Treadmill walking with body weight support in subacute non-ambulatory stroke improves walking capacity more than overground walking: a randomised trial

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Questions: Is treadmill walking with body weight support during inpatient rehabilitation detrimental to walking quality compared with assisted overground walking? Does it result in better walking capacity, perception of walking or community participation? Design: Analysis of secondary outcomes of a randomised trial with concealed allocation, assessor blinding and intention-to-treat analysis. Participants: 126 patients unable to walk within 4 weeks of a stroke who were undergoing inpatient rehabilitation. Intervention: The experimental group undertook up to 30 minutes of treadmill walking with body weight support via an overhead harness per day while the control group undertook up to 30 minutes of overground walking. Outcome measures: The secondary outcomes were walking quality and capacity, walking perception, community participation and falls. Results: Six months after entering the study, there was no difference between the groups of independent walkers in terms of speed (MD 0.10 m/s, 95% CI –0.06 to 0.26) or stride (MD 6 cm, 95% CI –7 to 19). The independent walkers in the experimental group walked 57 m further (95% CI 1 to 113) in the 6 min walk than those in the control group. The experimental group (walkers and non-walkers) rated their walking 1 point out of 10 (95% CI 0.1 to 1.9) higher than the control group. There was no difference between the groups in community participation or number of falls. Conclusion: Treadmill training with body weight support results in better walking capacity and perception of walking compared to overground walking without deleterious effects on walking quality. Trial registration: NCT00167531. [Dean CM, Ada L, Bampton J, Morris ME, Katrak PH, Potts S (2010) Treadmill walking with body weight support in subacute non-ambulatory stroke improves walking capacity more than overground walking: a randomised trial. Journal of Physiotherapy 56: 97–103]

Key words: Randomized Controlled Trial, Stroke, Physical Therapy, Rehabilitation, Walking

Introduction

Only half of non-ambulatory stroke patients admitted to inpatient rehabilitation in Australia learn to walk again (Dean and Mackey 1992). Being able to walk is a major determinant of whether a patient returns home after stroke or resides in a nursing home. In 2005, a Cochrane review concluded that, as an intervention in non-ambulatory patients, the efficacy of treadmill walking with body weight support via an overhead harness was unclear (Moseley et al 2005). The MOBILISE trial set out to determine the efficacy of treadmill walking with body weight support compared with assisted overground walking in establishing walking in non-ambulatory people after stroke. The primary outcome therefore was the number who achieved independent walking. During the six months after admission to the study, 72% of non-ambulatory people after stroke who received treadmill walking with body weight support achieved independent walking compared with 60% of the control group who received assisted overground walking (Ada et al 2010).

It has been found that treadmill walking is biomechanically different to overground walking (Van Ingen Schenau 1980). Less well known is whether these differences are important in training walking after stroke. Hesse (2008) reported that some clinicians were reluctant to use treadmill walking as an intervention after stroke for fear patients would practise abnormal walking patterns. Others have noted that treadmill walking may not be comparable to overground walking (Collett et al 2007). Treadmill walking with body weight support not only needs to be shown to be effective, but it also needs to be shown not to be deleterious in terms of the quality of walking. This would then remove potential barriers to widespread implementation of the intervention in stroke rehabilitation. The MOBILISE trial therefore included secondary outcome measures, such as walking speed and stride length, that reflected walking quality.

Treadmill walking may also have potential benefits from the extra practice that treadmill walking with body weight support affords. For example, capacity in the form of being able to walk further may be enhanced as a result of the additional practice. Furthermore, confidence to walk and participate in the community may be enhanced. Therefore, other secondary outcome measures included were walking capacity, perception of walking ability, community participation and falls.

The purpose of this paper is to report the analysis of the secondary outcomes from the MOBILISE trial. Therefore, the specific research questions were:

1. Is treadmill walking with body weight support during inpatient rehabilitation detrimental to walking quality compared with assisted overground walking?
2. Does it result in better walking capacity, perception of walking or community participation, or fewer falls?

Answering these questions should facilitate the translation of evidence into practice.
Method

Design
An analysis of secondary outcomes of the MOBILISE trial was performed. The MOBILISE trial was a prospective, multicentre, randomised trial comparing treadmill walking with body weight support versus assisted overground walking in non-ambulatory people after stroke. Non-ambulatory stroke patients were screened by an independent recruiter and randomly allocated into either an experimental group or a control group. Randomisation was stratified by centre and severity using randomly permuted blocks of four or six patients. Sitting balance (Item 3) of the Motor Assessment Scale for Stroke was used to stratify severity. Those with scores 0–3 were randomised separately to those with scores 4–6. 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 randomisation was secure and concealed. The experimental group received treadmill walking with body weight support and the control group received assisted overground walking. The participants and therapists delivering the intervention were not blinded to the intervention. At 6 months after admission to the study, walking quality and capacity were measured in those participants who achieved independent walking while walking perception, community participation, and falls were measured on all participants. All outcomes were measured by an investigator who was blinded to group allocation.

Participants, therapists and centres
Stroke patients were included if they were within 28 days of their first stroke, aged between 50 and 85 years, diagnosed clinically with hemiparesis or hemiplegia, and were non-ambulatory, which was defined as scoring 0 or 1 on Item 5 (Walking) of the Motor Assessment Scale for Stroke (Carr et al 1985). They were excluded if they had: clinically-evident brainstem signs, severe cognitive and/or language deficits that precluded them from following instructions, unstable cardiac status, or any pre-morbid conditions that precluded them from rehabilitation. On entry to the study, the presence of sensory loss was measured using the Nottingham Sensory Assessment with the scores reversed so 0 is normal and 2 is absent sensation (Lincoln et al 1998). Neglect was measured by the line bisection test where 0 is < 5 mm from midline and 2 is > 20 mm (Parton et al 2004). Spasticity of the ankle plantarflexors was measured by the Ashworth Scale where 0 is normal and 4 is a rigid limb (Ashworth 1964).

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 doing a locum or about to rotate out of the multidisciplinary rehabilitation program. Years since graduation, highest qualification, and previous research experience were recorded. Centres with rehabilitation units were included if they had acute stroke units on site or had strong links with off-site units. The volume of strokes managed per year and the physiotherapist: patient ratio were recorded for each centre.

Intervention
The experimental group practised walking on a treadmill while 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, they stepped on the spot. The amount of body weight support was reduced once participants could (i) swing their affected leg through without help, (ii) maintain a straight knee during stance phase without hyperextension, and (iii) maintain an adequate step length without help. Once they attained a speed of 0.4 m/s without body weight support, 10 minutes of the session was devoted to overground walking. These guidelines had been tested for feasibility (Crompton et al 2001).

The control group practised 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, they practised standing and shifting weight and stepping forwards and backwards. Once participants could walk with the assistance of one therapist, they were instructed to increase their speed and assistance from both the therapist and aids was reduced. Both groups underwent a maximum of 30 minutes per day of walking practice with assistance from one therapist, five days a week, until they achieved independent walking or were discharged from hospital. Other intervention involving the lower limbs (ie, strengthening exercises, practising activities such as sitting, standing up and standing) was standardised to a maximum of 60 min 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, 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.

Outcome measures
Quality of walking was measured by quantifying speed (in m/s) and stride length (in cm) from a 10-m Walk Test. Participants were timed and the number of steps counted while walking at their comfortable speed over the middle 10 m of a 15 m track to allow for acceleration and deceleration.

Walking capacity was measured by quantifying the distance walked (in m) on a 6-min Walk Test. The instructions for the test were standardised according to Lipkin and colleagues (1986). Participants were instructed ‘Walk as far as possible in six minutes. You can slow down and rest if necessary but at the end of the six minutes you should aim to have been not able to have walked any further in the time period.’ No encouragement was given but the investigator informed participants at the half-way point (3 min) and when there was one minute remaining. Participants were allowed to wear shoes and use aids if necessary. Rests were permitted and recorded but the 6 min timer was not interrupted during rest periods.

Walking perception, falls and community participation were measured using questionnaires. Walking was self-rated as a score out of 10. Participants were asked ‘On a scale of 1 to
10, how do you rate your walking compared with before you had your stroke?' Number of falls since discharge was quantified by asking 'Have you had any falls since discharge from the rehabilitation unit? If yes, how many?'

Community participation was measured using the Adelaide Activities Profile (Bond and Clarke 1998), which has been shown to be a valid measure of the lifestyle activities of elderly people in Australia. The questions reflect performance on activities covering domestic chores, household maintenance, service to others and social activities over the last three months. Each activity is rated with four possible responses from 0–3, where a higher score reflects more participation. For the purposes of this study, and in line with recommendations, community participation was reported as a score out of 72. Further details on study protocols and data collection are in Appendix 1 on the eAddenda.

Data analysis
We undertook an a priori power calculation to determine sample size based on primary outcome measures. About 50% of non-ambulatory patients walk independently at discharge (Dean and Mackey 1992). We designed the study to detect a 25% increase in the proportion of non-ambulatory patients walking independently, ie, from 50% to 75%. The smallest number of participants to detect this difference between two proportions estimated from independent samples with 80% power at a two-tailed 5% significance level was 65 participants per group, ie, 130 participants in total (Fleiss 1981).

The secondary outcomes were analysed using independent sample t-tests with a significance level of $p < 0.05$. The mean difference between the groups and a 95% CI was calculated for all the outcome measures. For participants who withdrew or died, data were censored at the time of withdrawal or death.

Results
Flow of participants, therapists and centres through the trial
One hundred and twenty-six participants were recruited to the study between August 2002 and September 2008. The baseline characteristics of the participants are presented in Table 1. Sixty-four participants were allocated to the experimental group and 62 to the control group. Two participants in the experimental group withdrew because of anxiety when using the treadmill. At 6 months after admission to the study, there were 59 participants in the experimental group and 60 in the control group. Figure 1 outlines the flow of participants through the trial.

Twenty-five physiotherapists, on average 10 years (SD 9) since graduating, provided the intervention. Six (24%) had relevant postgraduate qualifications and 12 (48%) had research experience. On average, therapists were involved in the study for 3 years (SD 2, range 1 to 6) and trained 5 participants (SD 5, range 1 to 19). Most therapists trained both experimental and control participants, although 8 (32%) trained only one participant each.

Table 1. Characteristics of participants and centres.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Randomised (n = 126)</th>
<th>Lost to follow-up (n = 7)</th>
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<tbody>
<tr>
<td></td>
<td>Exp (n = 64)</td>
<td>Con (n = 62)</td>
</tr>
<tr>
<td>Participants</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Age (yr), mean (SD)</td>
<td>70 (9)</td>
<td>71 (9)</td>
</tr>
<tr>
<td>Gender, n males (%)</td>
<td>38 (59)</td>
<td>33 (53)</td>
</tr>
<tr>
<td>Side of hemiplegia, n right (%)</td>
<td>30 (47)</td>
<td>26 (42)</td>
</tr>
<tr>
<td>Time since stroke at enrolment (days), mean (SD)</td>
<td>18 (8)</td>
<td>18 (7)</td>
</tr>
<tr>
<td>Sitting balance (0 to 6), mean (SD)</td>
<td>3.1 (1.4)</td>
<td>2.9 (1.3)</td>
</tr>
<tr>
<td>Sensory loss (0 to 2), median (IQR)</td>
<td>1 (0–1)</td>
<td>1 (0–1)</td>
</tr>
<tr>
<td>Spasticity (0 to 4), median (IQR)</td>
<td>0 (0–1)</td>
<td>0 (0–1)</td>
</tr>
<tr>
<td>Neglect (0 to 2), median (IQR)</td>
<td>0 (0–0)</td>
<td>0 (0–1)</td>
</tr>
<tr>
<td>Centres, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>25 (39)</td>
<td>25 (40)</td>
</tr>
<tr>
<td>B</td>
<td>21 (33)</td>
<td>19 (31)</td>
</tr>
<tr>
<td>C</td>
<td>8 (13)</td>
<td>9 (15)</td>
</tr>
<tr>
<td>D</td>
<td>4 (6)</td>
<td>3 (5)</td>
</tr>
<tr>
<td>E</td>
<td>3 (5)</td>
<td>3 (5)</td>
</tr>
<tr>
<td>F</td>
<td>3 (5)</td>
<td>3 (5)</td>
</tr>
</tbody>
</table>

Exp = experimental group, Con = control group
Rehabilitation units at six centres participated in the trial: three had on-site acute stroke units, two were rehabilitation units only, and one had its acute stroke unit at a different location. The annual throughput of stroke patients averaged 314 (SD 121, range 118 to 444), and the physiotherapist:patient ratio averaged 1:8. The number of participants in each group was similar within each centre (Table 1). Centres were involved in the study for an average of four years (SD 2, range 2 to 6).

**Compliance with trial method**

Participants were scheduled to receive intervention for five sessions a week until they achieved independent walking or were discharged. The experimental group participated in 1336 sessions which represents 85% of possible sessions if the intervention was delivered 5 days/wk. The control group participated in 1490 sessions which represents 89% of possible sessions. Examination of the records of intervention revealed that intervention was given as randomly allocated 97% of the time.

For the independent walkers, data on walking quality and capacity were obtained 90% of the time. For all participants, data on walking perception, community participation, and falls were obtained 80% of the time. Reasons for missing data included incomplete questionnaires, moving out of the area, and declining to participate in assessment of outcomes.

**Effect of intervention**

Group data are presented in Table 2 and individual data in Table 3 (see eAddenda for Table 3). Over the six month period after admission to the study, 43/60 (72%) of the experimental group achieved independent walking. However, one of the experimental group walkers died before the 6-month measure, reducing the number of the experimental group independently walking at 6 months to 42/59 (71%) compared with 36/60 (60%) of the control group. In terms of the walking quality and capacity of the independent walkers at 6 months, the experimental group walked with a mean speed that was 0.10 m/s (95% CI –0.06 to 0.26) faster and took a mean stride that was 6 cm (95% CI –7 to 19) longer than the control group, neither of which were statistically significant. The experimental group walked a mean distance of 57 m (95% CI 1 to 113) further in six minutes than the control group which was statistically significant (Table 2).

At 6 months, the experimental group rated their walking 1.0 out of 10.0 points (95% CI 0.1 to 1.9) higher than the control group. However, both groups scored low on the Adelaide Activities Profile and the experimental group score was only 1 out of 72 points (95% CI –3 to 5) higher than the control group. Although 10% (95% CI –10 to 28) more of the experimental group fell, on average they had 0.1 (95% CI –0.6 to 0.8) fewer falls than the control group, neither of which were statistically significant (Table 2).

**Discussion**

The findings from this study suggest that in non-ambulatory people after stroke, treadmill walking with body weight support during inpatient rehabilitation is not detrimental to walking quality compared with assisted overground walking. For those who achieved independent walking, we found no difference between the groups in terms of speed or stride length.

Recently, Tilson and colleagues (2010) reported that
The walking speed achieved by our experimental group is similar to that achieved by repetitive locomotor training using a mechanical gait trainer (Pohl et al 2007). At six months, Pohl and colleagues (2007) reported a mean walking speed of 0.53 m/s which is almost identical to the 0.57 m/s speed achieved by our treadmill group. Furthermore, our finding that treadmill walking did not have a negative effect on quality is consistent with recent work by Kuys and colleagues (2008a) who found that walking on a treadmill did not result in a deterioration of overground walking pattern compared with walking overground in newly ambulating stroke patients undergoing rehabilitation. They (Kuys et al 2008a) also found that increasing the intensity of walking on a treadmill did not adversely affect the walking pattern or quality. Taken together, these findings suggest that one barrier to implementation of this intervention, ie, the fear that treadmill walking would have a deleterious effect on quality, is unfounded.

Another finding suggests that treadmill walking with body weight support results in a greater capacity for walking compared with assisted overground walking. At almost 60 m, the increased capacity is clinically significant. However, the CI is wide suggesting some uncertainty about the size of the effect. The magnitude of the improvement is similar to that reported by Pohl and colleagues (2007) who found a 44 m difference in favor of the repetitive locomotor group. This increased capacity is accompanied by a 10% higher rating of walking by the experimental group compared to the control group at 6 months. Although this is a positive rating, it may be the result of the participants not being blind to group allocation. However, importantly, participants undergoing treadmill walking with body weight support do not perceive themselves to be worse off than if they had been assisted to walk overground.

There was, however, no difference in community participation between the groups. Our participants had very low levels of community participation as measured by the Adelaide Activities Profile. This is perhaps not surprising given that, on entry to the study, all participants were unable to walk and therefore represent the most disabled patients with subacute stroke whose gait speed increased by at least 0.16 m/s were more likely to experience a meaningful reduction in disability. Our 95% CI excludes the possibility that treadmill training makes gait speed worse to a clinically meaningful extent. In the absence of an established clinically important difference in stride length, we consider 25 cm a clinically important difference. Again, our 95% CI excludes the possibility that treadmill training worsens stride length to that extent.

Table 2. Mean (SD) or number of participants (%) for each outcome in each group and mean or risk difference (95 % CI) between groups at 6 months after admission to study.

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Exp (n = 64)</th>
<th>Con (n = 62)</th>
<th>Difference between groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Independent walkers, n (%)</td>
<td>42/59</td>
<td>36/60</td>
<td>RD 11</td>
</tr>
<tr>
<td>Walkers only (n = 78)</td>
<td>(71)</td>
<td>(60)</td>
<td>(–6 to 27)</td>
</tr>
<tr>
<td>Walking speed (m/s), mean (SD)</td>
<td>0.57 (0.36)</td>
<td>0.47 (0.28)</td>
<td>MD 0.10</td>
</tr>
<tr>
<td>Walking stride (cm), mean (SD)</td>
<td>73 (31)</td>
<td>67 (24)</td>
<td>MD 6</td>
</tr>
<tr>
<td>Walking capacity (m), mean (SD)</td>
<td>240 (130)</td>
<td>183 (99)</td>
<td>MD 57</td>
</tr>
<tr>
<td>All participants (n = 119)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walking self-rating (0 to 10), mean (SD)</td>
<td>5.0 (2.3)</td>
<td>4.0 (2.3)</td>
<td>MD 1.0</td>
</tr>
<tr>
<td>AAP (0 to 72), mean (SD)</td>
<td>16 (12)</td>
<td>15 (8)</td>
<td>MD 1</td>
</tr>
<tr>
<td>Falls, n yes (%)</td>
<td>28/46</td>
<td>25/49</td>
<td>RD 10</td>
</tr>
<tr>
<td>Falls (n), mean (SD)</td>
<td>1.2 (1.5)</td>
<td>1.3 (1.9)</td>
<td>MD –0.1</td>
</tr>
</tbody>
</table>

Exp = experimental group, Con = control group; AAP = Adelaide Activities Profile.
terms of walking speed. A recent study by Tiedemann and colleagues (2008) suggested that a walking speed of less than 1 m/s was a predictor of multiple falls in community dwelling older persons. Using this criterion, 94% of our entire sample was at risk of multiple falls.

There are several limitations to our study. First, as in most clinical trials of complex interventions, we were unable to blind therapists, and patients cannot be blinded, creating a potential source of bias. In addition, the high levels of disability and co-morbidities resulted in an incomplete dataset, e.g. cognitive and language impairments often meant that it was not possible for questionnaires to be completed.

In conclusion, analysis of the secondary outcomes of the MOBILISE trial, measured six months after entry to the study, demonstrates that treadmill walking with body weight support results in a greater walking capacity and higher perception of walking ability six months after commencement of training compared with overground walking. There is no evidence to suggest that treadmill walking with body weight support has a deleterious effect on walking quality. Clinicians should therefore feel confident about implementing this intervention.

eAddenda: Appendix 1, Table 3 available at jop.physiotherapy.asn.au

Ethics: Sydney University Human Research Ethics Committee (08-2002/2916), Melbourne University Human Research ethics Committee (HREC No. 050881), Human Research Ethics committees from the following sites: Kingston Centre (Research Project Application No. 06018B), Sydney South West Area Health Service (Project no. 2007/066), South Eastern Sydney & Illawarra Area Health Service: Eastern section (Ref no. 98/043) / Southern section (Ref no. 02/79AdA), Royal Rehabilitation Centre Sydney (Research project 02/08) and Sydney West Area Health Service (Reference no. 2004/8/4.9 (1923)) approved this study. All participants gave informed consent before data collection began.

Competing interests: None declared.

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