Physiotherapy Research International, 5(4) 230–240, 2000 © Whurr Publishers Ltd

# Is dosage of physiotherapy a critical factor in deciding patterns of recovery from stroke: a pragmatic randomized controlled trial

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ABSTRACT **Background and Purpose.** *The best treatment and management of stroke patients has been shown to be in stroke units by multidisciplinary rehabilitation teams. Since the composition of stroke units differs it is important to know the extent to which the different components contribute to this result. Physiotherapy is one component of most rehabilitation teams and recent systematic reviews have shown that patients with stroke receiving more physiotherapy achieve more recovery from disability. However, information about the actual amounts of physiotherapy needed to achieve this result is not known.* **Method.** *A pragmatic, randomized, single-blind, controlled trial comparing recovery from disability in subjects receiving the current standard amount of 30 minutes' physiotherapy with those receiving double that amount (60 minutes). The study included measures of physical performance and function, psychological aspects of anxiety and depression, and perceived control over recovery.* **Results.** *Some 114 subjects were recruited to the study; full six-week data are available for 104 subjects and six-month data for 93 subjects. Comparison of initial to six-week difference scores in the control and intervention groups of the whole sample did not show a significant difference. Scrutiny of the recovery curves of the whole sample showed that, in half the sample, three distinct patterns of recovery were demonstrated.* **Conclusion.** *These results suggest that doubling the physiotherapy time available for patients in a stroke unit will not provide a measurable benefit for all patients. The subgroup analysis of patterns of recovery must be regarded as speculative, but provides the basis for hypotheses about those likely to respond well to more intensive therapy.*

**Key words:** physiotherapy, recovery, stroke

## INTRODUCTION

Stroke is still a leading cause of disability in adults (Khaw, 1996) and is more common in those over 60 years of age. Rehabilitation by multidisciplinary teams in stroke units has been shown to be effective in reducing both mortality and morbidity (Langhorne et al., 1993; Stroke Unit Trialists' Collaboration, 1997). Yet, little is known about which key components of the care in the unit contribute to this effectiveness. Physiotherapy is one component of rehabilitation which is now routinely available in most stroke units. Evidence to date from a critical review by Wagenaar and Meijer (1991), a meta-analysis of seven studies (Langhorne et al., 1996) and a research synthesis by Kwakkel et al. (1997) all show a relationship between the intensity of physiotherapy and recovery from disability, more beneficial recovery being found in patients receiving more treatment. In earlier studies, the actual amount of additional treatment received by patients in the groups compared was not clearly stated, and later work has not yet been able to show what amount of therapy is necessary to obtain an optimal result.

Recent clinical trials by Kwakkel et al. (1999a) and Feys et al. (1998) have shown that when physiotherapy is targeted at the hemiplegic arm or leg of patients with similar types of stroke there are significant differences in recovery of the targeted area between those receiving augmented physiotherapy and those receiving standard care, and, for Feys et al. (1998), this was still evident one year later. Hesse et al. (1995), in a series of seven single-case studies, also demonstrated a significant improvement in gait and velocity with treatment targeted at gait. In another study by Lincoln et al. (1999), where two of the four groups studied had additional physiotherapy for the arm and hand, the authors found no significant differences between the groups in measures of arm function or activities of daily living. However, by use of post hoc analysis of subgroups, these authors reported finding some differences between the groups in the less severely impaired group of patients.

These studies suggest that when physiotherapy is targeted at homogenous populations with specific problems it can be shown to be effective. However, this does not mirror current practice, in the UK at least. Most patients with stroke in hospital in the UK receive physiotherapy in line with the Bobath concept (Kwakkel et al., 1999b) for approximately 30 min/day. During this period the whole patient is treated, a key Bobath (1990) concept, although different techniques are used to target specific problems of the arm or leg.

Additional physiotherapy is expensive and unlikely to be funded routinely by the National Health Service (NHS) in the UK, or by health insurance companies. Evidence is needed about the effects of physiotherapy as practised by most clinicians. Ebrahim and Harwood (1999) commented that many of the trials to date '... do not tell us about the effectiveness of "conventional" physiotherapy'. The question being asked in the present pragmatic trial was whether doubling 'conventional' physiotherapy routinely available to patients would significantly alter their recovery profiles, in terms of motor performance, over a six-week and a six-month period. The project was approved by the local research ethical committee.

## METHOD

A pragmatic, single-blind, randomized, controlled trial comparing recovery from disability of patients receiving the standard amount of physiotherapy (30 min) currently available in the unit with others receiving 'standard plus' (60 min/day).

### Subjects

The study population comprised all patients with a diagnosis of stroke, according to WHO (1989) criteria, admitted over a two-year period to the Canterbury Stroke Unit, who fulfilled the study criteria and gave their informed consent to participation in the study. Exclusion criteria were: other intercurrent serious illness, poor mental state, Hodgkinson's (1972) score >8/10 and absence of physical disability (as assessed on the Profiles of Recovery (POR) scale; Partridge et al., 1987).

### Measurement instruments

The primary outcome measure was the POR scale, a 12-item hierarchical scale of gross body movements underlying function. The items were based on monitoring the milestones of recovery of 700 patients with stroke. Other measures included functional reach (Mackenzie, 1999) to test balance, step:time ratio (Wade, 1992), five-metre timed walk (Wade, 1992) and time taken to stand up from sitting in a chair.

Secondary measures included psychological variables shown to be associated with recovery from stroke, the *Hospital Anxiety and Depression Scale* (HAD) (Zigmond and Snaith, 1983) and perceived personal control over recovery by use of the *Recovery Locus of Control Scale* (RLOC) (Partridge et al., 1989).

### Treatment

It was decided to use the Bobath method of treatment as this is the most widely used in the UK (Kwakkel, 1997) and was the approach currently used by therapists in the unit. The guidelines put forward by Edwards et al. (1990) were followed for developing physiotherapy treatment packages for research: first examining the literature (Bobath, 1990) and then discussing the items identified with the clinical consultant and the three participating clinical physiotherapists. It was important to know what treatment each subject received, but early pilot work indicated that because of the variability of subjects' symptoms neither describing each treatment given nor developing a checklist of all possible treatments was feasible. The aims of treatment were therefore examined, as many treatments would come under one aim. After pilot work, consensus was achieved on 11 items which covered the majority of treatment aims with an 'Other' category provided (see Appendix). Further work was undertaken to find what treatment was given under each aim and considerable agreement was found between the treatments given under each aim by each therapist. These results are reported elsewhere, but all patients received similar treatment.

A clinical consultant, a specialist in Bobath methods, was appointed to the project. As the three clinical physiotherapists had different levels of experience, her role was to advise about clinical work throughout the study, to ensure that all treatments given were within the same philosophy and to help in the development of ways of describing and monitoring treatment given.

## Procedure

After subjects signed their informed consent forms, assessments were undertaken by the treating physiotherapist then after six weeks and six months, by the research associate. The aims of treatment were marked daily on a chart (see Appendix) by the physiotherapists and a weekly summary was provided.

The main analyses were a comparison of the difference scores between the intervention group and the control group on the POR over six weeks and six months. Statistical tests were parametric (for ratio data) and non-parametric (for ordinal data). Visual inspection and descriptive analysis of the raw data were also undertaken to examine recovery curves.

## Assignment

The unit of randomization was the individual. Allocation of the schedule was computer-generated. Sealed opaque envelopes were provided in batches of 10, with the group and subject number inside, and subject number only on the outside. When subjects were admitted to the unit, those who gave informed consent and fulfilled the entry criteria were randomized by opening the next envelope in the numbered sequence. Their names, numbers and date of first assessment were telephoned to the administrator, who registered the details (Figure 1).

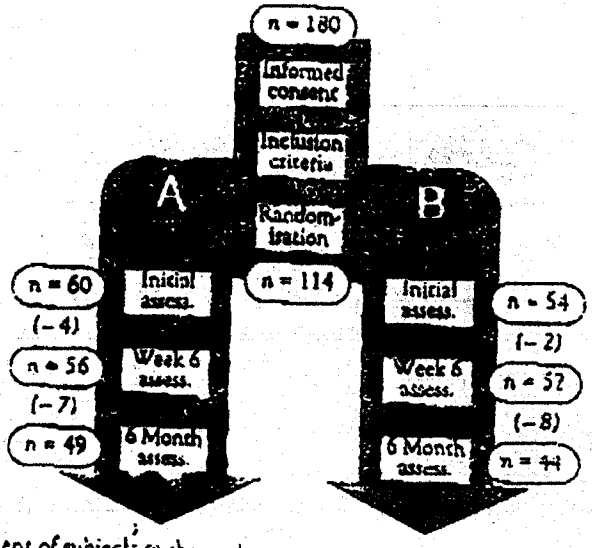


FIGURE 1: Assignment of subjects to the study.

### Masking

The control group received 30 minutes' treatment per day (that previously available in the unit), the intervention group received 60 minutes' treatment per day. An appointment system was set up whereby all subjects were allocated a one-hour slot, although only the intervention group spent that amount of time receiving physiotherapy. This ensured that other physiotherapists and staff were unaware of group allocation. The researcher who undertook the blind assessments was based at the university and remained blind to group allocation. The three participating physiotherapists rotated between treating the control and intervention groups on a three-monthly basis, which also helped in masking. The subjects had no knowledge of their group allocation.

## RESULTS

On the basis of scrutiny of the records in the unit and visits to the wards before the study, it was estimated that a population of 150 subjects could be recruited to the study within the two-year period. However, due to unforseen circumstances this number was less than anticipated and, even with a six-month extension, only 114 subjects were recruited to the study. However, the smaller than expected numbers are unlikely to have resulted in a Type II error.

A total of 114 subjects completed the initial assessment: 108 completed the six-week assessment and 93 remained by six months (Figure 1). Mean age of subjects was 76.5 years (range 60–94 years), 62 (54%) were female and 52 (46%) were male. The side of plegia was right in 53 (46%) subjects and left in 60 (53%) subjects; one patient had both sides affected. The majority of subjects (76) (67%) had suffered an infarct. Hemianopia was present in 32 (28%) subjects. The majority of subjects were independent (94) (82%) and mobile (80) (70%) before admission to hospital. At initial assessment 48 (42%) subjects were incontinent of urine, 39 (34%) had visual problems, 21 (18%) had impaired hearing and 58 (51%) had communication problems — of these 13 (11%) subjects' problems were severe. Sixty-six (58%) subjects had some proprioceptive problems and 69 (60%) had some diminished sensation. Thirty-seven subjects were not able to complete the full HAD scale, of the 77 subjects who did so 36 (31%) came within normal limits and 39 (34%) were anxious and depressed beyond normal limits. Analyses showed there were no statistically significant differences on any of these variables between the control and intervention groups at initial assessment. Means, medians, standard deviations (SD) and ranges of initial, six-week and six-month scores of the main variables are given in Table 1.

Mann–Whitney U tests were undertaken to compare the difference between initial and six-week POR scores in the two groups, but no significant differences were found at either six weeks or six months (Table 2).

TABLE 1: Initial, six-week and six-month means, standard deviations, medians and ranges between control and intervention groups

| *Variable* | *N* | *Mean* | *(SD)* | *Median* | *Range* |
|---|---|---|---|---|---|
| Control group | | | | | |
| Initial | | | | | |
| POR | 60 | 5.1 | (4.1) | 4.0 | 0–13 |
| Sit to stand | – | – | – | – | – |
| Timed walk | – | – | – | – | – |
| FR | – | – | – | – | – |
| HAD | 34 | 15.5 | (8.2) | 15.0 | 4–35 |
| RLOC | 39 | 35.0 | (4.6) | 36.0 | 25–43 |
| Six weeks | | | | | |
| POR | 56 | 9.8 | (4.6) | 11.5 | 2–14 |
| Sit to stand | 24 | 3.8 | (2.8) | 3.0 | 0.9–12 |
| Timed walk | 22 | 39.9 | (29.9) | 30.0 | 13.7–135 |
| FR | 21 | 64.5 | (15.4) | 69.0 | 17–80 |
| HAD | 46 | 12.9 | (7.1) | 13.0 | 1–30 |
| RLOC | 46 | 34.9 | (5.5) | 33.5 | 27–45 |
| Six months | | | | | |
| POR | 49 | 10.1 | (3.3) | 12 | 0–12 |
| Sit to stand | 27 | 4.3 | (5.3) | 3.3 | 0.5–28 |
| Timed walk | 33 | 49.4 | (32.1) | 41 | 10–125 |
| FR | 27 | 63.6 | (17.2) | 67.0 | 20.5–81.5 |
| HAD | 43 | 12.9 | (7.0) | 12.0 | 2–37 |
| RLOC | – | – | – | – | – |
| Intervention group | | | | | |
| Initial | | | | | |
| POR | 54 | 4.6 | (4.1) | 3.0 | 0–13 |
| Sit to stand | – | – | – | – | – |
| Timed walk | – | – | – | – | – |
| FR | – | – | – | – | – |
| HAD | 43 | 15.0 | (7.9) | 16.0 | 1–28 |
| RLOC | 40 | 34.9 | (4.9) | 34.5 | 25–45 |
| Six weeks | | | | | |
| POR | 52 | 9.5 | (4.6) | 11.5 | 1–14 |
| Sit to stand | 13 | 4.8 | (3.3) | 40.0 | 1.9–14.5 |
| Timed walk | 33 | 49.2 | (32) | 41.0 | 10.4–127 |
| FR | 23 | 57.1 | (15.8) | 59.0 | 23–77 |
| HAD | 48 | 12.6 | (7.6) | 11.5 | 2–32 |
| RLOC | 48 | 35.6 | (5.6) | 34.0 | 26–45 |
| Six months | | | | | |
| POR | 43 | 9.0 | (4.2) | 12 | 0–12 |
| Sit to stand | 23 | 3.5 | (2.3) | 2.8 | 1–9.8 |
| Timed walk | 27 | 35.8 | (16.5) | 33.9 | 12–71 |
| FR | 25 | 61.2 | (16.8) | 65.0 | 22–84 |
| HAD | 41 | 12.9 | (7.9) | 11.0 | 2–32 |
| RLOC | – | – | – | – | – |

POR = Profiles of Recovery; FR = functional reach; HAD = *Hospital Anxiety Depression Scale*; RLOC = *Recovery Locus of Control Scale*.

TABLE 2: Comparison between change scores in control and intervention groups

| | Mann–Whitney U test |
|---|---|
| Initial–six weeks | 1402.5 (p=0.74) |
| Six weeks–six months | 967.5 (p=0.775) |
| Initial–six months | 984 (p=0.896) |

Visual inspection of the recovery curves of all patients on the POR scale during the six-week period showed that in about half the sample (n=53) three subgroups could be discerned. Subgroup 1 (n=17) started with low scores of ≤3 and by Week 6 had made little or no progress. Subgroup 2 (n=16) started with high scores of ≥10 on the 12-item scale and most obtained the full score by Week 6. Subgroup 3 (n=20) started with scores similar to subgroup 1, scoring 3 or less but by Week 6 all had scores of ≥10. Subjects in subgroups 1 and 2 were fairly equally divided between the control and intervention groups, but in subgroup 3, 14/20 subjects (70%) were in the intervention group.

There was a small cluster of variables where differences were apparent in the subgroups — first age then impairment, in terms of problems of communication and spatial awareness, and also the psychological variables of mood and perceived control over recovery. The first subgroup that made little progress was older (mean age 79 years), had more communication problems (five severe, five moderate) and had more spatial problems (six moderate, seven severe). Subjects in this group were also more likely to be anxious and depressed (13 scored as 'abnormal' on the HAD scale) and to score lower on the on the RLOC scale (mean score 32). Subgroup 2 subjects, who started with high scores and were younger (mean age 75 years), all had anxiety and depression scores within the normal range, eight subjects had only mild communication problems and none had apparent spatial problems; they also had higher RLOC scores (mean score 35).

Subgroup 3 subjects made the most progress over the six-week period; they were younger (mean age 74 years) and none had abnormal HAD scores, they also had higher RLOC scores (mean score 35). Few had communication problems (seven moderate), none severe, and spatial problems (five subjects had moderate problems).

The remaining 55 subjects formed a middle group; they had initial POR scores higher than those in subgroups 1 and 3 but below those in subgroup 2 and made only moderate amounts of recovery, moving three or four points by six weeks. None reached the full POR score of 12. Again, other complicating factors came within the middle range.

## DISCUSSION

The overall finding of no significant differences in the change scores of the two groups over six weeks or six months was disappointing. There may be a number of reasons which can help to explain these results. A pragmatic trial was undertaken:

and a population of all stroke patients capable of collaborating with the study protocol was recruited, in one stroke unit, over a 30-month period. Selection was not made on the basis of type or location of stroke, as other more successful studies have done, nor were treatments targeted at the affected arm or leg, but the whole patient was treated, which reflects current practice in most hospitals in the UK. This introduced greater heterogeneity into all aspects of the study. As long ago as 1967, Bradford Hill (one of the first medical statisticians) highlighted problems associated with researching complex diseases, 'all patients in the trial should have similar types of the disease ... if you incorporate different groups and hope to sort out with statistics you may be courting disaster'. He recommended being more precise.

In studies of physiotherapy which have been more precise, where a homogenous group of subjects was selected and treatment targeted at a specific part of the body, significant differences have been shown between those receiving augmented physiotherapy and those who did not (Kwakkel, 1999a; Feys et al., 1998). Other studies, such as that of Lincoln et al. (1999), studied four groups of stroke patients receiving different intensities of treatment for the hand and arm and found no significant differences at post-intervention assessment in outcome at three or six months. However, in a post hoc analysis of subgroups these authors did find significant differences, but suggest that their results can only be speculative as they concerned subgroups of patients.

Ebrahim and Harwood (1999) comment that physiotherapy trials to date have often used novel methods and that the effectiveness of 'conventional' physiotherapy has not been demonstrated. The present study attempted a pragmatic trial of current practice, which could be termed 'conventional' physiotherapy. Though certain prognostic factors have been shown to be associated with a more favourable recovery and are summarized by Ebrahim and Harwood (1999) as 'site and extent of lesion', 'other complications', 'mood', 'morale', 'pre-stroke morbidity', 'social factors' and 'age', less is known about factors associated with a good response to therapy. Although the information from the subgroups in the present study must be viewed with caution and considered speculative as the numbers were small some of the factors do fit with other work. A number of authors, including Ebrahim and Harwood (1999), have identified older age as a factor associated with slower recovery, as did Partridge et al. (1993) by use of the same POR scale. There is also evidence to show an association between psychological factors, such as depressed mood (Schubert et al., 1992; House, 1987; Sinyor et al., 1986) and a greater belief in perceived personal control over recovery (Partridge et al., 1989; Johnston et al., 1999) being associated with slower recovery.

Giving additional physiotherapy to all patients is expensive and in the present financial climate unlikely to be funded even if moderate improvements can be demonstrated. It seems therefore that targeting those patients who are likely to benefit most from physiotherapy, and those who are not, is crucial. Kalra et al. (1993) suggest some criteria for patients unlikely to benefit from active rehabilitation they include those who have a severe motor deficit at two weeks and also presence of sensory and perceptual problems. Again, this is in line with the subgroup analysis of the present study.

Another reason that could have masked changes that did occur in this study is a key concept of treatment within the Bobath approach is to aim for quality of movement, and more normal movement patterns. Here, a scale was used which was not sensitive to measuring quality of movement, as it is notoriously difficult to measure it in a rigorous way. In the POR scale subjects were scored as either achieving or not achieving each gross body movement item, the way in which they performed was not noted or scored.

In the three subgroups identified, if they can be demonstrated to be accurate, the first — whose subjects made little progress by six weeks — could be discharged earlier with full community support and a programme to prevent the development of secondary problems. Subjects in the second subgroup — who started with high initial scores which showed a ceiling effect on our scale — could be moved earlier to activities in normal health clubs, as is done in North America, whereas subjects in the third subgroup are more likely to benefit from programmes of intensive physiotherapy. These propositions need to be tested, and perhaps the subgroups identified here could provide hypotheses to be tested in further work.

## APPENDIX

Aims of treatment for people with stroke working within the Bobath concept

1. Mid-line alignment, postural adjustment, symmetry and control.
2. Maintenance of full range of movement.
3. Working to improve base of support.
4. Facilitating all aspects of transfers.
5. Modifying muscle tone.
6. Sequencing of movements.
7. Balance re-education, stability and transfer of weight.
8. Inhibition of positive support reaction.
9. Working on shoulder girdle and scapulo-humeral rhythm.
10. Facilitating functional hand/arm movements.
11. All aspects of re-education of gait, including knee and foot control.
12. 'Other' category to be specified.

## ACKNOWLEDGEMENTS

The other members of the Canterbury Stroke Team who took part in this study include Jane Pollok and Lindsay van der Poot, superintendent physiotherapists at Nunnery Fields Hospital. The authors would like to thank Fiona Reid and Jean Saunders for statistical help and advice; also, Barbara Wall and Linda McDonnell who organized the masking procedures. The project was funded jointly by South East Thames R&D Directorate and East Kent Health Authority. Most importantly, we want to thank the patients who co-operated so enthusiastically with study protocols.

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*(Submitted December 1999; accepted July 2000)*