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The COSTAR wheelchair study: a two-centre pilot study of self-propulsion in a wheelchair in early stroke rehabilitation

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Objective: It is uncertain whether self-propulsion in a wheelchair should be encouraged or discouraged in the early stages of stroke rehabilitation.
Design: A two-centre pilot study to assess the feasibility of performing a multicentre randomized controlled trial on this subject.
Setting: Clatterbridge and Aintree Stroke Rehabilitation Units, Merseyside, UK.
Subjects: Forty early stroke patients (mean age 67 years) in whom it was uncertain whether self-propulsion in a wheelchair should be encouraged were studied.
Intervention: A central randomization service at Newcastle University was used to determine the policy about wheelchair provision and use for each patient. They were allocated to either an 'encouraged to self-propel' or a 'discouraged from self-propulsion group'.
Outcome measures used: Independent outcome assessment was performed by postal questionnaire and telephone interview using the Barthel ADL Scale, Nottingham Extended ADL Scales and the shortened General Health Questionnaire (GHQ-12) at 3 and 12 months. Patient's length of stay and their Ashworth tone score were also measured either at three months or when they were discharged from hospital.
Results: After considerable preparation time it was possible to conduct a trial on self-propulsion in early stroke rehabilitation in the two-pilot centres. No major differences were found between the pilot groups for any of the outcome measures.
Conclusions: A multicentre randomized controlled trial to assess this question is feasible but further work is being conducted before proceeding, to satisfy the concerns expressed to our group regarding the appropriateness of the intervention and the outcome measures.

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Introduction

As a temporary mobility aid, stroke patients view the use of wheelchairs positively[1] but there is a lack of consensus between clinicians about the benefits or otherwise of wheelchair use in stroke rehabilitation,[1–5] particularly soon after stroke onset.

In Britain the majority of physiotherapists treating stroke patients follow the treatment regimen described by Bobath[6] in which early self-propulsion is discouraged. It is believed to cause an increase in tone on the affected side, poor posture and adversely affect long-term recovery.[2]

Preliminary work, in a cross-sectional study of attendees at a day hospital, without a history of stroke, suggested that the majority (78%) would wish to use a wheelchair if they could not walk following a stroke (Watkins, 1993, personal communication). A survey of therapists in 10 hospitals in the North-West confirmed the lack of consensus as to which stroke patients should self-propel, what type of chair they should use and at what stage in their rehabilitation. Difficulties in gaining a consensus were also apparent when discussing the preliminary protocol for a potential multicentre study at the British Stroke Research Group and COSTAR (Collaborative Stroke Audit and Research) group meetings in 1994. It was apparent that at present most stroke rehabilitation units do not routinely provide patients with a wheelchair in the early stages of their rehabilitation. Both groups agreed that a trial is required to answer the question 'Does early self-propulsion in a wheelchair affect the outcome for patients in stroke rehabilitation?'

The feasibility of performing such a trial was examined in this pilot study.

Ethical approval was granted for this study by the Wirral and South Sefton Ethical Committees.

Methods

Setting

The pilot centres for the study were the stroke rehabilitation units of two District General Hospitals in the North-West of England which have different approaches to wheelchair provision and use after stroke. In the Aintree stroke rehabilitation unit, Liverpool wheelchairs are not routinely provided. Patients are usually seated in a suitable armchair during the day. Patients treated in the Clatterbridge stroke rehabilitation unit, Wirral usually sit in a wheelchair during the day but most are discouraged from self-propulsion (though some disregard this instruction).

New wheelchairs were provided for the study in both centres to ensure that wheelchair problems, e.g. flat tyres, were minimized and that a correct size chair would be available at randomization.

Subjects

All consecutive admissions to the Wirral and Aintree Hospitals with a diagnosis of acute stroke are recorded on a stroke register and a minimum set of data is collected (European Stroke Data Base). Patients were screened for inclusion in the study by the nursing and therapy staff when they were transferred to the stroke rehabilitation unit. Patients with severe perceptual neglect or severe communication difficulty were excluded from the study as it is very difficult to teach them how to self-propel.

Patients who were already able to walk independently on arrival in the stroke rehabilitation unit were considered 'too fit' for the study as they were unlikely to need to use a wheelchair. Others were considered 'not fit enough' for this study as they had not regained sitting balance and would not have been safe to sit in a wheelchair. The numbers in each group are summarized in the flow chart (Figure 1).

The uncertainty principle was used to determine whether it was reasonable and ethical to randomize the decision about early wheelchair self-propulsion. This decision was made by the treating therapist(s) (Bobath trained). They did not tend to invite patients with markedly increased tone to participate. The treating therapist and/or a research nurse provided information about the trial to patients that they considered suitable for inclusion. They explained the nature of the study and sought consent.

It is possible that the therapist's opinions and personal bias may have influenced whether consent was given. Some patients refused consent as they did not wish to be randomized to not self-propel as they wanted to have independence

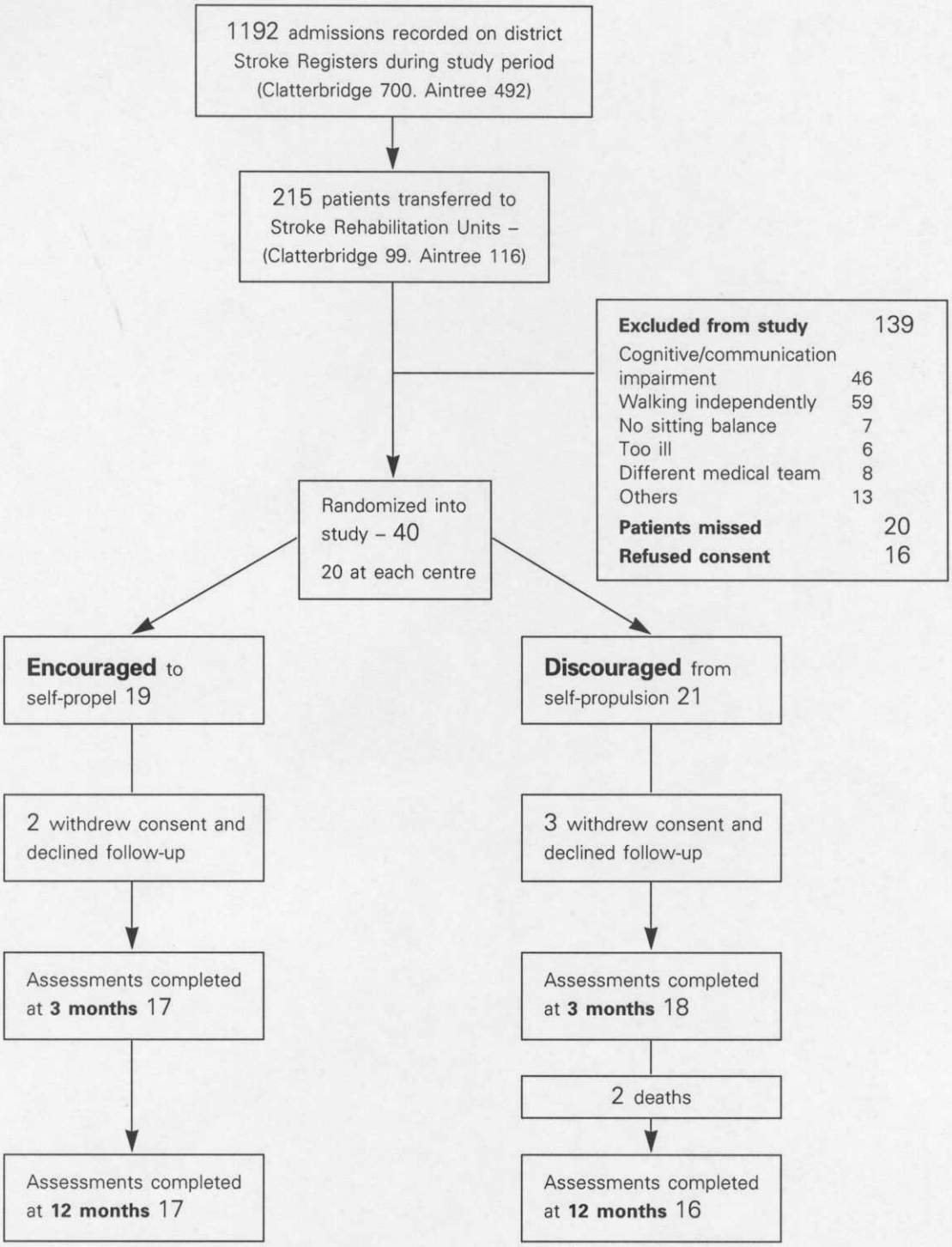

Figure 1 Flowchart to illustrate the source of patients recruited to the study and the number that remained in the study when the outcome questionnaires were completed at 3 and 12 months.

while on the ward. Others refused consent for the opposite reason, as they did not want to risk participating if it carried a risk of adversely affecting their recovery.

Randomization

An independent telephone computerized randomization service based in the COSTAR office in the University of Newcastle was used for this study.

The stroke rehabilitation unit physiotherapist or occupational therapist telephoned the randomization office with the patient's details, which were recorded for the trial database. They were then informed whether the patient was allocated to the 'encouraged to self-propel' group or the 'discouraged from self-propulsion' group. Equal allocation to each group was planned at each of the pilot sites without any stratification.

Intervention

Patients allocated to the 'encouraged to self-propel' group in both pilot centres were provided with a wheelchair on randomization. In the first week the physiotherapists instructed these patients each day on how to self-propel their wheelchair. They were then reminded at weekly intervals. The technique demonstrated was use of the nonaffected foot to paddle and propel and use of the nonaffected arm to provide extra propulsion and steering. They were encouraged to self-propel on the ward, e.g. to the dining room for meals (distance 10–50 m). The ward staff provided assistance for patients who were unable to master self-propulsion, e.g. going round in circles. The encouragement to self-propel continued for eight weeks or until the patient was discharged from the stroke rehabilitation unit.

The policy adopted for the patients allocated to the 'discouraged from self-propulsion' group differed slightly between the two centres. Patients at Aintree who were randomized to the discouraged group were seated in a suitable armchair between activities. At Clatterbridge a modified wheelchair was provided which had rear, attendant-operated brakes which were applied when the chair was stationary to prevent attempts at self-propulsion. Patients in this group were not encouraged to self-propel for eight weeks or until self-propulsion would normally have been recommended by the rehabilitation team treating the patient.

All other aspects of rehabilitation treatment remained unchanged in both hospitals.

Data collection

At randomization patients were assessed by both a physiotherapist/occupational therapist (OT) and a research nurse. The baseline data were collected by them before randomization and included basic demographic details and scores on Modified Ashworth Tone Scale,[7,8] Barthel Activities of Daily Living (ADL) Index,[9] and Oxford Community Stroke Project Classification (OCSP).[10]

During the study period the treating therapists (physiotherapist and/or OT) kept a record of the patient's compliance with the study instructions (on a 10-point visual analogue scale ranging from 0 (complete noncompliance) to 10 which indicated excellent compliance). Adverse events (e.g. falls) the date when the patient first walked 10 metres independently without supervision and length of stay were also recorded. The Modified Ashworth Scale was repeated by the physiotherapist providing treatment at three months or on discharge from hospital, whichever occurred sooner.

Two weeks after the patient's discharge from hospital a copy of Pound's Satisfaction Scales[11,12] was sent to both the patient and main carer for completion and return to the trial office. This time was chosen to enable patients to recall their experience of their hospital stay and the discharge process. The satisfaction questions used were not adjusted for this study.

The main outcome measures for both centres were independently assessed at 3 and 12 months post stroke by a research nurse who had not been involved in any of the patient's treatment using a combination of telephone interview and postal questionnaire. The questionnaire included the Barthel ADL Index,[9] Nottingham Extended ADL (NEADL),[13] Shortened General Health Questionnaire (GHQ-12)[14] and the question 'Do you feel sad or depressed?'

Lindley's two simple questions from the International Stroke Trial were also used in the 12 months questionnaire[15] to assess long-term outcome after stroke. The two questions were '*Have*

you needed help from another person in the last 2 weeks?' and '*Do you consider yourself to have made a good recovery from your stroke?*'

Analysis of results

An intention-to-treat analysis of the data was performed using the Epi-info statistical package. The summary statistics are presented but detailed statistical analysis of the results has not been performed, as this pilot study was not powered to produce a significant result.

Results

Forty patients were randomized into the study (20 patients per hospital). They were recruited between November 1995 and October 1996 at Clatterbridge and between August 1996 and May 1997 at Aintree. Eighteen per cent of the acute stroke patients admitted to the two centres were transferred to the stroke rehabilitation units. The reasons why patients were excluded from the study are summarized in Figure 1. Demographic data and length of stay information are presented in Table 1.

The two groups were well-matched for age, length of stay and Barthel score at randomization. There was a female preponderance in the encouraged group. A slight problem in the randomization service led to an unintended imbalance in the numbers allocated to each group.

The median length of stay of patients on the stroke rehabilitation unit was 86 days (interquartile range, IQR 55–149) in the encouraged group and 91 days (IQR 49–131) in the discouraged group. These were both longer than the median length of stay of all the stroke rehabilitation unit patients on the district stroke registers at that time (42 days; IQR 22–64.5).

No major differences were found between the two groups in the median scores for Barthel ADL, Nottingham Extended ADL or General Health Questionnaire (GHQ-12) at 3 or 12 months (Tables 2 and 3) as were the Modified Ashworth scores at three months or discharge (Table 4).

The median score given by the ward staff for

Table1 Demographic data amalgamated for the two centres. Patients were randomized to either the 'encouraged to self-propel' group or the 'discouraged from self-propulsion' group

	Encouraged (n = 19)	Discouraged (n = 21)
Age (years)		
Mean (SD)	67.5 (10.4)	66.7 (12.0)
Median (IQR)	70 (65–73)	70 (59–75)
Female	10 (53%)	6 (29%)
OCSP Classification[10]		
Total anterior circulation stroke (TACS)	3	4
Partial anterior circulation stroke (PACS)	7	9
Lacunar stroke (LACS)	8	7
Posterior circulation stroke (POCS)	1	1
Time after stroke onset when randomized (days)		
Mean (SD)	16.1 (8.8)	15.6 (8.1)
Median (IQR)	14 (11–22)	13 (9–21)
Length of stay on stroke rehabilitation unit (days)		
Mean (SD)	99.9 (54.3)	103 (68.0)
Median (IQR)	86 (55–149)	91 (49–131)
Total length of hospital stay (days)		
Mean (SD)	116.1 (54.7)	118.6 (69.1)
Median (IQR)	104 (77–171)	108 (68–151)

SD, standard deviation; IQR, interquartile range.
OCSP, Oxford Community Stroke Project.

compliance with study instructions appears to be quite low for the patients who were encouraged to self-propel compared with the good compliance scores in those who were discouraged (see Table 2). No serious adverse events were reported.

There was no apparent difference between the groups in the number of patients who were able walk 10 metres independently by the end of the eight weeks treatment part of the study (see Table 2).

Discussion

This study investigated the feasibility of performing a trial on whether patients should self-propel in a wheelchair in early stroke rehabilitation. The question applies to a group of stroke rehabilitation unit patients who have a median length of stay of about three months, which is longer than other stroke unit patients. Shorter stay patients may have problems which render them unsafe for early hospital discharge without stroke rehabilitation input (e.g. cognitive, perceptual or communication difficulty), but who remain independent. They are therefore unlikely to need to use a wheelchair.

Table 2 Functional outcome measure results obtained for the patients randomized to the study

	Encouraged	Discouraged
Barthel ADL		
Randomization		
Mean (SD)	7.4 (1.9)	7.0 (2.5)
Median (IQR)	7.0 (6–8)	7.0 (5–9)
3 months		
Mean (SD)	11.4 (4.0)	9.8 (5.0)
Median (IQR)	10.5 (8–13.5)	10.0 (6–12)
12 months		
Mean (SD)	11.9 (5.2)	11.9 (4.1)
Median (IQR)	11.0 (9–16)	12.5 (8.5–15)
Nottingham Extended ADL		
3 months		
Mean (SD)	5.8 (5.2)	5.3 (4.0)
Median (IQR)	4.5 (2.5–6.5)	5.0 (1–7)
12 months		
Mean (SD)	7.1 (4.7)	8.0 (5.3)
Median (IQR)	5.0 (4–8)	7.5 (3.5–11)
Number who walked 10 m independently by end of the randomized treatment period	7 (36%)	6 (29%)
Time from onset of stroke to first walk (days)		
Mean (SD)	81.6 (36.3)	170.0 (127.1)
Median (IQR)	68.0 (60–94)	126.5 (59–284)
Compliance with instructions		
Mean (SD)	5.3 (3.5)	8.0 (3.1)
Median (IQR)	6.3 (1.5–8.4)	9.5 (8.1–9.7)
Lindley's two simple questions		
Have you needed help from another person in the last 2 weeks?		
Yes	14	13
No	1	1
Do you consider yourself to have made a good recovery from your stroke?		
Yes	5	9
No	10	5

Although both centres in this study missed the chance to enter patients into the study it is possible that the inclusion of all the eligible patients would have only increased the study recruitment to approximately 30% of the patients treated on these well-established stroke rehabilitation units.

The potential for increasing recruitment elsewhere within the hospital was investigated. In one of the centres an active rehabilitation ward in the Department of Medicine for the Elderly adjoining the stroke rehabilitation unit was also set up to enter patients into the study. There were, however, no suitable patients on that ward during the study period (they were usually too ill to be able to self-propel). The issue of whether to self-propel in early stroke rehabilitation therefore appears to mainly appertain to patients undergoing treatment in a stroke rehabilitation unit (or following their discharge home from hospital).

Each centre in this pilot study required considerable preparation time prior to participating

Table 3 Psychological outcome measure results obtained for the patients randomized to the pilot study

	Encouraged	Discouraged
Do you feel sad or depressed?		
3 months		
Yes	9 (60%)	11 (69%)
No	6	5
12 months		
Yes	11 (73%)	10 (63%)
No	4	6
General Health Questionnaire (GHQ-12)		
3 months		
Mean (SD)	17.9 (6.6)	20.2 (5.8)
Median (IQR)	19.0 (16–22)	21.5 (15–25)
12 months		
Mean (SD)	19.6 (7.7)	20.1 (6.9)
Median (IQR)	22.0 (14–26)	21.0 (17–26)
Patient satisfaction		
Total hospital satisfaction score		
Mean (SD)	16.8 (2.8)	14.3 (2.1)
Median (IQR)	16.5 (15–18)	15.0 (13–16)
Total discharge satisfaction score		
Mean (SD)	10.8 (1.7)	10.2 (1.4)
Median (IQR)	10.5 (9.5–11.5)	10 (10–11)
Carer satisfaction		
Total hospital satisfaction score		
Mean (SD)	6.6 (2.9)	5.3 (1.9)
Median (IQR)	6.0 (4–8.5)	4.0 (4–7)
Total discharge satisfaction score		
Mean (SD)	11.8 (2.5)	9.3 (1.6)
Median (IQR)	11.5 (10–13)	10 (8–11)

Clinical messages

- It is uncertain whether patients should self-propel in a wheelchair during early stroke rehabilitation.
- Early self-propulsion may lead to physical changes, e.g. in muscle tone or influence functional ability or psychological status.
- The design of a multicentre randomized controlled trial is evolving to clarify whether self-propulsion should be encouraged or discouraged.

Table 4 Modified Ashworth Tone Scale results. The results are presented as the number of patients in each of the tone categories, defined in the scale

Modified Ashworth Tone Scale category		Encouraged	Discouraged
At randomization			
Normal tone	0	6	10
	1	8	4
	2	1	5
	3	4	1
Very high tone	4	0	1
At hospital discharge or 3 months after randomization (whichever was sooner)			
Normal tone	0	6	5
	1	6	5
	2	2	4
	3	1	3
Very high tone	4	2	1

in the trial (more than five years from the initial discussions to randomizing the first patient). The need to have the full co-operation and commitment of all members of the multidisciplinary team is the biggest target to achieve or obstacle to overcome. It is not possible to proceed without that as the intervention for each patient lasts many weeks with large numbers of staff involved in their care and treatment.

Many members of the rehabilitation team have strong views on this subject,[1,2] which may influence their willingness to participate and randomize patients. During the preparation and conduct of the pilot study it has become apparent that there are at present many anxieties among UK therapists about proceeding on to a full multicentre randomized controlled trial. They have concerns, which were expressed to our group, regarding the appropriateness of the intervention and the outcome measures being used. They also feel that the pragmatic design of the trial, similar to the design of the International Stroke Trial of Aspirin Use in Early Stroke,[16] is likely to miss important effects, which are not being measured. These worries need to be addressed before further progress can be made.

The design of this pilot study concentrated on the functional outcome measures rather than addressing the therapists' main worry, which is the effect that early self-propulsion has upon muscle tone, posture and movement. It will be important to measure both in a future study though the ability to effectively measure all of these effects in a large study is not yet fully developed.

The measurement of muscle tone, posture or movement is at present based on the use of clinical assessment scales. There is a debate at present on the reliability of these scales.[17,18] Technological developments may possibly overcome some of these difficulties and enable objective measurements of tone, posture and movement to be made in a manner that makes them useful for both research and clinical use.

Whenever the definitive study on wheelchair self-propulsion is performed, it will need to include regular recording of important predetermined variables during the treatment phase, probably at weekly intervals. These are likely to include the amount of self-propulsion, the content and amount of therapy given, the progress made during treatment sessions (particularly in relation to muscle tone, posture and movement) and/or any adverse effects during treatment. Patient's psychological progress will also need to be recorded.

Despite the therapists' beliefs, many stroke patients are desperate to be able to move themselves around the stroke rehabilitation unit under their own power. There was an excellent example of this in one of our centres following the delivery of the study wheelchairs. The patients on that unit commandeered the wheelchairs and would not return them as they wished to use them to self-propel. Other patients, however, withheld their consent as they did not wish to self-propel due to fear that it would jeopardize their long-term recovery. Patients' views therefore differ considerably.

We found it difficult to be certain that bias was excluded in the selection of patients for this study, particularly as it challenges a central element of current stroke treatment. This factor may also have influenced the degree of encouragement patients were given to self-propel and may have contributed to the possible difference in compliance observed between the two groups.

Further developmental work is still needed in the measurement of the possible psychological benefits of early wheelchair use. In this pilot study we used 'off the shelf' measures for mood/misery (GHQ-12)[14] and satisfaction but perhaps the potentials for greater independence and control are missed by these measures. We would also suggest that the satisfaction questions should include some that are specific to the trial question rather than rely on general satisfaction questions.[11,12]

This pilot study has provided valuable data, which have allowed us to estimate the sample size for a large multicentre trial of wheelchair self-propulsion in early stroke rehabilitation. The null hypothesis is that there would be no difference between the two treatment groups in the length of stay in hospital, Barthel ADL, Nottingham extended ADL, GHQ-12, Satisfaction, or Modified Ashworth Tone Scale at three months or 12 months. Other measurements are, however, likely to be added or to replace some of these after further preparatory work.

Although the pilot study data are ordinal in nature, parametric comparisons have been used to give a rough estimate of sample size. The data from the Barthel ADL scores at three months have been used to calculate that 208 patients would be required in each group to detect a statistically significant difference between the encouraged and discouraged groups with 90% power and an α of 5%.

We hope that it will be possible to proceed to a full multicentre trial on self-propulsion in early stroke rehabilitation in the future. It will be important in such a trial to ensure that the difference between the management of patients in the two study groups is large enough potentially to make a difference. Our experience indicates that centres in a such a trial should randomize to either the provision of a wheelchair and active encouragement to self-propel or no wheelchair provided and therefore unable to self-propel. We found that even the most elaborate braking system cannot prevent a determined patient self-propelling or asking a well-meaning passer-by to release the brakes (assuming that they have been applied in the first place).

The patients allocated to the 'encouraged to self-propel' group will also need strong encouragement to self-propel as our measurement of compliance with instructions in this study suggests that some of our patients did not self-propel much, despite being in the encouraged group.

We look forward to the definitive study on this question being performed to produce an evidence-based policy on wheelchair use post stroke rather than having to rely on opinions.

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