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An exploration of the effects of weighted garments on balance and gait of stroke patients with residual disability

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Objective: To explore the effects of weighted garments on the balance and gait of stroke patients.
Design: A pilot randomized controlled study with blinded measurement.
Setting: Weighted garments were worn by patients living in the community and measurement was made in a hospital-based gait laboratory.
Subjects: Twenty-four adults who were at least six months post stroke and were able to walk 10 metres with or without assistance or a walking aid.
Intervention: The six-week treatment-phase subjects were given a set of weighted garments which they were shown how to apply and instructed to wear on their paretic side. Subjects randomly allocated to the six-week control phase were not given any weighted garments.
Main outcome measures: Balance was measured with the Berg Balance Scale. Gait was measured using GaitMat II, an instrumented walkway. Gait parameters of interest were velocity and symmetry of: step length; single support time; double support time; and support base width. Measures were made at baseline before randomization (baseline) and at the end of the six weeks of intervention (outcome).
Results: No statistically significant differences were found between the treatment and control groups at outcome for balance (Mann–Whitney *U*-test; $p = 0.74$), gait velocity ($p = 0.68$) or symmetry of gait parameters ($p = 0.33$ to $p = 0.75$).
Conclusions: We found no evidence to support the clinical use of these weighted garments for stroke survivors.

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Introduction

Rehabilitation is effective following stroke[1] but many patients continue to be dissatisfied with the level of function they achieve.[2,3] Even after a period of inpatient rehabilitation, strength may only be approximately 50% of normal even for patients who are able to perform voluntary movements early post stroke.[4] The level of post stroke disability is also illustrated by the finding that 22% of patients who survive to one year post stroke may be resident in a nursing home.[5]

Clinical experience suggests that many patients are searching for alternatives to conventional rehabilitation. Recently an innovative idea for therapy has emerged from the observation that holding heavy objects appears to improve muscle control and lead to improvements in balance and functional ability. Building on this idea, a set of weighted garments has been designed by a commercial organization. These weighted garments are now being marketed on the claim that wearing them immediately improves balance and gait following stroke and that improvement continues for at least 12 weeks (manufacturer's communication). These claims have not been tested. Although there are reports of reduction of intention tremor (ataxia) with the wearing of weighted garments[6–8] or the application of weights[9] there is insufficient evidence to justify the use of weighted garments to improve balance and gait post stroke. It is essential that systematic testing is undertaken before this novel therapy joins the 'black box' of existing yet largely untested therapies.

The primary aim of this study was:

1) To explore effects of the garments on balance and gait in a group of patients who sustained a stroke at least six months previously.

Additional aims were:

2) To explore whether patients experience difficulty in using the weighted garments;
3) To explore whether patients consider that balance, gait and or activities of daily living (ADL) improve when wearing weighted garments.

Method

A pilot randomized controlled trial with blinded measurement.

Twenty-four adult stroke patients were included in this study. All:

- were at least six months post stroke and not participating in any other physical rehabilitation activity;
- were able to walk 10 metres with or without assistance or a walking aid;
- had no receptive aphasia (scoring 18 or above on the Body Part Identification and 13 or above on the Commands section of the Boston Diagnostic Aphasia Examination[10]);
- had no visual unilateral neglect (scoring 52 or above on the Star Cancellation Test[11]);
- were able, on a daily basis, to don and doff the garments themselves or with the help of a carer and had access to laundry facilities so that garments could dry overnight;
- in the opinion of their general practitioner had no other neurological or musculoskeletal disorder which would be expected to result in clinical changes in balance or gait, had no severe heart disease and were not taking any sedative medication during the time course of this study.

All subjects were living in the community, so we did not have access to CT scans. We therefore asked either the patients or their carers which side was most affected and confirmed this by clinical assessment.

It was decided to include 12 subjects in each group as this was achievable and would probably also provide sufficient data to enable a power calculation. All subjects included in this study gave informed consent. Ethical approval was granted by the local ethical committee.

Procedure

Balance and gait were measured in the gait laboratory with the subjects not wearing the garments. The two research assistants were blind to the allocated study condition. Measures were made: at the beginning of week one before randomization was effected (baseline) and at the beginning of week 7 (outcome). At each measurement point the Berg Balance Scale was com-

pleted once and then five trials of walking were completed.

Following the completion of baseline measures a research physiotherapist, blind to the measurements made, randomized each subject to treatment (weighted garments) or to control (no weighted garments) using a sealed envelope system. All subjects were asked not to talk to the research assistants in the gait laboratory about whether or not they had been wearing the garments.

During weeks 2–6 each subject was contacted by telephone once a week by the same research physiotherapist. All subjects were asked if they were experiencing any difficulty or improvement in their balance and walking. In addition, those subjects issued with the weighted garments were asked if they were experiencing any problems which prevented them continuing to wear the weighted garments which they felt were most suitable. After the six-week intervention phase the 12 control subjects were given the garments and asked to complete the logbooks. During weeks 8–12 they were contacted by telephone as above.

The procedure for this study is shown in Figure 1.

Intervention

The weighted garments consist of 'simple' wrist, biceps, thigh and ankle bands as well as more complex bands designed to fit around the pelvis and shoulder girdle. Velcro fastening allows for individual adjustment. All of the garments have a number of 'pockets' into which 60 g lead weights can be inserted. Thus varying combinations of garments and weights can be used as the wearer considers most appropriate. The weighted garments are worn on the paretic side only.

When first given the set of weighted garments each subject practised putting them on, taking them off and adjusting the weights. The subject was then fitted with a full set of garments which was completely weighted for 10 minutes. During this time the subject walked within the room, as much as possible. At the end of this 10-minute period the weight in each garment was reduced to a third (procedure as advised by the manufacturer). From this point the subject was instructed to adjust the weights and garments on a daily basis according to how able or unable they felt. They were asked to wear the garments from when they got dressed in the morning to when they went to bed at night. An instruction sheet was given to each subject.

Measurement

Balance was measured using the Berg Balance Scale.[12] This examines balance during functional movement such as standing still and picking up an object from the floor from a standing position. The maximum score possible is 56.

Gait was measured using GaitMat II (EQ Inc., Chalfont, USA) which is an instrumented walkway that automatically measures basic gait parameters such as step length and walking velocity. All subjects were instructed to walk at their normal speed along a 12-metre walkway which has GaitMat II inserted into the middle 3.8 metres. The temporal–spatial parameters recorded were: step length, single support time, double support time, support base width and velocity.

Asymmetry is a characteristic of post-stroke gait. Consequently improvements in symmetry provide an important clinical marker of recovery.

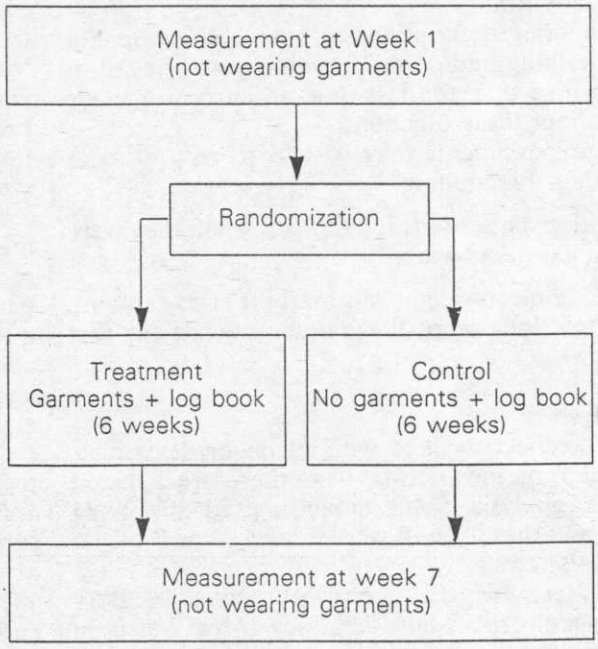

Figure 1 Schematic illustration of the study design.

The symmetry indices for step length, single support time, double support time and support base width were calculated using the formula[13]:

$$2 \times [(\text{paretic side} - \text{nonparetic side}) / (\text{paretic side} + \text{nonparetic side})] \times 100$$

For this study the paretic side is defined as the side of the body contralateral to the brain lesion whereas the nonparetic side is that ipsilateral to the brain lesion, although it is recognized that the nonparetic side is probably also affected.

Cadence is also of interest and this was calculated using the formula:

$$60 \text{ s/total step time in trial} \times \text{total no. of steps in trial} = \text{cadence (steps per minute)}$$

To assess whether subjects found the garments beneficial each subject was given a logbook and asked to record:

1) whether balance was better or worse today than last time an entry was made about balance;
2) whether walking was better or worse than the last time an entry was made about walking;
3) whether they were able to perform their everyday activities better or worse than the last time an entry was made about everyday activities;
4) a brief description of how balance and/or walking and/or ADL walking was better or worse than the last time an entry was made about these functions;
5) any comments they wished to record about their functioning.

Additional questions for subjects when they were given garments were:

6) how much weight was used for each garment;
7) how long were the garments worn for that day.

Analysis

All subjects walked without major deviations. All steps on the GaitMat were therefore included in the analysis. Some subjects used a walking stick and these 'steps' were erased from GaitMat before analysis.

To test for the treatment effect in Berg Balance Score a Mann–Whitney *U*-test was used on the change in score from baseline. To test for the treatment effect in all other outcomes a regression model was fitted, allowing for pre-treatment value.

The notes from the telephone conversations and the content of subjects' comments in the logbooks were examined to identify:

1) What subjects felt about using the garments (aim 2).
2) Whether subjects felt improvements in balance, gait or ADL occurred as a result of using the weighted garments (aim 3).

Results

Of the 24 subjects included in this study 18 were male and six female, 16 had a left paretic side and eight a right paretic side. Two subjects withdrew from the study after the baseline assessment. Their baseline scores are shown in Table 1. At baseline subject groups were comparable for balance and gait parameters and showed asymmetry of single support and double support time (Table 2).

At outcome, no significant difference was found between the change in balance between the weighted garment and the control group (median change for weighted garment and control group respectively, 1.0 $p = 0.74$ from Mann–Whitney *U*-test) and no significant difference was found between the groups for any of the gait parameters measured (single support time symmetry index, $p = 0.33$; to step length symmetry index, $p = 0.75$; Table 3).

Examination of the logbooks revealed that the majority had been completed in an inconsistent manner and therefore the results of this examination should be interpreted with caution. Information was only given by 11 of the 24 subjects about the effects of the garments on balance, gait and/or ADL. Three subjects reported no difference, six reported that balance and gait was a little better, one subject felt better when wearing the garments and one subject felt that the paretic ankle was 'less bulky' (direct quote). Many more subjects made comments about their experience of using the garments (Table 4). Only one of the 14 comments though is clearly positive; 'waist garment seems to help'. The thigh band appeared to cause the most problems, with 12 subjects

Table 1 Baseline measurements for the two subjects who withdrew from the study

	Subject withdrawing from experimental group	Subject withdrawing from control group
Balance		
Berg Balance Score	37	42
Gait parameters – mean (SD)		
Velocity (m/s)	0.36	0.50
Cadence (steps/min)	80.60	81.00
Step length symmetry index	–0.30	9.80
Single support time symmetry index	–27.30	–12.00
Double support time symmetry index	3.10	–20.40
Support base width symmetry index	1.70	–1.10

Table 2 Baseline measurements for the experimental and control groups

	Weighted garments (n = 12)	Control (n = 12)
Balance – median (25pct, 75pct)		
Berg Balance Score	52.00 (43, 53.5)	50.00 (41, 54)
Gait parameters – mean (SD)		
Velocity (m/s)	0.82 (0.37)	0.80 (0.35)
Cadence (steps/min)	97.34 (13.75)	90.30 (20.80)
Step length symmetry index	6.46 (15.89)	–3.21 (9.15)
Single support time symmetry index	–15.03 (13.45)	–12.11 (17.52)
Double support time symmetry index	–16.88 (18.99)	–16.33 (19.43)
Support base width symmetry index	–3.98 (9.04)	0.03 (6.10)

25pct, 25th percentile; 75pct, 75th percentile; SD, standard deviation.

reporting that it slips down the leg. This problem was also attributed to the upper armband but to a lesser extent; six subjects. The other garment that appeared to be causing problems was the shoulder band which was reported to: slip; become unfastened; be uncomfortable; and/or be too complex (eight subjects).

Discussion

This pilot study found no difference in the balance and gait of stroke patients as a result of wearing weighted garments for a six-week period. Although there might have been a lack of power to detect an effect the differences found were not clinically significant.

An obvious explanation for the lack of effect is the possibility that the garments were not worn for a long enough time period for an effect to become apparent. However several studies have found that a 2–6 week treatment period produces beneficial changes in patients who are more than six months post stroke (reviewed by Pomeroy and Tallis[15]). For example, Dean and Shepherd[16] found significant improvements in balance following ten 30-minute sessions of sitting balance training over a two-week period. Another example is the finding of significant improvements in gait velocity following the provision of positional feedback and EMG feedback given twice a week for four weeks.[17] This experimental evidence in combination with the lack of discernible trends found in this study indicate that even if a longer time period is required for weighted garments to produce beneficial changes other types of intervention might be more effective.

These findings are surprising considering the manufacturer's report of positive feedback from satisfied customers. The manufacturer's report

Table 3 Comparison of outcome measures of balance and gait of the weighted garment and control groups

	Weighted garment group	Control group	Coefficient for difference between groups (Control – WG)	Confidence interval	Test statistic[a]	*p*-value
Balance – median (IQR)						
Berg Balance Score	51 (48, 52.5)	50 (44, 53.5)	NA	NA	0.33	0.74
Gait parameters – mean (SD)						
Velocity	0.88 (0.39)	0.83 (0.37)	–0.01	(–0.07, 0.04)	–0.42	0.68
Cadence	100.41 (13.76)	91.39 (21.23)	–1.60	(–6.03, 2.82)	–0.76	0.46
Step length symmetry index	7.08 (13.70)	–2.17 (12.83)	0.97	(–5.27, 7.21)	0.33	0.75
Single support time symmetry index	–14.94 (14.86)	–15.41 (22.93)	–2.52	(–7.77, 2.72)	–1.01	0.33
Double support time symmetry index	–17.78 (19.21)	–13.87 (20.48)	1.52	(–7.80, 10.84)	0.34	0.74
Support base width symmetry index	–2.54 (4.08)	0.78 (9.06)	2.53	(–4.06, 9.13)	0.80	0.43

WG, weighted garments, IQR, interquartile range; SD, standard deviation.
[a]Berg Balance, *Z* statistic from Mann–Whitney *U*-test; Gait parameters, *T* statistic 1 df from regression.

Table 4 Subjects' experience of using the garments

Subjects' experience	Number of subjects reporting experience (24 subjects received garments)
Stopped using garments because of itching, discomfort, cumbersome and/or unhappy going out in them	3
Blue colour ran into clothes and also colours the skin when gets damp	1
Greater effort required because of extra weight	1
Tiring to wear or had to sit down more	2
Garments were cumbersome and or made movement awkward even without weight	2
Shoulder garment slipped, would not stay fastened, uncomfortable and/or too complex	8
Upper arm band slips down	6
Wrist band catches on watch strap	1
Waist garment uncomfortable and/or chaffs skin	2
Waist garment seems to help	1
Thigh band slips down leg	12
Ankle band catches shoe, irritates skin and/or makes leg drag more	3
Ankle band worn when trousers worn	1
Hemi leg seems to need ankle weight to pull it down	1

Clinical messages

- This study found that stroke patients who wore weighted garments showed no change in balance and gait.
- The findings suggest that stroke patients experienced problems with the current design of the weighted garments.
- We found no evidence to support the clinical use of these weighted garments.

contrasts with the finding that only seven of the 24 subjects in this study expressed the view that the garments had either made balance or gait feel better or had improved it a little, although the level of compliance was difficult to ascertain because the logbooks were completed inconsistently. However, it is interesting that examination of the logbooks found more comments about problems with the garments than there were about the effects on balance and gait. It is possible that compliance was reduced by problems which subjects experienced with the garments. If these could be remedied a replicated study might find that weighted garments could have a beneficial effect on gait. Alternatively, it is also possible that the comments the manufacturer has received from customers were influenced by the personal financial investment customers had made. Yet another possibility is that the satisfied customer comments have been made by a group of stroke patients who have different balance and gait characteristics to the subjects in this study. All of these possibilities are open to further research.

Any future research might also need to give attention to bilateral weighting of limbs, as unilateral weighting of the ankle has been found to increase asymmetry of gait by: reducing single support time; reducing stance phase time; and increasing swing phase time in the weighted limb.[18] Any adverse effects might be accentuated with increasing age as older people might have a reduced ability to adapt to the destabilizing effect of an ankle weight of 5% of body weight (G Giakas *et al.*, unpublished). In addition, the application of ankle weights has been shown to increase the energy required to walk in healthy adults, an increase which was significant for bilateral weights.[18] As fatigue is often experienced post stroke (e.g. described by Brodal[19]), it is reasonable to suggest that the application of weight could increase effort even further and thus detract from possible benefits of weighted garments. In support of weighting is the finding that the application of weight has been found to decrease postural sway in healthy adults.[20] More knowledge of the effects of different forms of

weighting on healthy adults and stroke patients is needed. This information is needed across the entire adult age range.

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