

A six-week, resource-efficient mobility program after discharge from rehabilitation improves standing in people affected by stroke: Placebo-controlled, randomised trial

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Although intervention is effective in reducing the disability associated with stroke, limited resources mean that physiotherapy services often cease by six months after stroke. The purpose of this clinical trial was to investigate the efficacy of resource-efficient physiotherapy services in improving mobility and quality of life after stroke. Twenty-six people with residual walking difficulties after stroke were randomised into an experimental or control group after discharge from physiotherapy services. The experimental group participated in a six-week, home-based mobility program. The control group participated in a six-week, home-based program of upper-limb exercises (i.e. 'sham' mobility exercises). Subjects met with the therapist for prescription of exercises only three times during the six weeks. Strategies used to offset potential problems associated with minimal subject-therapist interaction included videotaped instructions to encourage correct performance of exercises, modification of the environment and involvement of carers to enhance safety, and telephone contact and self-monitoring to promote compliance. Standing (Functional Reach), walking (MAS Item 5) and quality of life (SA-SIP30) were measured prior to, immediately after, and two months after intervention ceased by an assessor who was blinded to group allocation. Subjects in the experimental group demonstrated significant improvement in standing compared to the control group ($p = 0.01$) which was maintained two months after the cessation of intervention ($p = 0.04$). There was no difference between the groups in walking ($p = 0.50$) or quality of life ($p = 0.70$). The six-week, resource-efficient mobility program was effective in improving some of the mobility in people after discharge from stroke rehabilitation. The provision of resource-efficient programs is recommended wherever possible so that people affected by stroke may continue rehabilitation for longer. [McClellan R and Ada L (2004): A six-week, resource-efficient mobility program after discharge from rehabilitation improves standing in people affected by stroke: Placebo-controlled, randomised trial. *Australian Journal of Physiotherapy* 50: 163–167]

Key words: Physical Therapy (Specialty); Randomized Controlled Trial; Cerebrovascular Accident; Patient Discharge

Introduction

Stroke is the leading cause of long-term disability in Australian adults (Australian Institute of Health and Welfare 2001), with many survivors experiencing a significant reduction in quality of life (Greveson et al 1991). This places a considerable burden on health care services. With the rapid ageing of the Australian population and an increase in the proportion of people surviving a stroke, it is predicted that the number of people who will live with a permanent disability will increase (Australian Institute of Health and Welfare 2001). The consequence will be an increased demand on finite health resources. Therefore, consideration needs to be given to ensure efficient utilisation of the resources available to people affected by stroke.

It is common for lack of mobility to be an ongoing problem after stroke, e.g., difficulty standing (Hill et al 1997, Lee et al 1988, Lindmark and Hamrin 1995, Mayo et al 1999) and walking (Australian Institute of Health and Welfare 2001, Hackett et al 2000, Hill et al 1997, Lindmark and Hamrin 1995, Mayo et al 1999). In Australia, it is common for physiotherapy services to cease at about six months. However, there is evidence that intervention is effective in improving mobility even years after stroke (Dean et al 2000, Green et al 2002, Tangeman et al 1990, Wade et al 1992, Weiss et al 2000, Werner and Kessler 1996). These benefits from continued physiotherapy services are often the result of

resource-intensive programs, with individual patient-therapist interaction ranging from 20 to 48 sessions and taking up to 96 hours (e.g. Weiss et al 2000, Tangeman et al 1990, Werner and Kessler 1996). Furthermore, programs that are less resource-intensive have not always had the same effect (e.g. Green et al 2002, Wade et al 1992). Given that in the current economic climate there are limited resources, it is important to use resource-efficient but effective methods of providing these services.

Two recent investigations into home-based exercise programs indicate that they are an effective method of improving the mobility of people affected by stroke (Duncan et al 1998, Monger et al 2002). However, both programs were resource-intensive, with a therapist supervising the home exercises three times a week. A home-based exercise program could be a resource-efficient method of providing physiotherapy services because there is minimal use of hospital facilities and exercises could be practised without direct therapist supervision. However, lack of ongoing patient-therapist interaction can result in incorrect performance, decreased safety, and reduced compliance. The challenge is to implement strategies that can address these three potential problems.

The first of the three potential problems associated with lack of patient-therapist interaction is incorrect practice of exercises due to the lack of feedback usually provided by the therapist. Given that instructional videotapes assist in

Table 1. Subject characteristics.

Characteristic	Experimental group (n = 13)	Control group (n = 10)	Drop outs (n = 3)
Age in years			
Mean (SD)	69 (13)	72 (9)	68 (10)
Gender			
M:F	10:3	2:8	1:2
Side of hemiplegia			
R:L	8:5	3:6	2:1
		1 bilateral	
Months between stroke and admission to study			
Median (IQR)	6.5 (5.5)	4.5 (3.0)	3.5 (3.0)

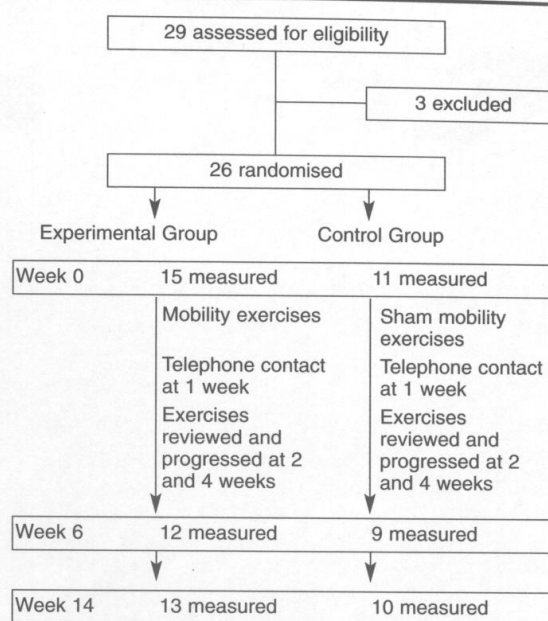
learning new skills (Renton-Harper et al 1999, Weeks et al 2002), exercises can be videotaped to assist with practice at home. Demonstration of the exercise by the therapist (therapist-modelling) (Talvitie 1996, Williams 1993) and by the subject (self-modelling) (Dowrick and Dove 1980, Dowrick 1983, Neef et al 1995) have both been shown to be effective in encouraging correct performance. The second potential problem associated with lack of patient-therapist interaction is decreased safety. Strategies that enhance safety include modifying the practice environment and involving carers in the assistance of exercises. The third potential problem is reduced compliance. Videotaped instructions (Mahler et al 1999, Roddey et al 2002, Weeks et al 2002), telephone contact (King et al 1988), and self-monitoring (King et al 1988, Noland et al 1989) have all been shown to assist in promoting compliance.

Therefore, a resource-efficient mobility program that included videotaped instructions to encourage correct performance of exercises, modification of the environment and involvement of carers to enhance safety, and telephone contact and self-monitoring to promote compliance was designed. The research questions were: In people affected by stroke who have been discharged from physiotherapy services:

- Does a six-week, resource-efficient mobility program increase mobility and quality of life?
- Are any improvements gained maintained eight weeks after intervention ceases?

Method

Design The study was a double-blind, randomised, placebo-controlled trial (Figure 1). To ensure allocation was concealed, randomisation was by numbered, sealed, opaque envelopes. Subjects in the experimental group were prescribed mobility exercises while subjects in the control group were prescribed upper-limb exercises (i.e. sham mobility exercises) to control for the placebo effect. To increase the likelihood that subjects were blind to group allocation, neither the exact purpose of the research nor the types of exercises that subjects would be receiving were specified and both mobility and upper limb function was measured. The period of intervention was six weeks. After this time contact ceased and subjects were informed that it would be their decision to continue with the exercises. Outcome measures were collected at Weeks 0, 6, and 14 by a measurer blinded to group allocation.

**Figure 1.** Flow of subjects through the trial showing timing of intervention and measurement.

Subjects Subjects were recruited on discharge from physiotherapy services in five public and one private hospital in metropolitan and regional NSW. The discharging physiotherapist contacted the investigator (RM) who assessed potential subjects for eligibility. Subjects were included if they: had a stroke within the past 18 months, were aged > 45 years of age, were living in the community, scored > 0 and < 6 on Item 5 of the Motor Assessment Scale (MAS) for stroke (Carr et al 1985), and scored < 6 on Item 7 or 8 of the MAS. They were excluded if they: were unable to give informed consent, had uncontrolled cardiac symptoms or other medical conditions that limited exercise, or had a pacemaker. The study was approved by the individual hospital and university ethics committees. Subjects gave informed consent before data collection began.

Intervention The exercises prescribed for the *experimental* group were aimed at improving mobility in standing and walking (Carr and Shepherd 1987, Berg et al 1989). Intervention was standardised by prescribing the first five exercises that the subject could not perform successfully from a list of 23 predetermined exercises. The exercises were arranged loosely hierarchically, based on their challenge to balance. Initially exercises were prescribed that involved standing with a wide base of support with little perturbation. Exercises were progressed by systematically decreasing the base of support and increasing the perturbations until subjects were performing exercises such as stepping backwards on and off a step.

The exercises prescribed for the *control* group were aimed at improving the function of the affected upper limb (Carr and Shepherd 1987). As with the experimental group, intervention was standardised by prescribing the first five exercises that the subject could not perform successfully from a list of 39

Table 2. Mean (SD) scores, mean (SD) differences within groups, and mean differences between groups (95% CI) for all outcomes.

Outcome	Scores						Differences within groups				Differences between groups	
	Wk 0 (n = 23)		Wk 6 (n = 21)		Wk 14 (n = 23)		Wk 6–Wk 0 (n = 21)		Wk 14–Wk 0 (n = 23)		Wk 6–Wk 0 (n = 21)	Wk 14–Wk 0 (n = 23)
	Exp	Con	Exp	Con	Exp	Con	Exp	Con	Exp	Con	Exp-Con	Exp-Con
Standing Functional Reach (cm)	17.3 (7.3)	20.5 (5.3)	21.9 (9.4)	17.8 (7.4)	20.2 (9.4)	17.7 (8.4)	4.5 (4.8)	-3.2 (6.7)	2.9 (5.5)	-2.9 (6.9)	7.7 (2.5 to 12.9)	5.8 (0.4 to 11.2)
Walking MAS Item 5 (score/6)	3.9 (0.8)	4.1 (0.7)	4.3 (1.2)	4.7 (1.0)	4.2 (1.1)	4.4 (1.3)	0.3 (0.6)	0.4 (0.5)	0.2 (0.7)	0.3 (0.7)	-0.1 (-0.6 to 0.4)	-0.1 (-0.7 to 0.5)
Quality of life SA-SIP30 (score/30)	16.5 (6.1)	12.6 (5.9)	15.5 (6.2)	11.0 (5.7)	14.2 (7.0)	11.5 (6.3)	-1.5 (4.0)	-0.8 (2.9)	-2.3 (5.0)	-1.1 (3.1)	-0.7 (-4.0 to 2.6)	-1.2 (-5.0 to 2.6)

predetermined exercises that were arranged loosely hierarchically. Exercises were initially prescribed that involved only the movement of one joint such as elbow extension and were progressed until subjects were performing complex tasks such as shuffling a deck of cards.

Each subject attended local physiotherapy outpatient department for the initial prescription of exercises by one of the investigators (RM). The exercises were recorded on videotape to reinforce correct and therefore effective practice. The videotape recording consisted of each exercise being demonstrated by the therapist, followed by three attempts by the subject with feedback from the therapist. Strategies to enhance safety such as modification of the environment (e.g. performing exercises next to a wall) and assistance from carers (e.g. standing on the affected side) were also included in the recording. Subjects in each group were instructed to practise each exercise twice a day in front of the videotape. They were telephoned at the end of Week 1 to encourage compliance, and returned to their local physiotherapy outpatient department to have their exercises reviewed and progressed at Weeks 2 and 4. Subjects were required to keep a record of practice during the six weeks of intervention.

Outcome measures Two areas of mobility were measured: standing and walking. Standing was measured using the Functional Reach Test (FR) (Duncan et al 1990) and walking was measured using Item 5 of the MAS. In addition, quality of life was measured using the stroke-adapted 30-item version of the Sickness Impact Profile (SA-SIP30) (Van Straten et al 1997).

Statistical analysis Two-way ANOVA tests (group x time) were used to determine whether there was a greater effect of the mobility program than the sham mobility program on standing, walking, and quality of life. One ANOVA conducted on data from Weeks 0 and 6 compared the immediate effect of the mobility program with the sham mobility program, while a second ANOVA of data from Weeks 0 and 14 determined whether any gains were maintained. Descriptive data are presented as means (SD).

Results

Flow of subjects through trial Twenty-nine people affected by stroke were screened for eligibility and, after three were excluded (two for exceeding the inclusion criteria and one for having a pacemaker), 26 subjects agreed to participate in the study and gave informed consent. Fifteen were randomised to the experimental group and 11 to the control group (Figure 1). There were three dropouts, two from the experimental group (both died) and one from the control group (who had another stroke). In addition, there were missing data for two subjects at Week 6, one subject from the experimental group (who failed to attend) and one from the control group (who was unable to attend due to a sprained ankle). Therefore, 81% of the sample was available for analysis at Week 6 and 88% at Week 14. The characteristics of the experimental group, control group and dropouts are summarised in Table 1.

Compliance During the six-week, resource-efficient mobility program, subjects were required to attend their local physiotherapy outpatient departments three times to have their exercises prescribed and then reviewed and progressed. On average, subjects attended 96% of these appointments (the experimental group attended 98% and the control group 94%). Subjects in both groups were also required to keep a record of when they practised their exercises. On average, subjects practised their exercises 75% of the time they were prescribed (the experimental group practised 78% and the control group 70%). In the eight weeks after intervention had ceased, 87% of subjects (92% of subjects in the experimental group and 80% of subjects in the control group) continued to practise their exercises. In both groups, the most common reason subjects reported for continuing their exercises was that they wanted to improve.

Outcomes Between Weeks 0 and 6, FR had increased significantly more in the experimental group than in the control group ($F_{(1,19)} = 9.5, p = 0.01$). Between Weeks 0 and 14, FR had increased significantly more in the experimental group than the control group ($F_{(1,21)} = 5.0, p = 0.04$) (Figure 2a, Table 2).

Between Weeks 0 and 6, Item 5 of the MAS increased slightly in both groups, with no significant difference between them ($p = 0.50$). Between Weeks 0 and 14, Item 5 of the MAS

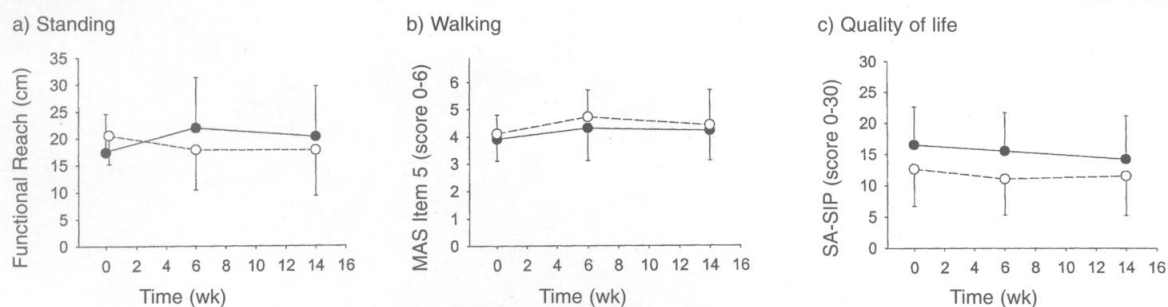


Figure 2. Means and standard deviations for the experimental group (closed circles) and the control group (open circles) at Week 0, 6, and 14 for a) standing, b) walking, and c) quality of life.

remained relatively unchanged in both groups, with no significant difference between them ($p = 0.80$) (Figure 2b, Table 2).

Between Weeks 0 and 6, SA-SIP30 was relatively unchanged in both groups, with no significant difference between the groups ($p = 0.70$). Between Weeks 0 and 14, SA-SIP30 remained relatively unchanged in both groups, with no significant difference between groups ($p = 0.60$) (Figure 2c, Table 2).

Discussion

This randomised, placebo-controlled trial demonstrated that a resource-efficient, mobility program was effective in improving standing ability after discharge from physiotherapy services in people affected by stroke. As a result of six weeks of intervention, subjects in the experimental group improved their reaching by a mean distance of 8 cm (95% CI 3 to 13) more than the control group, arguably a clinically significant result. Furthermore, there was still a mean difference of 6 cm (95% CI 0 to 12) eight weeks after intervention ceased. The improvement was achieved in a resource-efficient manner, with subjects required to come to the hospital only three times (totalling 2 hours) in 14 weeks for the prescription of exercises. Furthermore, there was reduced use of hospital resources because of limited subject-therapist interaction, with only two hours of direct interaction for an estimated 30 hours of practice. This result is in line with the findings from another resource-efficient program utilising circuit classes with a ratio of six subjects to two therapists (Dean et al 2000).

The provision of resource-efficient programs may allow people affected by stroke to continue rehabilitation for longer. It is common for people affected by stroke in Australia to cease receiving physiotherapy services at about six months. A home-based exercise program is an effective method of providing resource-efficient physiotherapy intervention, and the potential problems resulting from lack of patient-therapist interaction can be offset by using videotaped instructions to encourage correct performance of exercises, modification of the environment and involvement of carers to enhance safety, and telephone contact and self-monitoring to promote compliance. In the present study, these strategies were found to be effective in ensuring effective practice. When the prescribed exercises were reviewed at Weeks 2 and 4, there were high rates of successful performance, no adverse effects, and good compliance.

Subjects in this study were typical of people affected by stroke living in the community soon after the cessation of formal rehabilitation. They were motivated to continue rehabilitation in that only one person approached for the study was not interested in undertaking further exercise. All subjects could walk but with difficulty, with two of the subjects using a wheelchair outside the home. While they all had enough cognitive ability to give informed consent, three had expressive dysphasia and seven spoke English as a second language with two requiring an interpreter. Half of the subjects lived alone, while only half of the available spouses attended the sessions where the exercises were prescribed. Implementing strategies such as those used in the present study, to provide resource-efficient intervention immediately after discharge from inpatient rehabilitation, would allow more sustained service provision with the available resources, thus providing people affected by stroke with the opportunity to reduce their disability.

There was no difference in outcome between the groups in terms of walking ability or quality of life. However, given that there were a small number of subjects, this result may be due to a lack of statistical power rather than a lack of effect. If we regard a difference of one point on Item 5 of the MAS and three points on the SA-SIP30 as the smallest clinical effect worth detecting, then the 95% CIs for the effect on these outcome measures (Table 2) exclude a worthwhile effect. This suggests that the resource-efficient mobility program provided to the experimental group in the present study was ineffective in improving walking ability and quality of life after discharge from physiotherapy services in people affected by stroke. There is evidence, however, that with the provision of physiotherapy services people affected by stroke are able to improve in walking even years after stroke (Dean et al 2000, Green et al 2002, Wade et al 1992, Weiss et al 2000, Werner and Kessler 1996). Effective interventions included significantly more subject-therapist interaction, task-specific training, and lower-limb strengthening exercises. It is possible that improvements in walking require more resource-intensive intervention than that provided in the present study. However, it is more likely that the intervention provided in the present study was ineffective in improving walking because 84% of the exercises prescribed during the trial were specific to standing. Although the predetermined list also included exercises specific to walking, the easiest exercises on the list were in standing and subjects were prescribed those exercises first. Therefore, subjects improved at what they practised, in this case, standing rather than walking.

Werner and Kessler (1996) showed that people affected by stroke are able to improve their quality of life, even years after stroke. However, the improvement in quality of life in this study was associated with an improvement across a number of areas (e.g. dressing, bathing, stair climbing, and eating) as a result of a resource-intensive program (e.g. 48 hours of individual physiotherapy intervention and 48 hours of individual occupational therapy intervention) over a 12-week period. It appears that the improvement in only one area (i.e. in standing ability) in the present study was not enough to affect quality of life.

Conclusion

Participation in a six-week, resource-efficient mobility program was effective in improving some of the mobility in people after discharge from stroke rehabilitation. The limited resources available to people affected by stroke need to be utilised wisely. For those people able to continue rehabilitation after discharge from hospital, the use of strategies such as those employed by this study may allow rehabilitation to continue for longer and therefore reduce disability. However, intervention aimed at reducing disability after stroke should include exercises specific to the disability.

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