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A randomized trial evaluation of the Oswestry Standing Frame for patients after stroke

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Background: Standing is believed to have benefits in addressing motor and sensory impairments after stroke. One device to facilitate standing for severely disabled patients is the Oswestry Standing Frame.
Objective: To evaluate the effectiveness of the Oswestry Standing Frame for severely disabled stroke patients.
Design: A single centre, randomized controlled trial.
Setting: An inpatient stroke rehabilitation unit.
Subjects: Patients were recruited if they had a clinical diagnosis of stroke, were medically stable and unable to achieve any score on the Trunk Control Test or unable to stand in mid-line without the assistance of two therapists.
Intervention: The intervention ($n = 71$) and control ($n = 69$) groups both received usual stroke unit care but the intervention group also received a minimum of 14 consecutive days' treatment using the standing frame.
Main outcome measures: The primary outcome measure was the Rivermead Mobility Index (RMI). Secondary measures included the Barthel Index; the Rivermead Motor Assessment; the balanced sitting and sitting to standing components of the Motor Assessment Scale; the Trunk Control Test and the Hospital Anxiety and Depression Scale. Blind assessment was undertaken at baseline, six weeks, 12 weeks and six months post stroke. Information on resource use was also collected.
Results: There was no statistically significant difference between groups in any of the outcome measures or for resource use. Mann–Whitney *U*-tests for the RMI change from baseline scores to six weeks, 12 weeks and six months post stroke were $p = 0.310$; $p = 0.970$ and $p = 0.282$, respectively.
Conclusion: Use of the Oswestry Standing Frame did not improve clinical outcome or provide resource savings for this severely disabled patient group.

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Introduction

Multidisciplinary rehabilitation team care is a fundamental component of organized stroke care[1] but the effectiveness of the constituent activities and techniques that underpin the team processes are less well understood. Robust evaluations of the separate components of rehabilitation have been advocated[2,3] and we report on an evaluation of one treatment approach used in clinical practice.

The use of standing as a treatment strategy early after stroke is highlighted in several standard texts.[4–8] Suggested benefits include prevention of muscle shortening, stimulation of anti-gravity muscle activity and promotion of well-being. However, robust evidence of effectiveness is scarce; we were unable to identify any studies that evaluated the use of supported standing as a treatment intervention after stroke.

The Oswestry Standing Frame[9] has been used on the Bradford Stroke Unit to assist in the rehabilitation of heavily dependent patients but the benefits in terms of clinical outcomes and possible impact on staff resources were uncertain. We sought to investigate these clinically generated questions by a prospective, randomized controlled trial.

Methods

Pilot work undertaken in the five months before study recruitment began collected information on existing use of the Oswestry Standing Frame on the Bradford Stroke Unit. Patient characteristics and typical treatment schedules were defined and used to inform the trial inclusion criteria and treatment schedules.

Participants

A research nurse (JS) screened all patients and their carers (defined as a patient supporter who shared the same address) referred to the Bradford Stroke Unit between 1 December 1999 and 22 February 2002. Patients were considered for inclusion into the study if they had sustained a new stroke, had no concurrent medical condition likely to need palliative care, and were medically stable and sufficiently alert to participate in physiotherapy. The latter features were defined as fit enough to sit out in a chair for more than half an hour and score 11 or more on the Glasgow Coma Scale (GCS).[10] Patients fulfilling these criteria were then assessed by physiotherapy staff and considered eligible for the study if they were unable to achieve any score on the Trunk Control Test[11] or unable to stand with an erect trunk without the support of two therapists. The Trunk Control Test is a valid and reliable measure of motor impairment that has been shown to have predictive value for future walking ability.[11,12] If eligible, patients and carers were approached for informed consent and recruited to the trial by the research nurse (JS). Ethical approval was obtained from the local research ethics committee.

Stratification and randomization

Patients were stratified by two factors known to be influential in stroke outcome: first, by the presence/absence of urinary incontinence or a catheter in the first two weeks post stroke;[13–16] secondly, by stroke type using the Oxford Stroke Classification.[17,18]

The random allocation sequence was generated by researchers otherwise uninvolved with this project using a computer program (SAMPSIZE version 2.0[19]) and random length-restricted permuted blocks (block lengths of 2, 4 and 6).[20,21] Concealed, centralized randomization using opaque allocation envelopes was used.

Intervention

To reflect the clinical practice identified in the pilot work, patients in the intervention group were expected to receive 14 consecutive daily treatments using the Oswestry Standing Frame. When consecutive treatments were not possible, for example due to illness, the aim was to provide a total of 14 standing frame treatments. Analysis of the pretrial treatment records identified that sessions varied in therapy content and duration. Treatment schedules were therefore not specified but remained flexible so that they could be organized to meet the needs of individual patients. Additional therapy sessions (without using standing frame) could be provided as required.

Control group

The control group were similarly to receive 14 consecutive treatments, but without access to the Oswestry Standing Frame. A tilt table was available if required for safe patient handling.

The same multidisciplinary rehabilitation team treated all patients in the study. In common with the majority of UK physiotherapists,[22] therapists on the stroke unit adopt an eclectic stance to treatment which, although centred around the principles of the Bobath Approach,[6] also include the task-specific techniques of Carr and Shepherd.[4,23]

Resource use

The treating physiotherapists recorded information on treatment duration and number of staff involved after each patient treatment session. To compare the differences in rehabilitation staff resources used between the intervention and control groups, entries in these treatment records were analysed for the first 14 treatment sessions for each study patient. The total number of treatments received by each patient during their hospital stay was also calculated and compared.

Outcome measures

The primary outcome for the study was the Rivermead Mobility Index (RMI) measured at six weeks post stroke.[24] The RMI was selected for this purpose as it is a valid and reliable measure[25] and includes activities important for patient independence. The RMI was devised as a self-report questionnaire but, because we expected to recruit patients with cognitive problems, the assessor scored the RMI activities according to patient performance.

Secondary outcome measures are listed in Table 1. Data collected at baseline also included age, sex, classification of stroke, presence or absence of incontinence, assessment of comprehension and expression of language by the Frenchay Aphasia Screening Test (FAST)[26]; visuospatial neglect by the star cancellation test[27] and Alberts (line cancellation) test.[28,29] Proprioceptive deficit was identified by two tests: thumb finding and limb matching, originally described by Head and Holmes (1911).[30] Carers completed the General Health Questionnaire-28[31] at baseline, 12 weeks and six months post stroke. The carers of patients who returned home also completed the Caregiver Strain Index[32] at six months post stroke.

The primary and secondary outcome measures were administered at baseline, six weeks, 12 weeks and six months post stroke except the Nottingham Extended Activities of Daily Living Scale,[33] which was administered at six months post stroke only. Assessments were conducted in a separate rehabilitation facility remote from the stroke unit to avoid unblinding the assessor (PB) and, following discharge, in the patient's home. Any episodes of unblinding were recorded and a guess of group allocation was made after each follow-up assessment. Agreement between guess and actual group allocation was measured with the kappa statistic.

Sample size

Sample size was determined by a power calculation using Altmans' Nomogram.[34] Pretrial RMI data for patients on the stroke unit was available. For patients with an initial RMI score of 0 or 1, 33% later scored 4/15 when re-assessed at six weeks post stroke. An increase to 60% of patients achieving ≥ 4 was considered a clinically meaningful result. The estimated sample size required to demonstrate this improvement with a significance level of 5% and power of 85% was 120 patients,[34] uplifted to 140 patients to address expected deaths.[17]

Analysis

An intention-to-treat analysis was performed using SPSS version 11. The primary analysis was a between-group comparison using the Mann–Whitney *U*-test for the RMI change scores from baseline to six weeks post stroke. A second 'per protocol' analysis of the six-week RMI scores excluded patients who did not receive the stipulated 14 Oswestry Standing Frame or control treatment sessions.

Other analyses were the RMI change scores from baseline to the other assessment points, and the secondary outcome measures with between-group comparisons at six weeks, 12 weeks and six months, for the change scores from baseline using the Mann–Whitney *U*-test.

Table 1 Secondary outcome measures

Measure	Subscales	Score range (worst to best)	Domain
Barthel Index[41]	–	0–20	Activities of daily living (ADL)
Hospital Anxiety and Depression Score[42]	Anxiety	21–0	Mood
	Depression	21–0	
Nottingham Extended ADL Scale[33] (6/12 post stroke only)	Mobility	0–6	Extended ADL
	Kitchen	0–5	
	Domestic	0–5	
	Leisure	0–6	
	Total	0–22	
Rivermead Motor Assessment[43]	Gross function	0–13	Motor function
	Leg and trunk	0–10	
	Arm	0–15	
	Total	0–38	
Motor Assessment Scale[44]	Balanced sitting	0–6	Motor function
	Sitting to standing	0–6	
Trunk Control Test[11]	–	0–100	Motor function

Results

A total of 412 patients were referred to the stroke unit during the recruitment period, of whom 167 fulfilled the inclusion criteria. Of these, eight patients were unable to give consent due to cognitive impairment and did not have a next of kin to provide assent, 18 patients/carers refused consent/assent and one patient deteriorated and subsequently died before baseline assessments could be conducted. Therefore, 140 patients were recruited to the study and subsequently randomized: 69 to the control group, and 71 to the intervention group (Figure 1).

The characteristics of the two groups and baseline assessment scores were similar (Tables 2 and 3). Thirty patients died (13 control; 17 intervention) prior to the final six-month assessment and one patient was withdrawn due to a misdiagnosis. There was a substantial interval between stroke and baseline assessment for eight patients (four patients from each group) who were recruited more than six weeks post stroke so precluding the six-week assessment.

Treatment

Excluding the seven patients who died (1 control, 6 intervention) during the early treatment phase, 21 patients (16%) (8 control and 13 intervention) did not receive all 14 treatments as set out in the protocol. This was mostly because some patients became too unwell to receive rehabilitation (4 control, 7 intervention), or because they refused treatment (2 patients in both groups). One patient allocated to the control group received treatment within the Oswestry Standing Frame in error. However, only three patients in the control group, and seven in the intervention group, received less than eight treatment sessions.

Primary outcome (Table 3)

There was little difference between the groups for RMI score changes from baseline to six weeks post stroke (Mann–Whitney U-test $p = 0.310$, median change; intervention = 0, interquartile range 0 to 2; control = 1, interquartile range 0 to 2). The supplementary analysis using the per-protocol population (patients receiving 14 treatments as allocated) also showed no difference between the intervention and control groups (Mann–Whitney U-test $p = 0.744$).

Secondary outcomes (Table 3)

There were no significant differences between the groups for RMI score changes from baseline to 12 weeks, or baseline to six months. Changes from baseline to six weeks, 12 weeks and six months post stroke for the secondary outcome measures, and for the Nottingham Extended Activities of Daily Living Scale administered at six months post stroke, also demonstrated no significant differences between the intervention and control groups.

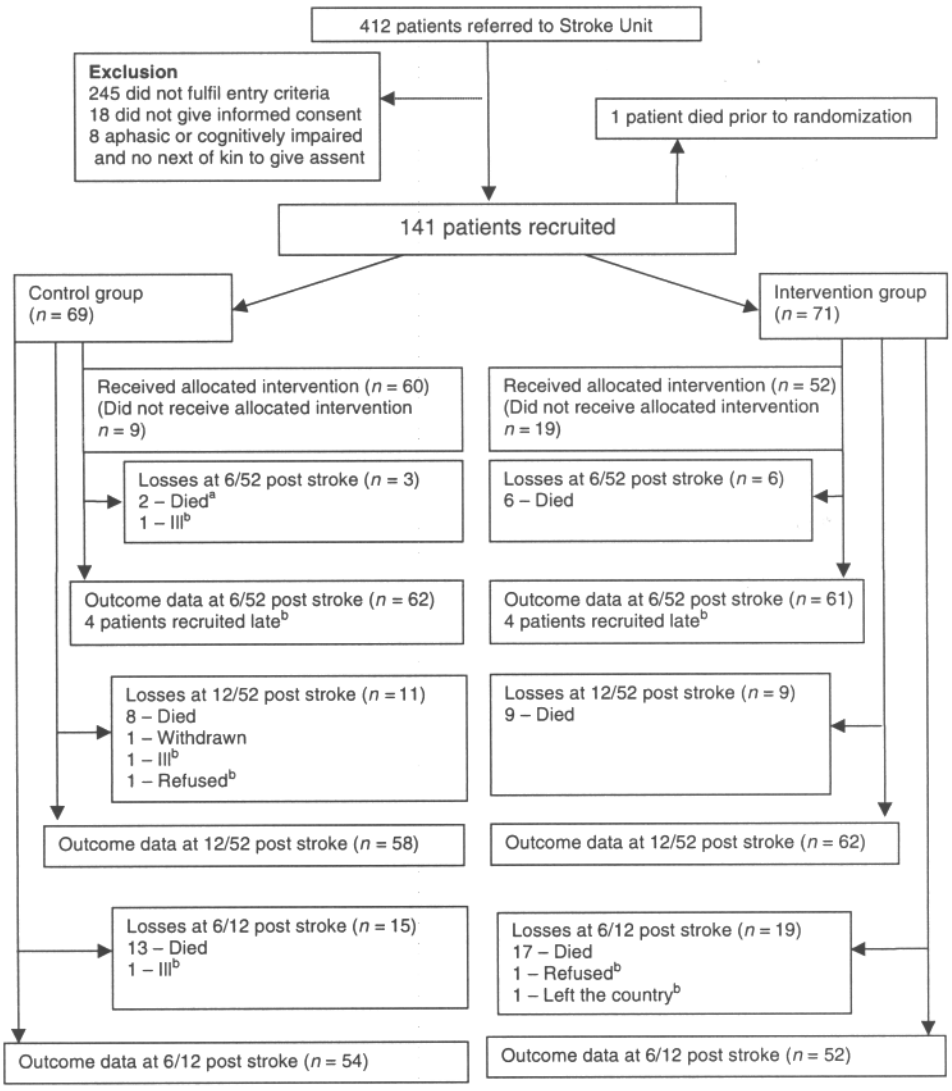

Figure 1 Trial profile. [a]One patient received treatment but died prior to 6 week assessment. [b]Patient unavailable for assessment at this time point only.

There were no significant differences in results of carer responses to the General Health Questionnaire, or the Caregiver Strain Index, at 12 weeks or six months.

Resources used

Summaries of the treatment records for the patients are presented in Table 4. There was no significant difference in length of the treatment sessions between the two groups, or in the number of staff required to treat each patient. Patients in the intervention group spent a mean of 26 min in the Oswestry Standing Frame (SD 10.1; interquartile range 20–30 min) during their treatment sessions. There was little difference between the two groups for total number of sessions during their hospital admission (intervention group mean = 34, SD 25.1; control group mean = 36, SD 20.8).

Table 2 Baseline characteristics of the intervention and control groups

		Control ($n = 69$)	Intervention ($n = 71$)
Age (years)	Mean (SD)	75.1 (9.4)	75.8 (11.5)
	Range	50–93	31–92
Sex	Male	25 (36.2%)	30 (42.3%)
Carer	Yes	40 (58.0%)	43 (60.6%)
Carer recruited	Yes	32 (46.4%)	36 (50.7%)
Previous stroke	Yes	18 (26.1%)	13 (18.3%)
Classification	TACI/S	43 (62.3%)	48 (67.6%)
	PACI/S	14 (20.3%)	14 (19.7%)
	POCI/S	2 (2.9%)	2 (2.8%)
	LACI/S	10 (14.5%)	7 (9.9%)
Incontinent of urine		65 (94.2%)	64 (90.1%)
Side of hemiparesis	Right	20 (29.0%)	31 (43.7%)
	Left	49 (71.0%)	40 (56.3%)
Prestroke Barthel Index score	Median	20	20
	Range	6–20	3–20
	Missing	0	1
Abbreviated Mental Test	Score < 7	13 (28.3%)	16 (32.7%)
	Unable[a]	23	22
Visuospatial neglect	Present	29 (50.9%)	29 (56.9%)
	Unable[a]	12	20
Thumb finding test	Failed	30 (58.8%)	30 (61.2%)
	Unable[a]	18	22
Limb mirroring test	Failed	29 (63.0%)	24 (57.1%)
	Unable[a]	23	29
Receptive aphasia		3 (4.3%)	2 (2.8%)
Expressive aphasia		4 (5.8%)	8 (11.3%)
Global aphasia		21 (30.4%)	21 (29.6%)
Time from stroke to baseline (days)	Mean (SD)	18.1 (9.2)	19.5 (12.1)
	Median	16.0	16.0
	Range	6–42	2–59

[a]Patients were unable to complete these tests due to cognitive impairments, linguistic difficulties or dysphasia.
TACI/S, total anterior circulation infarct/syndrome; PACI/S, partial anterior circulation infarct/syndrome; POCI/S, posterior circulation infarct/syndrome; LACI/S, lacunar infarct /syndrome.

Blinding

The assessor was unblinded to one patient at the six-week assessment, a further two patients at the 12-week assessment and one patient at the six-month assessment. All four patients were treated in the intervention group. The percentage of correct allocation guesses at six weeks post stroke were 48.8% (kappa −0.024), 54.5% at 12 weeks (kappa −0.087) and at six months 52.3% (kappa 0.053) indicating 'poor' agreement and that the assessor was not unblinded.

Discussion

Standing is an important component of gait retraining after stroke. However, standing for severely disabled stroke patients is difficult and resource intensive and it was hypothesized that assisted standing using the Oswestry Standing Frame might facilitate longer treatment sessions, be resource efficient and produce better outcomes for this group of patients. We failed to demonstrate any evidence of benefit associated with the use of the standing frame based on the primary or secondary outcome measures selected for this study. Moreover, using the frame was not resource releasing as it was not associated with a reduction in therapy staff time.

The strengths of our study include the randomized controlled design; embedding the project within a stroke rehabilitation unit where clinical outcomes are optimized[1]; using a unit that had prior expertise with the Oswestry Standing Frame

Table 3 Primary and secondary outcome measures – scores and change from baseline scores to each assessment point

	Control				Intervention			
	Baseline	6/52 ($n=67$) Missing = 5	12/52 ($n=60$) Missing = 2	6/12 ($n=55$) Missing = 1	Baseline	6/52 ($n=65$) Missing = 4	12/52 ($n=62$) Missing = 0	6/12 ($n=54$) Missing = 2
RMI								
Median	1				1			
IQR	0 to 2				0 to 2			
Median change		1	1	2		0	1	1
Mean change (SD)		1.4 (2.1)	2.07 (3.1)	3.13 (3.5)		1.28 (2.3)	2.23 (3.2)	2.73 (3.8)
IQR		0 to 2	0 to 2	0 to 4.25		0 to 2	0 to 3.25	0 to 4
Barthel Index								
Median	2				1			
IQR	1 to 3				0 to 3			
Median change		2	4	5		2	3	4
Mean change (SD)		2.89 (3.6)	4.76 (4.6)	6.2 (5.2)		3.2 (4.3)	4.66 (4.9)	5.44 (5.9)
IQR		0 to 5	1 to 7	2 to 10		0 to 5	1 to 8.5	1 to 9.75
TCT								
Median	12				12			
IQR	0 to 25				0 to 36			
Median change		12.5	24	24.5		0	13	13
Mean change (SD)		15.23 (24.1)	19.86 (26.6)	26.09 (28.2)		12.21 (22.6)	17.38 (26.6)	18.92(30.7)
IQR		0 to 25	0 to 37	9.25 to 49		0 to 25	0 to 37	0 to 37
RMA total								
Median	1				1			
IQR	0 to 3.5				0 to 4			
Median change		1	2	3		0	1	2
Mean change (SD)		3.34 (5.6)	5.26 (7.7)	7.31 (9.1)		2.9 (5.5)	4.52 (7.2)	5.38 (9.2)
IQR		0 to 5.25	0 to 10.5	1 to 13.25		0 to 3.5	0 to 8	0 to 11.25
MAS balanced sitting								
Median	1				2			
IQR	1 to 3				1 to 3			
Median change		1	2	1		1	1	1
Mean change (SD)		1.27 (1.6)	1.54 (2)	1.74 (1.8)		1 (1.6)	1.43 (1.8)	1.56 (1.9)
IQR		0 to 2	0 to 3	0 to 3.25		0 to 2	0 to 3	0 to 3

MAS sitting to standing								
Median	0				1			
IQR	0 to 1				0 to 1			
Median change		0	1	1		0	1	1
Mean change (SD)		0.56 (0.9)	0.95 (1.5)	1.37 (1.8)		0.57 (1.9)	0.79 (1.5)	1.04 (1.9)
IQR		0 to 1	0 to 1	0 to 2		0 to 1	0 to 1	0 to 1
HAD anxiety[a]								
Median	8.5				7			
IQR	6 to 14				4.5 to 11.5			
Median change		1	0	−1.5		−1	0	−2
Mean change (SD)		1.27 (4.5)	−1.16 (5.2)	−1.33 (6.0)		−0.8 (5.6)	−0.19 (4.9)	−1.64 (5.7)
IQR		−2 to 4	−5.5 to 2.5	−5.75 to 2.75		−3 to 2.75	−3 to 2	−5 to 0.25
HAD depression[a]								
Median	7				8			
IQR	5 to 13.5				6 to 11			
Median change		−0.5	−1	−1		−3.5	−2	−4
Mean change (SD)		0.38 (5.7)	−1.12 (4.9)	−1.63 (5.2)		−1.96 (5.3)	−1.78 (4.8)	−3.18 (3.3)
IQR		−4 to 3.25	−4.5 to 4	−5 to 2.75		−5 to 2	−5 to 1	−6 to 0

[a] At baseline control group missing 37 patients, intervention group missing 38; at 6/52 both groups missing 41 patients; 12/52 both missing 35 patients; 6/12 control group missing 31, intervention group missing 32.
RMI, Rivermead Mobility Index; TCT, Trunk Control Test; RMA, Rivermead Motor Assessment; MAS, Motor Assessment Scale; HAD, Hospital Anxiety and Depression Scale.

Table 4 Treatment duration and number of staff involved for the first 14 treatment sessions

	Control	Intervention
Treatment session length (min)		
Mean (SD)	41 (14.4)	40 (12.9)
Median	40	40
Range	5–90	5–120
Interquartile range	30–50	30–48
Number of staff per treatment		
Mean (SD)	2 (0.65)	2 (0.66)
Range	1–4	1–5

and inclusion criteria designed to identify a group of acute stroke patients for whom prolonged standing as a therapeutic option would be difficult without the use of assistive equipment. Trial procedures were robust with steps taken to minimize bias and the use of clinically relevant outcome measures with proven reliability, validity and sensitivity. Recovery curves reported by Partridge *et al*.[35] demonstrate steepest recovery rates during the first six weeks post stroke. This was therefore selected as an appropriate primary outcome assessment point at which early treatment differences might become apparent but medium term outcomes were also investigated.

There are a number of potential reasons why this negative finding may be a false negative (type II error). First, the study sample may have been too small and the study underpowered to detect a difference. However, there were no trends in any of the outcome measures used to suggest a positive outcome might be obtained in a larger study. Secondly, it has been postulated that early mobilization (within 24 h) is an important contributing factor to the effectiveness of acute stroke unit care.[36] In this study use of the standing frame was only instigated once the patient was medically stable: an average of 18 days post stroke onset. It is therefore possible that the intervention was provided too late to demonstrate effectiveness. Thirdly, although the two study groups were well matched at baseline and then provided with distinct therapy regimes, the intervention using the Oswestry standing frame may not have been optimal. Some intervention patients (18%), mostly for clinical reasons, received less than the stipulated number of treatment sessions and this might have resulted in an underestimate of any treatment effectiveness. Duration of treatment in the standing frame was left to the therapists' discretion and the treatment records indicate that mean length of treatment was 26 min. A greater intensity of treatment might have been more beneficial but this would have had associated resource implications.

Fourthly, there was the potential for treatment preference bias by participating staff directed at either group to have influenced the results. However, staff rotations and new appointments over the two years of the study meant that many stroke unit staff were involved with study patient treatments during the course of the trial and therefore systematic bias in favour of one or other treatment approach is unlikely.

Lastly, the principal study inclusion criterion (patients who were unable to stand upright without the assistance of two therapists) necessarily led to a majority group (65%) of stroke patients with large cortical lesions. These patients have a poor prognosis for recovery of function.[17,37] Therefore, whilst this study was attempting to identify a treatment with the potential to benefit patients with severe stroke disability, functional improvements for these patients might be difficult to achieve.

The role of supported standing as a treatment strategy for patients unable to stand independently after stroke remains uncertain. One laboratory-based study has suggested that standing balance is not a necessary precursor to gait training.[38] Gait training has been investigated by use of a treadmill with body weight support but a recent Cochrane review[39] concluded that there was no significant improvement associated with this approach. Several studies have suggested that task-specific activities can be beneficial[40] and a programme of

Clinical message

- Use of the Oswestry Standing Frame to promote therapeutic standing for severely disabled stroke patients did not improve clinical outcomes or provide resource savings.

repetitive sit-to-stand activities might be a more dynamic strategy to improve mobility outcome after a stroke. These issues can only be addressed in new studies.

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