

# Randomized Trial of Treadmill Walking With Body Weight Support to Establish Walking in Subacute Stroke

## The MOBILISE Trial

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**Background and Purpose**—The main objective of this randomized trial was to determine whether treadmill walking with body weight support was effective at establishing independent walking more often and earlier than current physiotherapy intervention for nonambulatory stroke patients.

**Methods**—A randomized trial with concealed allocation, blinded assessment, and intention-to-treat analysis was conducted. One hundred twenty-six stroke patients who were unable to walk were recruited and randomly allocated to an experimental or a control group within 4 weeks of stroke. The experimental group undertook up to 30 minutes per day of treadmill walking with body weight support via an overhead harness whereas the control group undertook up to 30 minutes of overground walking. The primary outcome was the proportion of participants achieving independent walking within 6 months.

**Results**—Kaplan–Meier estimates of the proportion of experimental participants who achieved independent walking were 37% compared with 26% of the control group at 1 month, 66% compared with 55% at 2 months, and 71% compared with 60% at 6 months ( $P=0.13$ ). The experimental group walked 2 weeks earlier, with a median time to independent walking of 5 weeks compared to 7 weeks for the control group. In addition, 14% (95% CI,  $-1-28$ ) more of the experimental group were discharged home.

**Conclusions**—Treadmill walking with body weight support is feasible, safe, and tends to result in more people walking independently and earlier after stroke.

**Trial Registration**—ClinicalTrials.gov (NCT00167531). (*Stroke*. 2010;41:1237-1242.)

**Key Words:** physical therapy ■ randomized controlled trial ■ rehabilitation ■ stroke ■ walking

Only half of nonambulatory stroke patients admitted to inpatient rehabilitation in Australia learn to walk again.<sup>1</sup> Being able to walk is a major determinant of whether a patient returns home after stroke or resides in a nursing home. Treadmill walking with body weight support via an overhead harness is an intervention that has an unclear efficacy in nonambulatory patients. Research to date has been characterized by studies including both ambulatory and nonambulatory participants. Before the commencement of this study, there had been 4 randomized trials<sup>2-5</sup> that had subsets of nonambulatory patients. Extracting these data showed no effect (risk difference,  $-3\%$ ; 95% CI,  $-15-10$ ) of treadmill walking with body weight support in assisting more nonambulatory patients to learn to walk than did overground walking for nonambulatory patients. However, these studies were of variable size and quality. Not surprisingly, the Cochrane review<sup>6</sup> on treadmill walking recommended that separate,

large, high-quality studies of nonambulatory patients be undertaken to examine the efficacy of treadmill walking with body weight support after stroke. Therefore, we planned a large, randomized trial.<sup>7</sup>

Barriers to completion of more walking practice in nonambulatory stroke patients include marked muscle weakness and poor coordination, which result in an inability to practice the whole task. Because it is well-recognized that skill in performance is a direct function of the amount of practice,<sup>8</sup> we hypothesized that the benefit of treadmill walking with body weight support for nonambulatory patients is that it allows more practice than assisted overground walking. Even with the assistance of a therapist, it may be difficult to complete even a few steps of overground walking. Body weight support via an overhead harness means that patients can complete some walking practice<sup>9</sup> without contravening occupational health and safety standards in that the therapist is not lifting

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the patient and the patient is less likely to fall. Even if patients only walk for 10 minutes at the slowest speed of 0.2 m/sec supported on a treadmill, they will “walk” 120 m. There is evidence from systematic reviews that outcome after stroke is associated with the amount of practice undertaken.<sup>10</sup> However, research has shown that little practice is completed in rehabilitation.<sup>11,12</sup> We wanted to find out, in patients early after stroke who are unable to walk, if treadmill walking with body weight support is more effective than assisted overground walking in establishing more independent walking, and if it reduces the time taken to achieve independent walking.

To enhance external validity, we designed a randomized trial to mimic real-life rehabilitation. Therefore, the comparison intervention was assisted overground walking, which is usual practice, and we also controlled the duration of each intervention and the amount of assistance provided.

## Methods

### Design

A prospective, multicenter, single-blind, randomized trial was undertaken. Nonambulatory stroke patients were screened by an independent recruiter and randomly allocated into either an experimental group or a control group. Randomization was stratified by center and severity using random permuted blocks of 4 or 6 patients. Severity was based on sitting balance because all participants were unable to walk on admission to the study and sitting balance has been found to predict walking outcome.<sup>13–15</sup> Item 3 (sitting balance) of the Motor Assessment Scale for stroke<sup>16</sup> was divided into two severity strata: 0 to 3 and 4 to 6. The allocation sequence was computer-generated before commencement of the study and centrally located. After recruitment, the central office was contacted for allocation so that randomization was secure and concealed. The experimental group received treadmill walking with body weight support and the control group received overground walking. The participants and therapists delivering the intervention could not be blinded to the intervention. Walking was measured weekly until participants were independently walking or discharged from the hospital and again at 6 months by an assessor blinded to group allocation. Blinding was ensured using several strategies: assessors worked remote to the therapy area, participants were asked not to reveal details of intervention to the assessors, and assessments were collected outside therapy hours. Survival analysis was performed by a biostatistician (JMS) blinded to group allocation. The study was approved by the Human Research Ethics Committees of the universities and each of the centers involved in the study.

### Participants, Therapists, Centers

Stroke patients were included if they were within 28 days of their first stroke, between 50 and 85 years of age, had hemiparesis or hemiplegia clinically diagnosed, and were nonambulatory, which was defined as scoring 0 or 1 on item 5 (walking) of the Motor Assessment Scale for Stroke.<sup>16</sup> They were excluded if they had clinically evident brain stem signs, had severe cognitive and/or language deficits that precluded them from following instructions, had unstable cardiac status, or had any premorbid conditions that precluded them from rehabilitation. The presence of sensory loss, neglect, and spasticity was recorded using the Nottingham Sensory Assessment, the line bisection test, and the Ashworth Scale.

Therapists were included if they were registered physiotherapists and prepared to undergo specific training to follow the trial protocol. Students were only involved under supervision of a trained therapist. Therapists were excluded if they were performing a locum or were about to rotate out of the rehabilitation unit. Years since graduation, highest qualification, and previous research experience were recorded.

Centers with rehabilitation units were included if they had acute stroke units on-site or had strong links with off-site units. Volumes of strokes per year and physiotherapist-to-patient ratio were recorded for each center.

### Intervention

Both the experimental and the control groups underwent a maximum of 30 minutes per day of walking practice with assistance from one therapist for 5 days per week. The total daily time of intervention was 30 minutes from beginning (ie, from when the participant was in a wheelchair) to end (ie, when the participant was back in a wheelchair). The 30 minutes therefore included putting on assistive devices or setting up equipment, getting from the wheelchair into standing, and rests. The amount of assistance during walking was standardized to one therapist; however, additional help was allowed during setting up (ie, getting the participant onto the treadmill for treadmill walking or into standing for overground walking). Other intervention involving the lower limbs (ie, strengthening exercises, practicing activities such as sitting, standing up, and standing) was standardized to a maximum of 60 minutes per day. No other part of the multidisciplinary rehabilitation program was controlled. Therapists were provided with written guidelines describing progression and were trained in delivering both interventions. Information describing the specific features of the walking sessions such as treadmill speed and amount of weight support or use of aids, distance walked, and assistance required were recorded for each session. Adherence to the guidelines by therapists was enhanced by training, regular review of the recording sheets, and spot observations.

### Experimental Group

Intervention for the experimental group involved walking on a treadmill supported in a harness. Initial body weight support was set so that the knee was within 15 degrees of extension in mid stance. Initial speed of the treadmill was set so that the therapist had time to assist the leg to swing through while maintaining a reasonable step length. If a participant was too disabled to walk on a moving treadmill with the assistance of a therapist, then the participant walked on the spot. A reduction in body weight support occurred once participants could: (1) swing the affected leg through without help; (2) maintain a straight knee during stance phase without hyperextension; and (3) maintain an adequate step length without help. Once they attained a speed of 0.4 m/sec without body weight support, they commenced 10 minutes of overground walking. These guidelines had been tested for feasibility and published.<sup>17</sup>

### Control Group

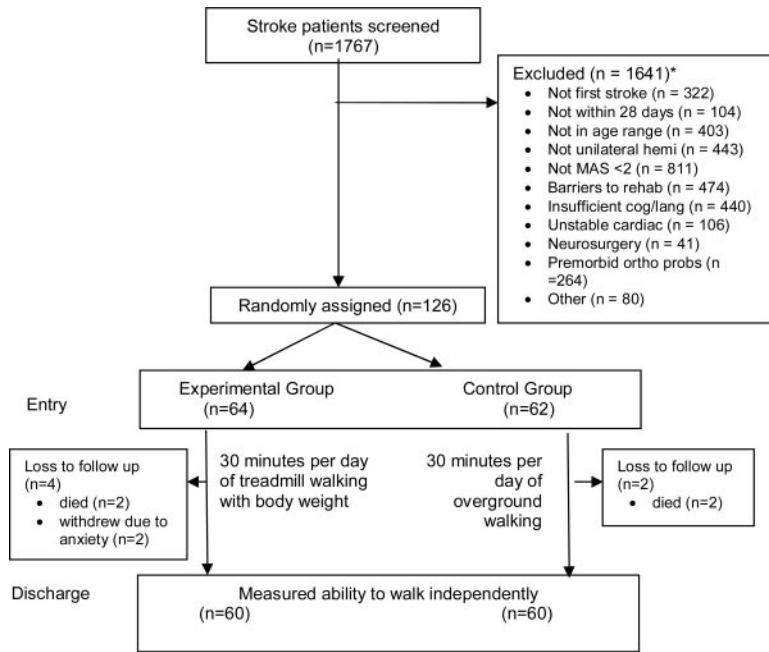
Intervention for the control group involved assisted overground walking. Aids such as knee splints, ankle-foot orthoses, parallel bars, forearm support frames, and walking sticks could be used as part of the intervention. If a participant was too disabled to walk with the help of a therapist, then the participant practiced shifting weight and stepping forwards and backwards. Once participants could walk with assistance, they were instructed to increase their speed and assistance from both the therapist and aids was reduced.

### Outcome Measures

The primary outcome was proportion of participants walking independently within 6 months. Independent walking was operationally defined as being able to walk 15 m continuously across flat ground barefoot without any aids. Participants were tested once per week before intervention and continued to be tested until they achieved independent walking or were discharged from the rehabilitation unit. They were tested again at 6 months.

### Statistical Analysis

We undertook an a priori power calculation to determine sample size. Given that 50% of nonambulatory patients walk independently at discharge,<sup>1</sup> we designed the study to detect a 25% increase in the proportion of nonambulatory patients walking independently from 50% to 75%. The smallest number of participants to detect this difference between 2 proportions estimated from independent sam-



**Figure 1.** Flow of participants through the trial.  
\*There can be >1 reason for exclusion.

ples with 80% power at a 2-tailed 5% significance level was 65 participants per group, ie, 130 participants total.<sup>18</sup>

Data were analyzed on an intention-to-treat basis using Kaplan–Meier survival curve analysis. Participants were followed-up until they achieved independent walking or until 6 months. For those who did not achieve independent walking before discharge from hospital and were still not walking at 6 months, the time to achieve independent walking (survival time) was censored at 6 months. Those who did not achieve independent walking before discharge from hospital but were walking at 6 months were assigned time to walking on the basis of their last measured walking ability before discharge by an assessor blinded to group allocation. For participants who withdrew or died, data were censored at the time of withdrawal or death. The proportion of independent walkers was compared between the 2 groups using the log-rank test. Time taken for 50% of each group to walk was calculated from the Kaplan–Meier curves. We report Kaplan–Meier estimates of the proportion of participants who achieved independent walking and risk difference (95% CI) of discharge destination.

## Results

### Flow of Participants, Therapists, and Centers Through the Trial

The flow of participants through the trial is summarized in Figure 1. One hundred twenty-six participants (55 female, 71 male), with mean age of 71 (SD, 9) years and mean of 17 (SD, 7) days after stroke, were recruited to the study between August 2002 and September 2008. Sixty-four participants were allocated to the experimental group and 62 were allocated to the control group. Four participants died (experimental, 2; control, 2) and 2 withdrew (experimental, 2). At baseline the groups were similar in terms of age, gender, days from stroke to admission to the study, side of hemiparesis, sitting balance, and impairments, such as sensory loss, spasticity, and neglect (Table).

Twenty-five physiotherapists, with an average of 10 (SD, 9) years since graduating, provided the intervention. Six (24%) had relevant postgraduate qualifications and 12 (48%) had research experience. On average, therapists were in-

involved in the study for 3 years (SD, 2; range, 1–6) and trained 5 participants (SD, 5; range, 1–19). The majority of therapists trained both experimental and control participants, except 8 (32%) who trained only 1 participant each.

Rehabilitation units at 6 centers participated in the trial, with 3 having on-site acute stroke units, 2 being rehabilitation units only, and 1 having its acute stroke unit at a different location. The annual throughput of stroke patients averaged 314 (SD, 121; range, 118–444), and physiotherapist-to-patient ratio averaged 1:8. The number of participants in each group was similar at each center (Table). Centers were involved in the study for an average of 4 years (SD, 2; range, 2–6).

### Compliance With Trial Method

Examination of the records of intervention revealed that intervention as allocated was given 97% of the time. The reasons for variation from allocation were participant-driven, eg, wanting to try the treadmill for 2 control participants, not wanting to use the treadmill for a period of time for 1 experimental participant, and wanting to do >10 minutes of overground walking for 1 experimental participant. Data for these participants were analyzed according to their original group allocation, ie, intention-to-treat analysis.

Participants were scheduled to receive intervention for 5 sessions per week until they achieved independent walking or were discharged. The experimental group participated in a total of 1336 sessions, which represents 85% of 1572 possible sessions if the intervention was delivered 5 days per week. The control group participated in 1490 sessions, which represents 89% of 1674 possible sessions. The main reason for missed sessions was illness (experimental, 104; control, 99). Other reasons included refusing intervention (experimental, 42; control, 35), off ward (experimental, 41; control, 42), and therapist absence (experimental, 10; control, 8). An additional 40 sessions were missed for the experimental

**Table. Characteristics of Participants and Centers**

Characteristic	Randomized (n=126)		Lost to Follow-Up (n=6)	
	Exp (n=64)	Con (n=62)	Exp (n=4)	Con (n=2)
<b>Participants</b>				
Age, yr, mean (SD)	70 (9)	71 (9)	73 (6)	75 (5)
Gender, n male (%)	38 (59)	33 (53)	1 (25)	1 (50)
Side of hemiplegia, n right (%)	30 (47)	26 (42)	4 (100)	0 (0)
Admission to study, days since stroke, mean (SD)	18 (8)	18 (7)	23 (2)	9 (0)
Sitting balance,* 0–6, mean (SD)	3.1 (1.4)	2.9 (1.3)	1.8 (1.0)	2.5 (0.7)
Sensory loss,† 0–2, median (IQR)	1 (0–1)	1 (0–1)	0.5 (0–1.5)	0 and 0
Spasticity,‡ 0–4, median (IQR)	0 (0–1)	0 (0–1)	0 (0–0)	0 and 2
Neglect,§ 0–2, median (IQR)	0 (0–0)	0 (0–1)	0 (0–0)	0 and 2
<b>Centers, n (%)</b>				
A	25 (39)	25 (40)	1 (25)	0 (0)
B	21 (33)	19 (31)	3 (75)	0 (0)
C	8 (13)	9 (15)	0 (0)	1 (50)
D	4 (6)	3 (5)	0 (0)	1 (50)
E	3 (5)	3 (5)	0 (0)	0 (0)
F	3 (5)	3 (5)	0 (0)	0 (0)

Con indicates control group; exp, experimental group; IQR, interquartile range; SD, standard deviation.

\*Sitting balance measured with item 3 of Motor Assessment Scale for stroke (15), where 6 is the highest score.

†Sensory loss measured 0 to 2, where 0 is normal.

‡Spasticity measured with Ashworth scale and reported as 0 to 4, where 0 is normal.

§Neglect measured with line bisection test and reported as 0 to 2, where 0 is <5 mm from midline and 2 is >20 mm.

group because of the treadmill not working. In week 1, the median distance walked per session was 129 m (interquartile range, 77–203) by the experimental group compared with 26 m (interquartile range, 1–77) by the control group. In the final week of training, the median distance walked per session was 254 m (interquartile range, 164–485) by the experimental group compared with 120 m (interquartile range, 73–227) by the control group.

There were few adverse events in either group. There were 47 reports of adverse events in the experimental group (0.04% of sessions) and 27 reports in the control group (0.02% of sessions). The adverse events were musculoskeletal problems (including back, hip, knee, calf, foot pain, and gout), headaches, dizziness, and chest pain. There were 6 reports of falling, 1 of which resulted in a fracture and none of which occurred during the delivery of intervention. Two (3%) participants in the experimental group experienced anxiety attributable to being on a treadmill that was severe enough for them to withdraw from the study.

## Effect of Intervention

Within 6 months of entering the trial, 43 of 60 experimental participants achieved independent walking compared with 36 of 60 control participants, with 6 participants dropping out. Kaplan–Meier estimates of the proportion of experimental participants who achieved independent walking were 37% compared with 26% of the control group at 1 month, 66% compared with 55% at 2 months, and 71% compared with 60% at 6 months (Figure 2). Although >10% more of the experimental group were walking independently after 4 weeks, and this was maintained at 6 months, this difference was not statistically significant (log-rank  $\chi^2=1.77$ ;  $P=0.13$ ).

In terms of the time taken to walk independently, the experimental group walked 2 weeks earlier, with a median time of 5 weeks compared to 7 weeks for the control group (Figure 2).

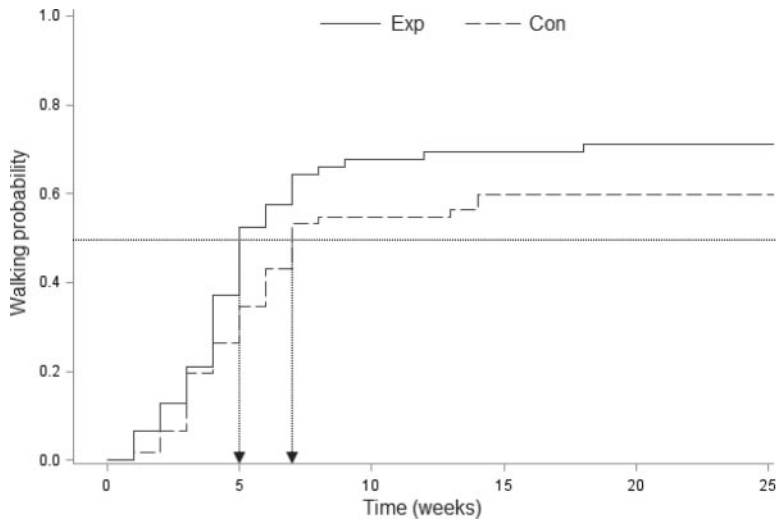
In terms of discharge destination, fewer of the experimental group (9/60) were discharged to supported accommodation, such as hostels and nursing homes (risk difference, –14%; 95% CI, –28–1), than the control group (18/62).

## Discussion

In nonambulatory people early after stroke, we found that treadmill training with body weight support resulted in more people walking compared with assisted overground walking. Specifically, 71% of the experimental group achieved independent walking within 6 months compared with 60% of the control group, and 50% of the experimental group attained independent walking by 5 weeks compared to 7 weeks for the control group. Although these differences were not statistically significant, with no serious adverse events, we have demonstrated that treadmill walking with body weight support can be safely provided for nonambulatory stroke patients. Furthermore, since the commencement of our study, there have been three other large trials,<sup>19–21</sup> all reporting a beneficial effect of mechanically assisted walking training with body weight support in establishing independent walking in nonambulatory people after stroke.

We argue that the difference between the groups results not from the type of training (eg, mechanically assisted vs assisted ground) but from the amount of training afforded by the interventions. There is clear evidence from systematic reviews that more intensive intervention is associated with better outcome.<sup>10</sup> Assisting overground walking in nonambulatory people is labor-intensive and therefore limited. We hypothesized that using treadmill with body weight support system would allow more practice to be completed. Training logs support our hypothesis in that during week 1 the average distance walked per session by the control group was only 20% of the experimental group, and during the last week distance was still <50%. Similarly, in the Pohl et al<sup>19</sup> study, although total amount of physiotherapy rehabilitation was standardized to 45 minutes per session, on average the experimental group undertook 35 minutes of walking compared with 20 minutes in the control group.

Although our experimental group results are similar to those of Pohl et al<sup>19</sup> at 6 months, 60% of our control group walked compared with 36% of their control group. This difference may simply be attributable to the fact that our



**Figure 2.** Kaplan–Meier curves of independent walking for the experimental group (solid lines) and the control group (dashed lines). The vertical arrows represent the time taken for 50% (horizontal line) of each group to walk.

control group practiced walking for up to 10 minutes more than did the control group in the study by Pohl et al. The amount of practice undertaken by the control group in both these studies represents more practice than usual physiotherapy rehabilitation because, recently, Kuys et al<sup>22</sup> reported that nonambulatory stroke patients spend on average only 8 minutes per session being assisted to walk.

An important finding was that the experimental group tended to achieve independent walking 2 weeks earlier. Given that independence in walking is a major consideration in discharge planning, this earlier attainment of independent walking after treadmill walking with body weight support has the potential to reduce the cost of rehabilitation. Furthermore, the 14% reduction in discharge to supported accommodation may also represent cost savings to the community.

There are several limitations to our study. First, the recruitment process was lengthy and challenging despite using 6 centers. The number of participants from each center was variable because of the differences in volume combined with differences in when centers became involved in the study. Second, as in most clinical trials of complex interventions, therapists and patients cannot be blinded and therefore are potential source of bias. Interestingly, in this study our therapists had differing views on which intervention would be more effective. On average, there was an 11% difference between the groups after 4 weeks and this was not statistically significant; we would have needed >800 participants to have sufficient power to detect an effect of this size. However, the results are from a variety of centers and involve many therapists, which suggest good external validity.

In conclusion, this large trial suggests that treadmill training with body weight support results in more individuals walking independently and earlier. When combined with recent studies, it provides evidence that mechanical-assisted walking with body weight support is beneficial for nonambulatory patients after stroke.

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### Disclosures

None.

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