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Pilot randomized controlled trial to assess the impact of additional supported standing practice on functional ability post stroke

Rhoda Allison Stroke Unit and **Rachel Dennett** Physiotherapy Department, Newton Abbot Hospital, Devon, UK

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Objective: To investigate whether provision of additional standing practice increases motor recovery and mobility post stroke.
Design: A pilot randomized controlled trial.
Setting: A stroke rehabilitation unit in the UK.
Participants: Seventeen participants, seven women and ten men, age range 51–92 admitted to the unit 6–58 days post stroke.
Intervention: Each participant was randomly allocated into a control (conventional physiotherapy) or treatment (conventional therapy plus an additional session of standing practice) group. The period of intervention ranged from 14 to 28 days dependent upon length of stay on the unit.
Outcome measures: The Gross Functional Tool Section of the Rivermead Motor Assessment, the Trunk Control Test and the Berg Balance Scale were used on admission to the study, at weekly intervals during the intervention, and at 12 weeks (after discharge).
Results: Of the 17 participants recruited, three withdrew from the additional intervention group citing fatigue as a barrier and 15 completed the study. Participants completing additional standing practice demonstrated higher scores in all motor measures at week 12, but this difference was not statistically significant. There was a statistically significant difference ($P < 0.05$) in the changes in Berg Balance score when comparing week 1 with week 12, in support of the group receiving extra standing practice.
Conclusions: A larger study is required to establish the value of additional standing practice after stroke. This pilot demonstrates that the Gross Functional Tool Section of the Rivermead Motor Assessment and the Berg Balance Scale would be useful in such a study. Fatigue may be a significant barrier to ability to participate in more intensive programmes so screening participants for severe fatigue may be useful.

Introduction

Historically, there have been a number of different approaches to treating motor impairment after stroke.[1] Although there is strong evidence to support the effect of rehabilitation in terms of improving functional independence and reduced mortality,[2] there is currently

Address for correspondence: Rhoda Allison, Stroke Unit, Newton Abbot Hospital, Devon TQ12 4PT, UK.
e-mail: Rhoda.allison@nhs.net

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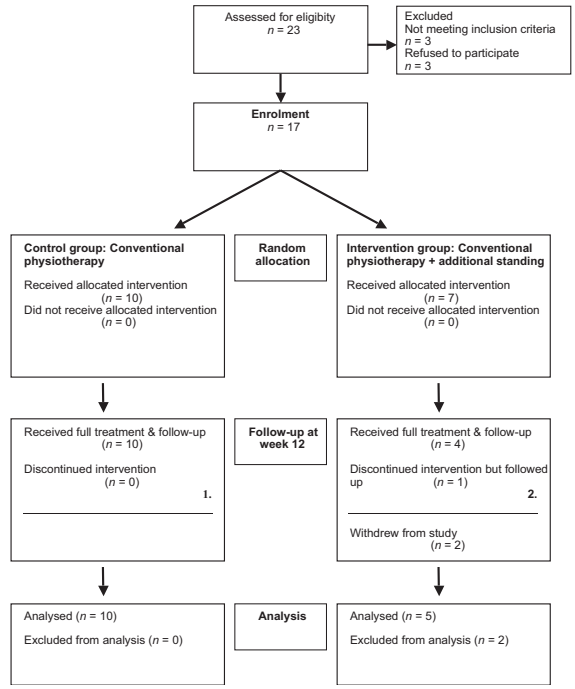

Figure 1 Flowchart of the study.

insufficient evidence to support the use of one specific approach over another.[3]

Emerging evidence suggests that giving patients the opportunity to practise functional tasks (task-specific training) may be a major element in improving outcomes.[4] There is also some evidence to support the hypothesis that higher intensity rehabilitation improves results.[5,6]

A number of studies have examined the impact of additional functional practice on outcome. Many of these have examined recovery of gait[7–9] but few have examined the ability to transfer. Ability to perform a safe bed-to-chair transfer is a key marker in enabling discharge from hospital,[2] so interventions aimed at improving this task need evaluation.

Barreca *et al.*[10] demonstrated that participants who practised an additional three sessions of sit-to-stand per week in addition to conventional therapy were more likely to achieve a safe, independent sit-to-stand transfer. The sample of participants used were, on average, 30 days post stroke at the start of the trial. Since the Early Discharge Trialists have indicated that discharge at three weeks is possible,[11] it would be pertinent to look at the impact of additional practice earlier in a person's rehabilitation. It is not always possible to practise sit-to-stand at this stage of recovery.

Table 1 Summary statistics of the participants recruited to the study

	Age (years)			Time since stroke (days)		
	Mean	Range	Standard deviation	Mean	Range	Standard deviation
Control group	78	65–92	7.9	15.1	6–58	16.0
Intervention group	72.4	55–88	17.9	20.6	9–57	20.5

However it is possible to achieve standing with the use of either tilt tables or standing frames if independent stand is not possible.

The aim of this study was therefore to investigate whether provision of additional standing practice would increase motor recovery and mobility post stroke, over the weeks before discharge.

Method

Twenty-three consecutively admitted patients were originally assessed from the Stroke Rehabilitation Unit at Newton Abbot Hospital. Patients with a confirmed diagnosis of recent stroke were eligible for inclusion. The following patients were excluded; those who were terminally ill, suffering from an unstable comorbidity or who were unable to participate safely (physically or mentally) in additional sessions of standing. The South Devon Ethics Committee gave approval for the study and all patients gave written or witnessed verbal consent. After giving informed consent participants were randomly allocated to one of the two treatment groups (Figure 1). Randomization was achieved via the use of 20 sealed envelopes, 10 of each containing a specific group allocation. A staff member who was blind to the study selected a sealed envelope for each participant, indicating the group allocation. A summary of the background characteristics of the participants is given in Table 1.

The first treatment group (control group) received conventional physiotherapy treatment from one of the three physiotherapists working on the ward. This was typically a session of 45 minutes treatment on each working day, including work on strengthening, improving movement, mobility, and upper limb function. The second treatment group (intervention group) received the conventional treatment session, and in addition had a further session of 45 minutes standing practice on each working day. This was provided by a physiotherapy assistant and typically involved the use of either standing frames, tilt tables or standing at tables to provide support while enabling standing to occur. Participants progressed to standing by a table for support or free standing during rehabilitation as able. Participants were encouraged to be active whilst standing – practising reaching tasks, sit-to-stand movements and so on, and were given rest periods as necessary throughout the 45-minute session. It was not possible for the physiotherapists providing the conventional treatment to be blind to the extra intervention occurring, due to the organization of therapy on the ward.

This treatment regime was continued throughout the participant's stay in the rehabilitation unit. After discharge from the unit the participant was referred for outpatient or community-based physiotherapy. Intensity of follow-up offered was based on community assessment and was typically one or two sessions of treatment per week.

Outcome measurement

Outcomes were evaluated with a number of measures of motor impairment and function: the Gross Function Tool Section of the Rivermead Motor Assessment, the Trunk Control Test and the Berg Balance Scale. Outcome measures were recorded on admission to the study, on a weekly basis during the inpatient stay (typically 3–4 weeks), and at 12 weeks after admission to the study (this measure was conducted after discharge).

The Berg Balance Scale is a staff-completed assessment scale of ability to maintain balance, either statically or while performing various functional movements. It has been utilized with an elderly population with impairment of balance and with patients with acute stroke.[12] The Rivermead Motor Assessment[13,14] contains a 13-point measure of gross function which can be used independently, and which contains reference to independent transfers. The Trunk Control Test is a simple 4-point measure of trunk control.[15]

The measurements were conducted by a staff member who did not work on the unit, and who was blind to the treatment allocation.

Results

Figure 1 shows the process of enrolment, allocation, follow-up and analysis. Seventeen participants were recruited to the study, with 10 allocated to the control group and seven allocated to the group receiving additional standing practice. Three of the participants allocated to the additional practice group withdrew from the additional treatment within the first week of the study, all of them citing fatigue as the reason they would not continue. One of these consented to further measures being taken but two withdrew totally from the study. Results were analysed on an intention to

Table 2 Comparisons of median measures and interquartile range

	Control group	Intervention group
Berg Balance score, median (IQR)		
Week 1	16.5 (2–26.5)	8 (2.5–21.75)
Week 2	28 (8–44)	24 (7.25–45)
Week 12	44 (11–52)	47 (11.25–51.5)
Difference from weeks 1 to 12	20.5 (1.5–31)	37 (6.5–42)
Gross Function Tool of Rivermead Motor Assessment, median (IQR)		
Week 1	2.5 (0.5–5.5)	3 (1.25–3.75)
Week 2	5.5 (1.0–7.5)	5 (1.5–9.75)
Week 12	7.5 (3.5–10.5)	9 (2.5–11.75)
Difference from weeks 1 to 12	4.5 (1.5–5.5)	5 (4.25–5.75)
Trunk Control Test, median (IQR)		
Week 1	74.5 (18–100)	61 (15.25–80.5)
Week 2	80.5 (31–100)	100 (21.75–100)
Week 12	87 (31–100)	100 (25–100)
Difference from weeks 1 to 12	0 (−13.5–50)	39 (9.5–39)

treat basis, but the two participants who only completed the first week of measures were excluded.

Data were not normally distributed, so median and interquartile range were used for descriptive statistics and data were analysed with Mann–Whitney tests. Comparisons of scores of the three measures between the two groups are shown in Table 2.

The majority of participants were discharged from the rehabilitation unit after 2–4 weeks of rehabilitation (mean length of stay was 18 days), so complete data are only available for the week of admission to the study (week 1), at week 2, and at the 12-week follow-up.

Thirteen of the participants who completed all measures showed improvement in scores over time. Two of the participants (one from the control and one from the intervention group) did not improve. The final median scores for all measures of motor function were higher for the group who received the additional intervention. Data were analysed using Mann–Whitney tests for non-parametric data to compare the two groups. Statistically there was no significant difference between the comparative scores at weeks 1, 2 or 12. However, there was a significant difference in change of scores from week 1 to week 12 for Berg Balance Scale ($P < 0.05$).

Discussion

The findings in this small pilot study indicate that the sample of participants who received extra standing practice in addition to convention physiotherapy achieved higher final median scores in all measures of motor function. However, this difference was not significant and does not support the hypothesis that additional standing practice in the early stages of rehabilitation after stroke increases motor recovery and mobility.

There was a significant difference in the change in one of the measures (Berg Balance score) when the two groups are compared at weeks 1 and 12. This reflects that the group receiving extra intervention started the study with lower scores than the control, and completed the study with higher scores. This may offer some support to the findings of Barreca *et al.*[10] who demonstrated that extra sit-to-stand practice improved function in a group of participants who were slightly longer post stroke. There was no significant difference in changes in Gross Function Tool of the Rivermead Motor Assessment and Trunk Control Test.

Clinical messages

- This study demonstrates that the Gross Functional Tool Section of the Rivermead Motor Assessment, and the Berg Balance Scale are useful measures in assessing the benefit of additional standing practice in people with stroke.
- Fatigue may be a barrier to participation in additional standing practice.

This small pilot has a number of weaknesses, mainly due to the low numbers involved. The mean age of the intervention group was 5.5 years younger than that of the control group. A number of studies have demonstrated a strong relationship between increasing age and poorer outcome[16] so it is possible that the differences that were detected may be a reflection of the bias in the sample.

A further source of bias is the subsequent withdrawal of three participants from the extra intervention group citing fatigue (two of these participants did not complete measurements). Fatigue is commonly reported as a difficulty after stroke,[17] and this suggests that a more intensive therapy programme may not suit all stroke patients. If a larger study of this type were to be conducted, or if more intensive practice is to be utilized in clinical practice, it may be worth considering the value of using a fatigue measure to screen those who may be able to engage with sessions of additional practice. Michael *et al.*[18] used the Fatigue Severity Scale with people after stroke to demonstrate a correlation between fatigue and balance, so this may be an appropriate measure to trial.

Additionally, as the physiotherapists providing the conventional sessions were not blinded to the allocation of participants receiving extra practice, this may be a further source of bias.

In this study both the Berg Balance Scale and the Gross Function Tool of the Rivermead Motor Assessment were responsive to change over the period of rehabilitation, so it would appear to be appropriate to use these measures in a larger study. The Trunk Control Test was a less sensitive measure in this instance, as 50% of the participants achieved the highest score by week 2 of the study. If a larger study were to be considered, Trunk Control Test would probably not be a useful measure to use.

If a larger study were to be designed, power calculations indicate that two groups of 26 participants each would be required to give a power of 80% for detecting a difference of 2 points in the Gross Function Tool of the Rivermead Motor Assessment (change from week 1 to week 12), based on a significance level of 0.05.

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Contributors

RA initiated and designed the study, undertook the analysis and writing up, and is the guarantor for the study. RD was involved in data collection and writing up of the study.

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