

Training unsupported sitting does not improve ability to sit in people with recently acquired paraplegia: a randomised trial

Lisa A Harvey¹, Donna Ristev², Mohammad S Hossain³, Mohammad A Hossain³, Jocelyn L Bowden¹, Claire L Boswell-Ruys⁴, Mohammad M Hossain³ and Marsha Ben²

¹Rehabilitation Studies Unit, University of Sydney, Australia, ²Moorong Spinal Unit, Royal Rehabilitation Centre Sydney, Australia, ³Centre for the Rehabilitation of the Paralyzed, Savar, Bangladesh, ⁴Neuroscience Research Australia, Australia

Question: Do people with recently acquired paraplegia benefit from a six-week motor retraining program aimed at improving their ability to sit unsupported? **Design:** A randomised controlled trial with concealed allocation, assessor blinding, and intention-to-treat analysis. **Participants:** 32 people with recently acquired paraplegia and limited ability to sit unsupported. **Intervention:** All participants undertook standard inpatient rehabilitation over a six-week period. Experimental participants received three additional 30-minute sessions per week of motor retraining directed at improving their ability to sit unsupported. **Outcome measures:** The three primary outcomes were the Maximal Lean Test, Maximal Sideward Reach Test, and the Performance Item of the Canadian Occupational Performance Measure (COPM). The secondary outcomes were the Satisfaction Item of the COPM, Participants' Impressions of Change, Clinicians' Impressions of Change, the T-shirt Test, and the Spinal Cord Injury Falls Concern Scale. **Results:** The mean between-group differences for the Maximal Lean Test, Maximal Sideward Reach Test and the Performance Item of the COPM were -20 mm (95% CI -64 to 24), 5% arm length (95% CI -3 to 13) and 0.5 points (95% CI -0.5 to 1.5), respectively. The secondary outcomes did not differ significantly between groups. **Conclusion:** People with recently acquired paraplegia do not benefit from a six-week motor retraining program directed specifically at improving their ability to sit unsupported. Their ability to sit unsupported does, however, improve over time, suggesting that the practice of activities of daily living has important carry-over effects on unsupported sitting, rendering additional training redundant. **Trial registration:** ACTRN12608000464369. [Harvey LA, Ristev D, Hossain MS, Hossain MA, Bowden JL, Boswell-Ruys CL, Hossain MM, Ben M (2011) Training unsupported sitting does not improve ability to sit in people with recently acquired paraplegia: a randomised trial. *Journal of Physiotherapy* 57: 83-90]

Key words: Spinal cord injuries, Physical therapy, Motor relearning

Introduction

The ability to sit unsupported is important for people with paraplegia because they perform most activities of daily living from a seated position (Anderson 2004). Paralysis of the trunk and lower limbs makes sitting unsupported difficult and, not surprisingly, physiotherapists devote large amounts of therapeutic attention to improving sitting ability. Therapy typically involves exercises and practice of functional activities in a seated position following the principles of motor relearning. For example, a person with complete paraplegia may practise reaching for objects while sitting unsupported over the edge of the bed. Alternatively, a person with incomplete paraplegia may practise lifting, moving, or manipulating objects while trying to maintain an upright seated position. A key aspect of this type of training is repetitive practice combined with clear instructions, well-timed and accurate feedback, and appropriate progression (Carr and Shepherd 2000, Harvey et al 2008).

Despite the time and effort devoted to training unsupported sitting, little is known about its effectiveness. In particular, it is not known whether people with paraplegia intuitively learn strategies to sit unsupported or whether they require specific training in this area. The question is important

because therapists need to ensure that they concentrate on the most important and most effective interventions during rehabilitation. A recent study indicated that people with spinal cord injury receive a mere 33 minutes of active therapy a day during their initial rehabilitation following injury (van Langeveld et al 2010). It is imperative that this time is spent on interventions with proven efficacy, but it is not clear whether training unsupported sitting is good use of therapists' and patients' time.

In a recent clinical trial (Boswell-Ruys et al 2010b), we demonstrated small changes in the ability of people with paraplegia to sit unsupported following an intensive motor training program (mean between-group difference for the Maximal Lean Test was 64 mm, 95% CI 20 to 108). This trial was conducted in people with chronic spinal cord injury (ie, at least one year after injury) when responsiveness to therapy is probably weakest. We were interested in investigating the effects of training unsupported sitting in people with recently acquired paraplegia. Therefore, the question underpinning this study was:

Do people with recently acquired paraplegia benefit from an intensive motor training program directed at improving the ability to sit unsupported?

Method

Design

An assessor-blinded, randomised controlled trial was undertaken, in which participants with recent spinal cord injury were randomised to standard inpatient rehabilitation or to standard inpatient rehabilitation with additional motor retraining directed at improving their ability to sit unsupported. A computer-generated random allocation schedule was compiled before commencement by a person not involved in the recruitment of participants. The randomisation schedules were blocked and stratified by site. Initially, the study was planned for just the Australian site. Therefore, a blocked randomisation schedule for 32 participants was developed. However, when the Bangladesh site entered the study a year later, a second blocked randomisation schedule was set up for 16 participants from the Bangladesh site. Participants' allocations were placed in opaque, sequentially numbered, sealed envelopes that were held offsite by an independent person based in Australia. Once a participant passed the screening process and completed the initial assessment, an envelope was opened and allocation revealed. The participant was considered to have entered the trial at this point.

Participants

Participants were included if they were over 18 years of age, had sustained a complete or incomplete spinal cord injury below T1, had sustained their spinal cord injury less than 6 months prior, and were receiving physiotherapy and occupational therapy as part of a comprehensive in-patient rehabilitation program. Participants were eligible for inclusion only if they had limited ability to sit unsupported as verified by a score of 5/7 or less on the unsupported sitting item of the Clinical Outcomes Variable Scale (Campbell et al 2003). Participants were excluded if they were unlikely to co-operate or had pressure areas necessitating bedrest. Participants were referred to the study by hospital-based therapists.

Intervention

Participants in the experimental group received 30 minutes of task-specific training by a physiotherapist skilled in the management of people with spinal cord injuries, three times a week for six weeks. This intervention was provided in addition to the participants' standard in-patient therapy. This was the most intensive dose of motor training that could be realistically provided within the rehabilitation facilities. The 30 minutes did not include time spent in set up, rest, or conversation. Consequently, each session took between 45 and 60 minutes. A stopwatch was used to ensure that 30 minutes of active therapy was achieved. The training was tailored to each participant's stage of rehabilitation with the emphasis on providing clearly defined goals for each therapy session as well as appropriate and well-timed instructions and feedback. Participants sat in an unsupported position on a physiotherapy bed with hips and knees flexed to 90° and feet supported on the ground. Participants were required to practise repeatedly specifically-designed exercises that involved moving the upper body over and outside the base of support (Figure 1). There were 84 different exercises each with three grades of difficulty (ie, a total of 252 exercises). The 84 exercises were developed as part of a previous trial and developed in consultation with senior spinal cord injury physiotherapists from Sydney (Boswell-Ruys et al 2010b).

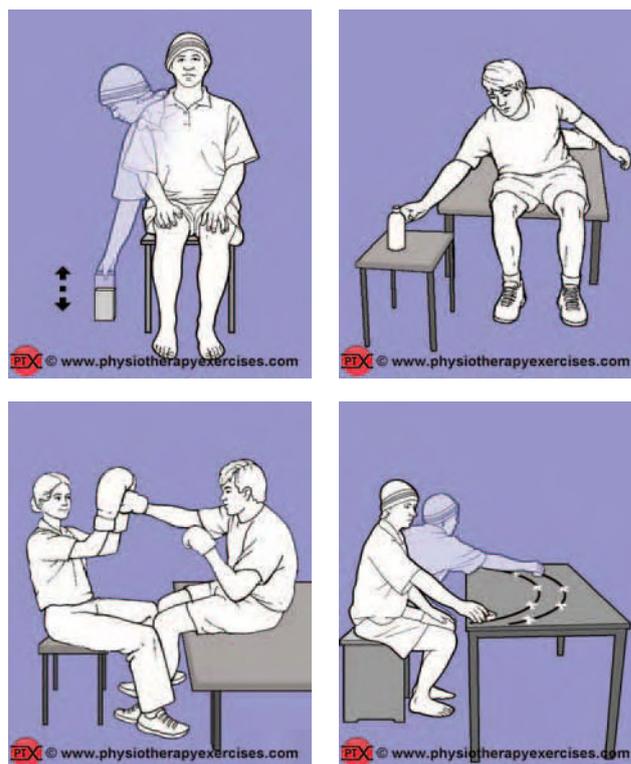


Figure 1. Examples of the types of exercises performed by participants (images courtesy of <http://www.physiotherapyexercises.com>).

Each of the 84 exercises was written on a card and placed in a pack. Participants arbitrarily chose cards from the pack for each session. Details about each participant's exercise program were recorded.

Control participants did not practise any of the 252 exercises. However, all participants continued to receive standard physiotherapy and occupational therapy which included training for transfers, wheelchair skills, dressing and showering. The protocol also dictated that control participants receive three 5-minute sessions per week of training in unsupported sitting. However, this was provided only to the control participants from the Bangladesh site. The control participants from the Australian site did not receive any training in unsupported sitting for the duration of the study.

Outcome measures

All assessments were conducted at the beginning and end of the 6-week study period by one assessor from the Bangladesh site and one of two assessors from the Australian site; all blinded to participants' allocation. Participants were asked not to discuss their training or group allocation with the assessors. The success of blinding was verified at the end of each participant's assessment by asking assessors to reveal whether they had been unblinded.

Three primary outcomes were measured: the Maximal Lean Test (also called the Maximal Balance Range), the Maximal Sideward Reach Test, and the Performance Item of the Canadian Occupational Performance Measure (COPM). Five secondary outcomes were used: the Satisfaction Item of the COPM, the T-shirt Test, Participants' Impressions of Change, Clinicians' Impressions of Change, and Spinal Cord Injury Falls Concern Scale. These outcomes were

selected on the basis of a study comparing the validity and reliability of each test (Boswell-Ruys et al 2010a, Boswell-Ruys et al 2009) and on the basis of the results of a similar clinical trial (Boswell-Ruys et al 2010b).

The Maximal Lean Test assessed participants' ability to lean as far forwards and backwards as possible without falling and without using the hands for support. The Maximal Sideward Reach Test assessed participants' ability to reach in a 45° direction to the right while seated unsupported on a physiotherapy bed (Boswell-Ruys et al 2009). The T-shirt Test measured the time taken for participants to don and doff a T-shirt (Boswell-Ruys et al 2009, Chen et al 2003). The best attempt of two trials was analysed for each outcome. A mean between-group difference equivalent to 20% of mean baseline data was deemed clinically important for the three outcomes prior to the commencement of the study.

The COPM determines participants' perceptions about treatment effectiveness in relation to self-nominated goals (Law et al 1990). The Performance and Satisfaction ratings of the COPM were averaged across the two activities identified as most important to the participant. A mean between-group difference of 2 points was deemed clinically important prior to the commencement of the study as recommended by others (Law et al 2010).

Participants' Impressions of Change were assessed at the end of the 6-week study period by asking both control and experimental participants to rate their global impressions of change in their ability to sit unsupported over the preceding six weeks on a 15-point Likert-style scale, in which -7 indicated 'a very great deal worse', 0 indicated 'no change', and +7 indicated 'a very great deal better' (Barrett et al 2005, Jaeschke et al 1989). Clinicians' Impressions of Change were assessed with the use of video clips (Harvey et al 2011). Short video clips of participants sitting unsupported were taken at the beginning and end of the 6-week study period. The video clips were then shown to two blinded physiotherapists who were asked to rate their global impressions of change in performance of each participant after viewing the first video clip in relation to the second video clip. The therapists used the same 15-point rating scale used by participants. A mean between-group difference of one point was deemed clinically meaningful prior to the commencement of the study for both outcomes as recommended by others (Schneider and Olin 1996).

The Spinal Cord Injury Falls Concern Scale is a standardised questionnaire that asks participants to rate their concern about falling when performing 16 common tasks such as dressing or pushing a wheelchair (Boswell-Ruys et al 2010a). Each task is rated on a 4-point Likert-style scale anchored at one end with 'not at all concerned' and at the other end with 'very concerned'. In addition, experimental participants were asked to rate the 'inconvenience' of the training on a 10-cm visual analogue scale anchored at one end with 'extremely inconvenient' and at the other end with 'not at all inconvenient'.

Data analysis

Power calculations were based on the results of two studies: one a clinical trial (Boswell-Ruys et al 2010b), the other a study of the psychometric properties of the scales used in this study (Boswell-Ruys et al 2009). The current study was, however, powered for only the three primary outcomes

using the best available estimates of standard deviation and where necessary predicted initial scores (ie, an initial score of 250 mm and SD of 50 mm for the Maximal Lean Test, an initial score of 100 and SD of 15 mm for the Maximal Sideward Reach Test, and a SD of 2 points for the COPM). The power calculations assumed a drop-out rate of 5%, a power of 80%, an alpha of 0.05, and a strong correlation (0.8) between initial and final values.

All statistical analyses were performed using the principle of 'intention to treat' although a secondary exploratory analysis was also performed excluding data from participants who completed less than 17 of the 18 training sessions. All data are reported as means (SD) unless otherwise stated. Data for the Maximal Lean Test, Maximal Sideward Reach Test, T-shirt Test, and Spinal Cord Injury Falls Concern Scale were analysed with a factorial analysis of covariance using a linear regression approach. The Performance Item of the COPM, the Satisfaction Item of the COPM, Participants' Impressions of Change, and Clinicians' Impressions of Change data were analysed using the 'cendif' routine in Stata software^a to derive the 95% CIs for median between-group differences. This method does not make assumptions about the distribution of the data. Significance for all tests was set at $p < 0.05$, but all data were interpreted with respect to pre-determined clinically meaningful change.

Results

Flow of participants through the study

Thirty-two people with recently acquired paraplegia were recruited from the Moorong Spinal Cord Injury Unit in Australia ($n = 16$) and the Centre for the Rehabilitation of the Paralyzed in Bangladesh ($n = 16$). The flow of participants through the trial is shown in Figure 2. Outcomes were attained for all variables on all participants with the following two exceptions: data for one participant were missing for Clinicians' Perceptions of Change (due to problems with the video clip) and data for one participant were incomplete for the Maximal Lean Test due to the participant's inability to tolerate the test. For this participant, the backward lean aspect of the measure was recorded but not the forward lean aspect of the measure.

Participant characteristics

The median age and time since injury were 27 years (IQR 24 to 31) and 11 weeks (IQR 8 to 16), respectively. According to the International Standards for Classification of Spinal Cord Injury, participants were categorised as American Spinal Injury Association Impairment Scale (AIS) A ($n = 29$), AIS B ($n = 2$), or AIS C ($n = 1$) with neurological and motor levels ranging from T1 to L1 (see Table 1). The groups were similar at baseline.

Compliance with trial method

Adherence to the study protocol was reasonable. The protocol dictated that participants receive 18 training sessions over six weeks. In reality, they received a median of 18 training sessions (IQR 12 to 18) over 6 weeks (IQR 6 to 7). There were four participants from the Sydney site who received only six (1 participant), 11 (2 participants), or 12 (1 participant) sessions due to poor compliance, and one participant from the Bangladesh site who received only five sessions due to back pain. All three assessors indicated that blinding had been maintained throughout the study.

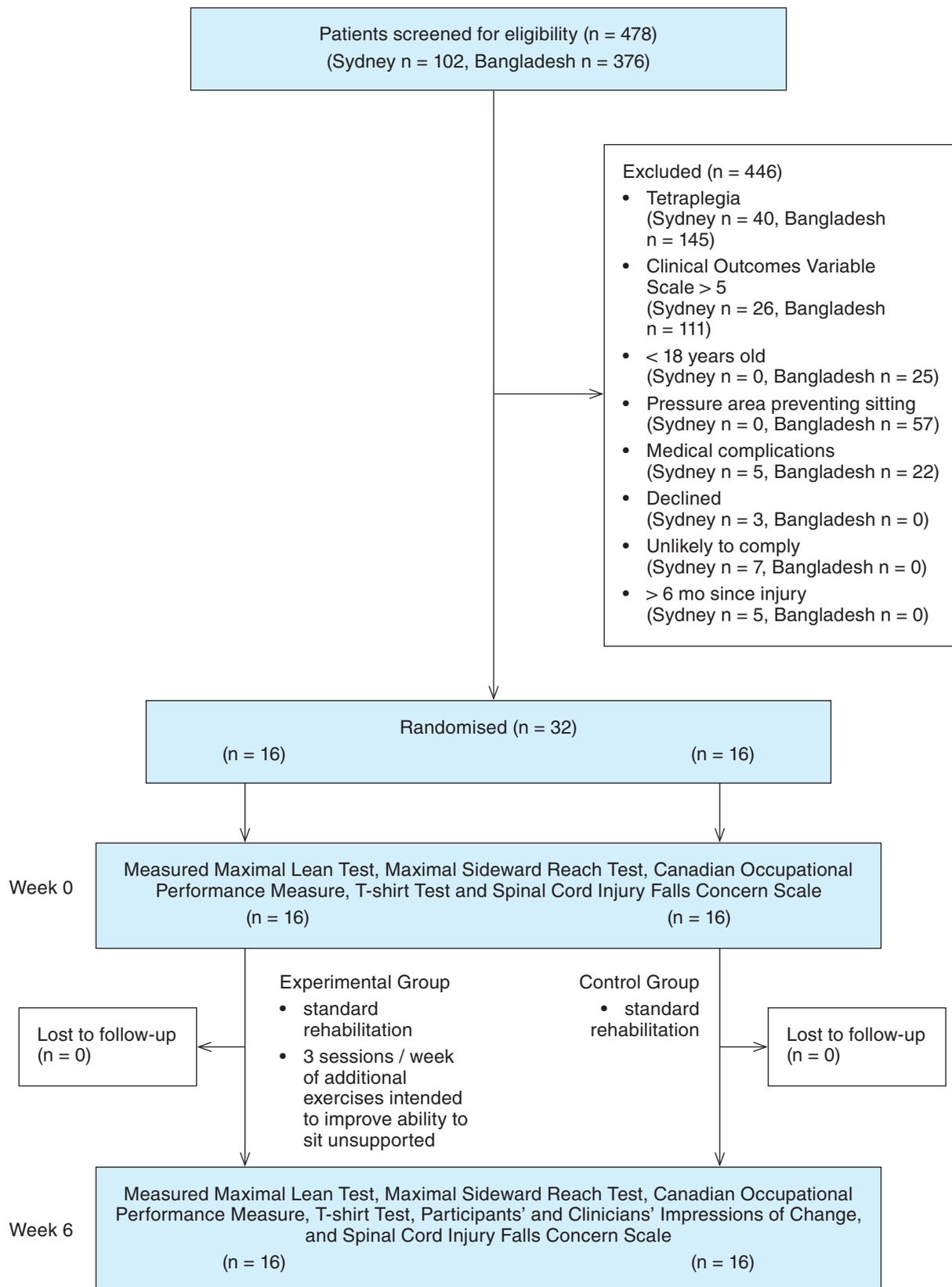


Figure 2. Design and flow of participants through the trial.

Table 1. Characteristics of participants at baseline.

Characteristic	Randomised (n = 32)	
	Exp (n = 16)	Con (n = 16)
Age (yr), median (IQR)	26 (24 to 31)	27 (24 to 31)
Time since injury (wk), median (IQR)	11 (9 to 17)	10 (8 to 14)
Gender (<i>male:female</i>)	14:2	16:0
Motor level, n		
T1 to T4	4	1
T5 to T8	3	4
T9 to L1	9	11
American Spinal Injury Association Impairment Scale, n		
A	16	13
B	0	2
C	0	1
Clinical Outcome Variables Scale score	2 (1 to 2)	2 (1 to 3)

Table 2. The intention-to-treat analysis. Mean (SD) pre and post values and mean between-group difference (95% CI) adjusted for baseline score for Maximal Lean Test, Maximal Sideward Reach Test, T-shirt Test and SCI Falls Concern Scale. Median (interquartile) pre and post values and median between-group difference (95% CI) for COPM Performance, COPM Satisfaction, Participants' Impressions of Change and Clinicians' Impressions of Change. The predetermined minimally worthwhile treatment effects are also indicated. NA indicates not applicable.

	Control group (n = 16)		Experimental group (n = 16)		Between- group difference	Minimally worthwhile treatment effect
	Pre	Post	Pre	Post		
Maximal Lean Test (mm)	125 (55)	206 (58)	111 (47)	177 (73)	-20 (-64 to 24)	24
Maximal Sideward Reach Test (% arm length)	94 (8)	98 (7)	102 (34)	112 (36)	5 (-3 to 13)	20
COPM Performance (points/10)	4.0 (2.3 to 4.8)	7.5 (6.5 to 8.3)	3.5 (2.3 to 4.5)	7.8 (7.3 to 8.5)	0.5 (-0.5 to 1.5)	2
COPM Satisfaction (points/10)	3.5 (3.0 to 4.8)	7.5 (7.0 to 9.0)	5.0 (3.3 to 7.0)	7.5 (7.0 to 8.5)	-1.0 (-2.5 to 0.0)	2
T-shirt Test (sec)	65 (40)	35 (15)	74 (35)	46 (27)	8 (-5 to 20)	14
Participants' Impressions of Change (points/7)	N/A	5.0 (4.0 to 6.0)	N/A	5.5 (5.0 to 6.0)	1.0 (0.0 to 2.0)	1
Clinicians' Impressions of Change (points/7)	N/A	3.0 (2.0 to 3.8)	N/A	3.0 (2.5 to 3.5)	0.0 (-1.0 to 1.0)	1
SCI Falls Concern Scale (points/64)	38 (12)	28 (9)	38 (12)	26 (6)	-2 (-8 to 3)	N/A

Treatment effect

The mean between-group difference for the Maximal Lean Test was -20 mm (95% CI -64 to 24). The mean between-group difference for the Maximal Sideward Reach was 5% of arm length (95% CI -3 to 13). The mean between-group difference for the Performance item of the COPM was 0.5 points (-0.5 to 1.5). Group data for these outcomes are presented in Table 2. Individual data are presented in Table 3 (see eAddenda for Table 3). None of these findings was statistically significant and the upper end of all 95% confidence intervals fell short of the pre-determined

minimally worthwhile treatment effects. The corresponding values for the secondary outcomes are also presented in Table 2. Individual data are presented in Table 3 (see eAddenda for Table 3). The results of the exploratory per-protocol analysis of all outcomes are presented in Table 4. The only notable deleterious effect was an increase in back pain in one participant. The median rating of inconvenience of the intervention provided by experimental participants was 9 (IQR 8 to 9) where 1 was 'extremely inconvenient' and 10 was 'not at all inconvenient'.

Table 4. The per-protocol analysis in which data from the five experimental participants who completed less than the 17/18 training sessions were removed. Mean (SD) pre and post values and mean between-group difference (95% CI) adjusted for baseline score for Maximal Lean Test, Maximal Sideward Reach Test, T-shirt Test and SCI Falls Concern Scale. Median (interquartile) pre and post values and median between-group difference (95% CI) for COPM Performance, COPM Satisfaction, Participants' Impressions of Change, and Clinicians' Impressions of Change. The predetermined minimally worthwhile treatment effects are also indicated.

	Control group (n = 16)		Experimental group (n = 11)		Between- group difference	Minimally worthwhile treatment effect
	Pre	Post	Pre	Post		
Maximal Lean Test (mm)	125 (55)	206 (58)	102 (44)	183 (82)	-14 (-70 to 42)	23
Maximal Sideward Reach Test (% arm length)	94 (8)	98 (7)	98 (14)	106 (15)	5 (-3 to 13)	19
COPM Performance (points/10)	4.0 (2.3 to 4.8)	7.5 (6.5 to 8.3)	3.5 (2.0 to 4.0)	7.5 (6.5 to 9.5)	1.0 (0.0 to 2.0)	2
COPM Satisfaction (points/10)	3.5 (3.0 to 4.8)	7.5 (7.0 to 9.0)	5.0 (3.0 to 6.0)	7.5 (7.0 to 9.0)	-1.0 (-2.5 to 0.5)	2
T-shirt Test (sec)	65 (40)	35 (15)	64 (29)	46 (30)	13 (-4 to 30)	13
Participants' Impressions of Change (points/7)	NA	5.0 (4.0 to 6.0)	NA	6.0 (5.0 to 7.0)	1 (0.0 to 2.0)	1
Clinicians' Impressions of Change (points/7)	N/A	3.0 (2.0 to 3.8)	N/A	3.3 (2.5 to 4.0)	0.5 (-1.0 to 1.5)	1
SCI Falls Concern Scale (points/64)	38 (12)	28 (9)	41 (12)	25 (7)	-4 (-10 to 3)	N/A

Discussion

The results of this study indicate no added benefit from a 6-week training program specifically targeting unsupported sitting. We can be confident that within the limitation of this study, the results are conclusive because the upper end of the 95% CIs from the three primary outcomes falls short of the pre-determined minimally worthwhile treatment effects. These findings are largely consistent when data from the five non-compliant experimental participants are removed although there is less precision and certainty associated with some outcomes. Needless to say, the interpretation of the results relies on what is considered a worthwhile treatment effect. Some may disagree with the values we set *a priori* and believe that any treatment effect is worthwhile regardless of how small it is. This approach ignores the cost of providing interventions as well as the pressing need to ensure that the limited time patients spend in physiotherapy is directed at the most important and effective interventions (Harvey 2011).

The results of this study indicate that both experimental and control participants improved over the 6-week intervention period. These findings are in contrast to those of a similar study we conducted in people with established paraplegia (Boswell-Ruys et al 2010b). In this previous study, experimental participants improved but control participants did not. The parallel improvements in control and experimental participants in the current study is critical to the interpretation of the results and highlights the importance of including control groups in

research investigating treatment effectiveness. Without control groups, one is tempted to merely look at pre to post changes in experimental participants and conclude that the training is highly effective. This logic is clearly flawed. The improvements seen in participants may be due to a number of factors. The most appealing interpretation for the improvements seen in the current study is that standard care provided to all participants improved their ability to sit unsupported rendering the additional therapy provided to experimental participants redundant. Standard care included training for activities of daily living. Participants may have learnt appropriate strategies for sitting as part of the new demands of dressing, showering, and adapting to a largely seated life. Of course, some of the improvements seen in participants may have been due to natural recovery or exposure to the testing protocol. The only way to determine the relative importance of all these factors is through future randomised controlled trials where each factor is examined.

It is possible that the training provided to participants was insufficient and if more intensive training had been provided then a more convincing treatment effect may have been demonstrated. This interpretation is supported by research in other areas of neurology demonstrating the importance of intensive and repetitious practice (Dean et al 1997, Kwakkel 2006, Kwakkel et al 2005, Kwakkel et al 1997). However it is difficult to envisage any rehabilitation facility being able to offer more than what was provided in this trial on a one-to-one basis, especially when one considers that 30 minutes of active practice equated to approximately 45 to 60 minutes of therapist and patient time and that

this time was devoted solely to one motor task. It is also difficult to envisage that participants would tolerate a more intensive training program. We had difficulties getting the full co-operation of some participants. (This was more of a problem at the Australian site than at the Bangladesh site.) Some participants complained that the training was boring and repetitious. We were acutely aware of this potential problem before we started the trial and tried to a guard against this possibility by devising 84 different exercises each with three variations. Yet, regardless, we exhausted the patience of some participants. Perhaps linking training with the playing of computer games might help overcome this issue; however, fundamentally, effective motor retraining requires repetitious practice, and repetitious practice is not well tolerated by everyone.

Perhaps only certain types of people with paraplegia benefit from the type of training provided and if we could identify these patients then we could target therapy appropriately. This may be the case, although the inclusion criteria in this study were already narrow and restricted to people with paraplegia and difficulties sitting. Four hundred and twenty people with recent spinal cord injury had to be screened over a two-year period to attain 32 suitable participants. If only a subgroup of our sample benefit from training, then one has to ask whether it is worth the time, money, and effort required to identify them. Interestingly, although people with incomplete paraplegia were eligible for inclusion, a majority of participants had motor complete lesions. A future study that focuses on people with incomplete lesions may reap different findings although triallists will have difficulties recruiting sufficient participants with incomplete lesions and difficulties sitting.

Some may question the validity of conducting this trial across two spinal cord injury units in such different countries as Australia and Bangladesh. While there are clearly very big differences between Australia and Bangladesh, the two spinal cord injury units provide remarkably similar rehabilitation, albeit tailored to their socioeconomic situations. The inclusion of the two sites therefore broadens the generalisability of the results. The Centre for the Paralyzed in Bangladesh is a 100-bed unit servicing the 1.1 million population of Bangladesh and provides comprehensive rehabilitation. Its services have been developed over 30 years with international support. Physiotherapy staff from the Australian and Bangladesh sites were highly experienced in the rehabilitation of people with spinal cord injury. Importantly, both sites were subjected to rigorous quality checks and all staff involved in the trial were trained. This included a 3-day training program for the Bangladesh site by the principal investigator, and a 4-week visit by the principal investigator of the Bangladesh site to the Australian site. In addition, we guarded against biasing by stratifying by site and entering site as a covariate in the analysis. Interestingly, site had no significant effect on outcome. This was further explored with *post-hoc* analyses indicating very similar improvements in all participants' ability to sit unsupported over the 6-week study period irrespective of site. That is, the improvements in the Australian and Bangladesh participants were comparable.

In some respects the results of this trial are disappointing because they do not support a widely administered approach to training unsupported sitting. However, by not spending time on training unsupported sitting, therapists and patients

can concentrate on practice of functional activities. Patients probably learn appropriate strategies to sit while mastering these activities and adjusting to a largely seated life, thus rendering additional training for unsupported sitting redundant. ■

Footnote: ^aStata v11, Statacorp, TX, USA.

eAddenda: Table 3 available at jop.physiotherapy.asn.au

Ethics: The study was approved by the ethics committees of the Northern Sydney Area Health Service and Royal Rehabilitation Centre, Sydney Australia. We certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed. All participants gave written informed consent before data collection began.

Competing interests: None declared.

Support: The Rehabilitation and Disability Foundation.

Acknowledgements: We acknowledge the assistance of Vivian Lau, Fatema Akhter, Corny Marina Momen, Paresh Chakma, and all the patients and staff of the Moorong Spinal Unit, Australia, and Centre for Rehabilitation of the Paralyzed, Bangladesh. We also thank Joanne Glinsky and Josh Simmons for rating the videos.

Correspondence: A/Professor Lisa Harvey, Rehabilitation Studies Unit, Royal Rehabilitation Centre Sydney, P.O. Box 6, Ryde, NSW, 1680, Australia. Email: l.harvey@usyd.edu.au.

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Submitting randomised trials to *Journal of Physiotherapy*

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