<sup>34</sup> This balances important prognostic covariates a priori. The factors minimized were: age; gender; side of stroke; the existence of communication problems (mild dysphasia determined through a clinical assessment by a SaLT, but not sufficient for exclusion); severity of stroke (assessed by the Barthel Index (BI) score); and time (in days) since onset of stroke.

Power for the study was 90% for between-group comparison and was calculated on the basis of a single point change in each category of the Motor Assessment Scale (MAS) and was estimated that 23 patients would be required in each group. This was increased by eight to allow for attrition on advice from the local ethics committee. Consequently, the target per group recruitment increased to 27. Data were analysed on an intention to treat basis.

Following recruitment by the independent observer (ID) details of patients were telephoned to a remote office where they were assigned by minimization and recorded. No information was given to the independent observer regarding the group allocation. The information was telephoned from the remote office to the study co-ordinator, who recorded and assigned patients into groups in accordance with the minimization program. Concealment of allocation was achieved by ensuring that other strategies were in place to prevent the independent observer from becoming aware as to which group patients had been assigned. This included asking nurses, therapists

and participating patients not to discuss any aspect of the study with the observer.

A flowchart of patient recruitment can be seen in Figure 1.

Nursing staff working at the weekend and who had taken part in the education programme provided the intervention. The intervention comprised the nurses working with the patients by repeatedly practising activities such as: lying to sitting on the side of the bed; achieving sitting balance; sitting to standing; achieving standing balance; and stepping. No specific duration of exercise was stipulated for these activities, but nurses were asked to record the amount of 'extra time' each spent on the combination of activities practised by the patient. Interventions took place during the course of usual nursing duties with each of the patients over the weekend. This was in order to minimize the burden of additional work for nurses. However, in order to avoid contamination between the intervention and control groups, the nurses were asked not to provide any *extra* input for the latter.

The aggregated score for the Motor Assessment Scale (MAS)<sup>35</sup> was used to assess differences between groups at the level of impairment and disability. The Barthel Index (BI)<sup>36</sup> was used to assess level of independence in activities of daily living. The Hospital Anxiety and Depression Scale (HADS)<sup>37</sup> was used to assess similarity of patients at baseline but was not used as a specific outcome measure. Additional outcome measures included total length of stay in hospital and on the stroke unit. Data were also collected from the computerized hospital records regarding the amount of therapy time received by patients.

The independent observer, unaware of the patient allocation, conducted the MAS every Monday, Wednesday and Friday throughout the length of each patient's stay on the unit. BI scores were recorded every two weeks by the blinded observer (ID). Information regarding the type of exercise that should be conducted with the patient at the weekend (since some patients were unable to stand/walk) was handed to the study co-ordinator on Fridays. The co-ordinator then discarded those in the control group and discussed weekend interventions with the nurses who were on the weekend roster.

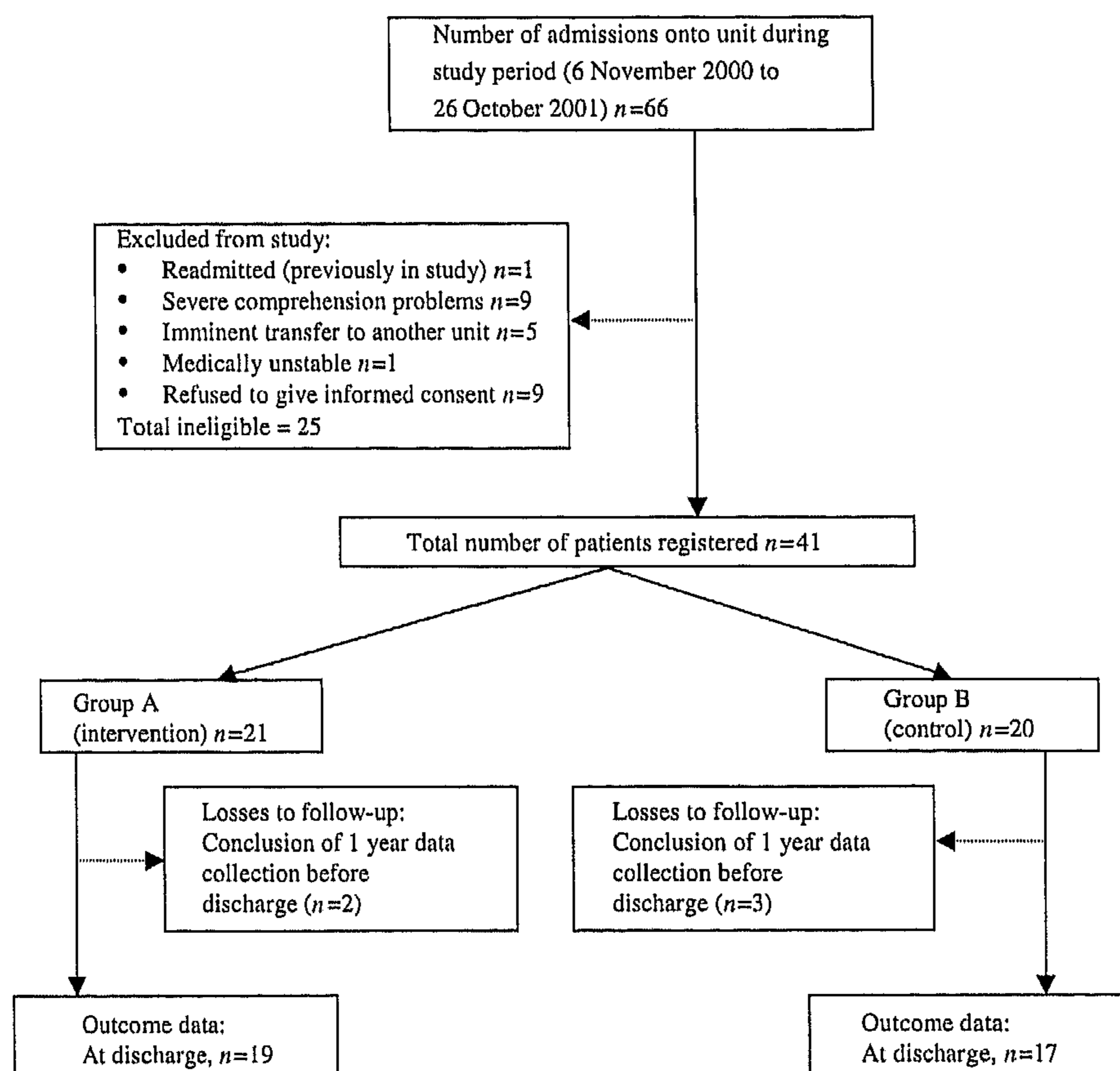


Figure 1 Flow diagram of patient recruitment.

The data were examined to identify if differences existed between the groups at discharge for four variables:

- Total MAS score
- Total BI score
- Length of stay on unit
- Length of stay in hospital.

Analysis was conducted using SPSS version 9 and STATA version 6.

Between-group analysis was assessed using independent groups *t*-test for parametric data and Mann-Whitney *U*-test for nonparametric data. Weekly serial measurements were assessed using the area under the curve (AUC)<sup>38</sup> to compare the pattern of improvement between the groups during the study period. Interpolation was

required for this in order to obtain complete data for a five-week period. In the majority of cases, this was necessary due to patient discharge and it was assumed that a steady state would be maintained in the short term. Consequently, the 'carry forward' method was deemed the most suitable method of imputation.

Since minimization had been used as the method of allocation, the analyses conducted within this study were unconditional (unadjusted for covariates), in the first instance. However, significant and borderline significant results were adjusted for important covariates in order to confirm the findings.

Local research ethics committee approval was granted for this study. The nurses involved on the ward agreed to take part in the study a priori and they were aware that their input would be assessed.

## Results

The baseline data for the 41 patients recruited in each group are shown in Table 1, from which it can be seen that the control group had a higher BI score than the intervention group (and so were less severe) had a shorter time from onset of stroke to transfer to the unit (and so were more acute) and a lower average age. However, baseline testing for significance for each showed there to be no significant difference between the groups.

However, this does not necessarily mean that imbalance had not occurred.<sup>39</sup>

Table 2 shows the average amount of intervention received each day by the intervention group over the whole of the inpatient stay compared with the amount of therapy received per day (based on a five-day working week).

The relatively low levels of intervention provided by nurses over the weekend are compared against the average amount of therapy provided per day by occupational therapists (OT) and physiotherapists

**Table 1** Baseline data for patients admitted onto study

Variable	Intervention (n = 21)	Control (n = 20)	Significance
Gender			
Male	11	12	0.76 <sup>a</sup>
Female	10	8	
Age			
Mean (SD)	68.9 (13.52)	63.55 (17.95)	0.29 <sup>b</sup>
Max	84	91	
Min	32	31	
Barthel score on admission to unit			
Median (IQR)	9 (3.5–14)	12.5 (6.25–16.5)	0.18 <sup>c</sup>
Max	18	20	
Min	1	1	
Side of stroke			
Left	11	10	1 <sup>a</sup>
Right	10	10	
Speech problems			
Yes	5	5	1 <sup>a</sup>
No	16	15	
Time since onset of stroke			
Mean (SD)	23.38 (28.37)	16.7 (9.84)	0.33 <sup>b</sup>
Max	113	37	
Min	4	3	
HADS Anxiety			
Median (IQR)	8 (3–11)	8 (3–15)	0.57 <sup>c</sup>
Max	17	19	
Min	0	1	
HADS Depression			
Median (IQR)	6 (5–9)	8 (4–9)	0.62 <sup>c</sup>
Max	13	14	
Min	1	1	

<sup>a</sup>Chi square.

<sup>b</sup>Independent samples *t*-test.

<sup>c</sup>Mann-Whitney *U*-test.

HADS scores: *n* = 15 and 17 for control and intervention groups respectively because of inability of some patients to complete this scale.

SD, standard deviation; IQR, interquartile range; HADS, Hospital Anxiety and Depression Scale.

**Table 2** Average daily durations of intervention

	Daily duration of intervention at weekend by nurses (min)	Daily duration of PT based on 5 days/week (min)	Daily duration of OT based on 5 days/week (min)	Daily duration of therapy <sup>a</sup> based on 5 days/week (min)
No. of cases	21	17	13	13
Mean (SD)	12.73 (13.77)	30 (12.44)	12.1 (9.7)	41.38 (19.36)
Minimum	0	7.57	2.25	12.11
Maximum	55	51.43	31.73	76.14

The smaller number of cases for occupational therapy (OT) and physiotherapy (PT) means that of the 21 patients in the intervention group, only 13 and 17 received OT and PT respectively.

<sup>a</sup>Therapy time = combined OT and PT.

(PT). It can be seen that the nursing input was about 43% of the physiotherapy mean and the same as that provided by OTs. The nurses provided around one-third of the amount of intervention time given by both PTs and OTs.

Table 3 shows the mean and median values and associated *p*-values between groups for MAS at discharge, BI score at discharge and total length of stay in hospital and on the stroke unit.

It can be seen from Table 3 that there was no statistically significant difference between the control and intervention groups in terms of the BI and MAS scores at discharge. However there is a borderline significant and significant difference in favour of the control group, in terms of length of stay, on the unit and in hospital respectively. Analysis of covariance eliminated this difference:

- Adjusted for age and BI score on admission to rehab unit: *p* = 0.15
- Adjusted for age and BI score on admission to hospital: *p* = 0.14.

This suggests that covariate imbalance existed between the groups.

For the AUC analysis, 13 cases (eight control and five intervention) needed at least one additional value. This was not extended to the sixth week since this would have required that more than half of the data required interpolation.

Table 4 shows the AUC derived from the total MAS score for the first baseline and first four full weeks of the study. There is no significant difference between the groups.

During the course of the study, three patients (all in the intervention group) were unmasked,

despite the precautionary measures taken to guard against this.

## Discussion

No effect between the groups could be detected in this present study. There are a number of possible reasons for this. First, the power calculation estimated that 23 patients per group would be needed with eight patients added to protect against attrition. These figures are similar to those cited by other authors<sup>40</sup> using the MAS as the primary outcome measure. However, slow recruitment and limited patient availability on the single unit made the possibility of a small sample size and consequently a type II error likely. The achievement of 41 patients recruited onto the study meant that the study was under powered and this was further augmented by the removal of five patients who had not been discharged by the end of the study. The low recruitment rate was in spite of the fact that the data collection continued for a period of one year as planned.

Continuance of the trial beyond one year was prevented by a number of local factors such as: introduction of rehabilitation assistants during the week and the weekend to augment the workforce; nursing turnover, which reduced the numbers of nurses available to take part in the weekend intervention by around 50% and lack of funding to repeat the original education programme for new nursing recruits.

A type II error can be made less likely, even with small sample sizes, if there is a large treatment effect in the intervention group compared with the control group. However, this study may not have

**Table 3** BI and MAS scores at discharge and total lengths of stay

	Barthel at discharge		MAS total at discharge		Length of stay on unit		Length of stay in hospital	
	Intervention (n = 19)	Control (n = 17)	Intervention (n = 19)	Control (n = 17)	Intervention (n = 19)	Control (n = 17)	Intervention (n = 19)	Control (n = 17)
Mean (SD)	16 (10–18)	18 (14–20)	36 (18–41)	37 (26–44)	94.8 (63.6)	57.65 (53.3)	115.2 (68.18)	72.24 (58.11)
Median (IQR)								
<sup>a</sup> p-value (Mann–Whitney U-test)	0.1 <sup>a</sup>		0.23 <sup>a</sup>		0.07 <sup>b</sup>		0.05 <sup>b</sup>	
<sup>b</sup> p-value (t-test)								

Cases add up to fewer than 41 because 5 patients (3 control and 2 intervention) were lost to follow-up. SD, standard deviation; IQR, interquartile range; BI, Barthel Index; MAS, Motor Assessment Scale.

**Table 4** Areas under the curve up to five weeks

	Allocation	N	Mean	SD	t	t-test for equality of means	Significance (2-tailed)	Mean difference	95% Confidence interval of the difference	
									Lower	Upper
AUC between week 1 and week 2	Intervention	19	22.11	13.52	-1.48		0.15	-6.26	-14.81	2.31
	Control	17	28.35	11.51						
AUC between week 1 and week 3	Intervention	19	46.05	27.69	-1.57		0.13	-13.48	-30.97	4.02
	Control	17	59.53	23.46						
AUC between week 1 and week 4	Intervention	19	71.37	41.9	-1.57		0.13	-20.22	-46.62	6.18
	Control	17	91.59	35.26						
AUC between week 1 and week 5	Intervention	19	97.45	56.31	-1.55		0.13	-26.85	-62.16	8.47
	Control	17	124.29	46.81						

produced a strong treatment effect for three reasons: First, insufficient intervention may have been provided by the nurses, both in terms of the amount of time allocated to the intervention (12.73 min/patient per day) and the intensity with which the exercises were executed. However, no guidance was given to the nurses about how much intervention should be given since, although the type of activity was within the nurses' professional remit, it was nevertheless given in addition to their normal duties. It is highly unlikely that the reported level of intervention provided by nurses is sufficient to have a training effect. It should also be noted that the accuracy of the recording of the additional input is unclear. Both accuracy of reporting and sufficient treatment strength<sup>41</sup> should be taken into consideration in future studies investigating intensification of physical activity.

Secondly, it is unclear whether nurses inadvertently or otherwise provided additional exercise to the control group. Had this occurred, it would have constituted contamination. Although this problem specifically was communicated to the nurses prior to the commencement of the study, there is no way of knowing whether deviations from protocol had taken place. Contamination serves to compound the problem of insufficient contrast of rehabilitation intervention between the control and intervention groups and has been highlighted by Kwakkel *et al.*<sup>42</sup> The use of multicentres can provide a solution to this problem but has adverse effects on costs and was beyond the resources available for this study.

Thirdly, any effect of the intervention may not have been detected by measurements that were insensitive to change. Despite its apparent robustness<sup>43</sup> the BI suffers ceiling and floor effects<sup>44</sup> and is insensitive to modest changes in physical state.<sup>45</sup> The MAS has been tested for concurrent<sup>46</sup> and predictive<sup>47</sup> validity and reliability,<sup>35,46,48</sup> however its sensitivity (responsiveness) to change has not been assessed. Both the BI index and MAS are aggregated scales and it is possible that scores will not show change even where change has taken place since one category may improve, only to have its effect neutralized by another category falling by the same amount. This problem with ordinal scales has been previously acknowledged.<sup>49</sup>

This study suffered a number of methodological difficulties. The finding that the control group stayed in hospital and on the unit less time than the intervention group was surprising. Although these borderline significant effects disappeared after adjustment, the finding was no less surprising given the use of minimization as the method of randomization.

The a priori balance provided by minimization should not require conditional testing (statistical adjustment for covariates). However, in this present study, the need for adjustment suggests that imbalance had occurred. It is therefore suggested that where minimization is used with many factors and with a small sample size, conditional testing should not be ruled out.

The problems encountered in this study are probably indicative of the length of time over which data were collected,<sup>50</sup> the small size of the unit and the continued reliance on volunteers to contribute to an intervention. However, the fact that these nurses persisted for the whole of the intervention period is to be commended.

Finally, three of the 36 patients who completed the trial were unmasked to the 'blinded' assessor. The frequent nature of the repeated measurements makes exposure to unmasking more likely.<sup>51</sup> In order to overcome this, patients were told at the outset and at unspecified periods throughout their study that they should not speak to the researcher (observer) about the weekend. All staff on the unit were repeatedly reminded that it was of the utmost importance that the researcher did not know to which groups the patients had been allocated.

Blinding physical treatments is difficult<sup>52</sup> and much the same can be said of surgical

#### Clinical messages

- An increase in one-to-one input by nurses for people with stroke over the weekend did not lead to a measurable difference in physical outcome in this small study.
- Minimization does not always guard against imbalances, particularly if the sample size is small.

interventions and 'talk' therapies.<sup>53</sup> This is a recognized weakness in single blind trials.<sup>51,52,54</sup> It was anticipated that the most likely means by which this would happen was through conversation with patients and on two occasions this did happen.

The unmasking of three out of 41 patients over a period of a year lays testament to the success of the design and the safeguards for concealing allocation. For this, great credit should also be given to all of the staff taking part in the trial.

This present study has highlighted a number of issues. First, the results indicate that the nurses did intensify treatment, albeit by relatively small amounts but that this did not appear to affect overall patients' physical outcomes positively. Secondly, using single units for long periods and high dependency on volunteers to provide interventions is fraught with problems that flow from the complex nature of rehabilitation research. Thirdly, it is not possible to presume that a priori covariate balance using minimization will necessarily remove the need for conditional testing, particularly where the sample size is smaller than anticipated and many factors are used in the minimization programme. This does not detract from assertions that skilled and knowledgeable nurses are key to the success of stroke units.<sup>13,55</sup> Further research should concentrate on means by which the weekend period can be converted into specific therapeutic time in the absence of therapists.

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**Appendix 1 – Outline of the education programme provided**

Session	Duration	Content
Classroom-based training programme presented by a senior I physiotherapist (TW)	1st half day (3 h) theory	<p>Analysis of normal and abnormal movement:</p> <ul style="list-style-type: none"> <li>• Rationale for the assessment of normal movement</li> <li>• Identification of abnormal movement and its associated problems</li> </ul> <p>What is understood by normal movement:</p> <ul style="list-style-type: none"> <li>• Definition and the requirements for normal movement</li> </ul> <p>Influences on abnormal movement:</p> <ul style="list-style-type: none"> <li>• This considered the environment, positioning and moving of patients and their influences on patients' movement</li> </ul> <p>Neuroplasticity:</p> <ul style="list-style-type: none"> <li>• Definition and simple explanation of the concept of neuroplasticity</li> </ul>
	2nd half day (3 h) theory and practice	<p>Analysis of normal movement through patient demonstration and active participation of the nursing staff</p> <ul style="list-style-type: none"> <li>• Appreciation of how abnormal movement can develop</li> <li>• Analyses of: lying; sitting; sitting to standing; standing; gait and transfers from bed to chair</li> <li>• Practice of handling/facilitation of movement</li> </ul>
Work-based education provided by a senior I neurophysiotherapist (TW)	Six weeks	<p>Aimed to deliver education in the real work environment by putting into practice the aspects learned in the formal teaching</p> <p>Teaching was conducted by analysing movement components by breaking them down into their component parts. This was facilitated using TELER normal movement indicators.<sup>56</sup> Nine different postures and movements were analysed in a structured manner. This potentially enabled the course participants to establish how normal movement was constructed as well as giving them insight into the problems with which their patients presented</p>