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ORIGINAL ARTICLE

Training unsupported sitting in people with chronic spinal cord injuries: a randomized controlled trial

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Study design: Randomized, assessor-blinded trial.
Objectives: To evaluate the effectiveness of a 6-week task-specific training programme on the abilities of people with chronic spinal cord injuries to sit unsupported.
Setting: NSW, Australia.
Methods: Thirty adults with spinal cord injuries of at least 1-year duration were recruited. Participants in the training group ($n=15$) performed up to 1 h of task-specific training three times a week for 6 weeks. Participants in the control group ($n=15$) did not receive any training or additional therapy. Primary outcome measures were the Canadian Occupational Performance Measure (COPM), and tests of Upper Body Sway, Maximal Balance Range and donning and doffing a T-shirt (the T-shirt test).
Results: The between-group mean difference (95% confidence interval) for the maximal balance range was 64 mm (95% confidence interval 20 to 108 mm; $P=0.006$). There were no significant between-group mean differences for the COPM and the Upper Body Sway and T-shirt tests.
Conclusions: This trial shows initial support for intensive task-specific training for improving the abilities of people with chronic spinal cord injuries to sit unsupported, although the real-world implications of the observed treatment effects are yet to be determined.
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Keywords: spinal cord injury; sitting; task-specific training; balance; rehabilitation

Introduction

The ability to sit unsupported is important for people with spinal cord injuries (SCIs) as many activities of daily living are performed from this position. For example, people often sit on the front lip of the wheelchair or commode, or over the edge of the bed to perform specific activities, such as reaching, dressing or transferring. Extensive paralysis of the trunk muscles renders sitting unsupported difficult and requires the use of non-paralysed muscles to maintain the centre of mass over the base of support.[1–3]

It is widely believed that intensive and appropriate therapy can improve patients' abilities to sit unsupported. The most commonly used therapy is task-specific training,[4,5] involving intensive and repetitious practise of purposeful activities in an unsupported sitting position. It is currently unclear whether this type of training is effective, or even whether it is possible to improve the abilities of people with SCI to sit unsupported. The aim of this trial was to determine the effectiveness of a task-specific training programme directed at improving the abilities of people with SCI to sit unsupported.

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Methods

Participants

Thirty people with SCI living in the community were recruited. Participants were included if they were over 18 years of age, had an SCI for at least 1 year, were able to sit out of bed for at least 2 h without undue pain or muscle spasm, had a motor level of between T1 and T12 and a motor score of 5/25 or less in both lower limbs according to the American Spinal Injury Association (ASIA) international standards for neurological classification of SCI.[6] Informed consent was gained from all the participants. The trial was registered with the Australian New Zealand Clinical Trials Registry before commencement (reference number: ACTRN12606000415505). We certify that all applicable institutional and governmental regulations concerning

the ethical use of human volunteers were followed during this research.

Design

An assessor-blinded randomized controlled trial was undertaken. A computer-generated random allocation schedule was created by a person not otherwise involved in the trial. To ensure concealment, the allocations were placed in numbered, sealed, opaque envelopes and kept off-site throughout the trial. At completion of each participant's initial assessment, a phone call was placed to an independent person who opened the numbered envelopes sequentially to reveal the participant's group allocation. A participant was considered to have entered the trial at this point.

Intervention

Participants in the training group received 1 h of task-specific training by one of three experienced physiotherapists three times a week for 6 weeks. Participants performed all training in an unsupported sitting position with hips and knees flexed to $\sim 90^{\circ}$ and feet resting on the floor. No back, arm or pelvic support was provided, although therapists stood close by, ready to assist if needed. Control group participants did not receive any intervention for the 6-week trial period. Participants in both groups were asked not to commence any new activities or modify existing exercise programmes.

The training programme was developed in consultation with senior therapists who had SCI expertise. Together they identified a battery of 84 commonly used training exercises.

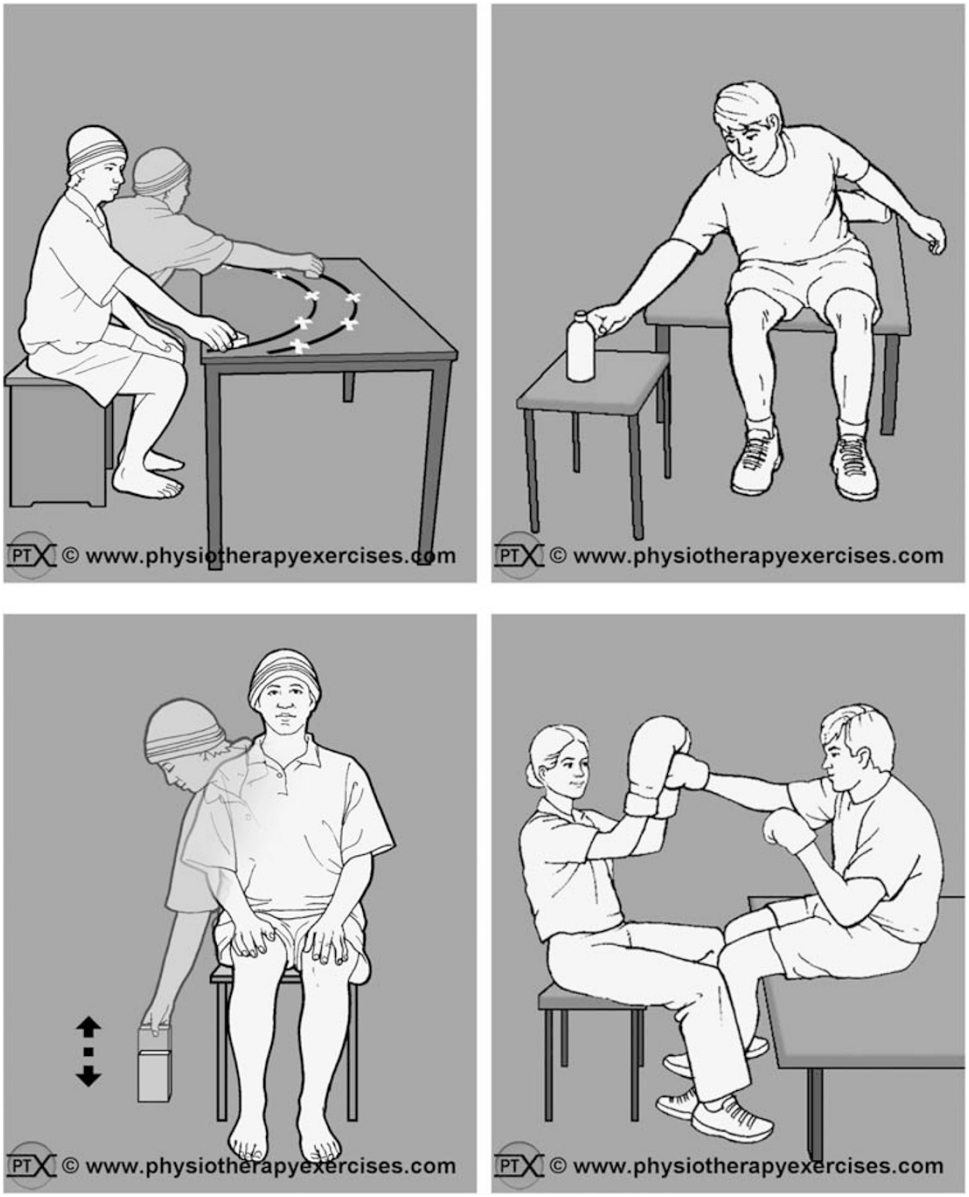

Figure 1 Examples of the types of exercises performed by the participants (images copied with permission from http://www.physiotherapyexercises.com).

The exercises included tasks that involved moving the upper body over and outside the base of support (Figure 1). Each exercise had three variations: one each for people with limited, average and very good ability to sit unsupported. Each of the 84 exercises was written on a card, numbered and placed in a pack. Participants arbitrarily chose 12 cards from the pack each session. This was carried out without replacement so that participants cycled through all exercises approximately three times during the 6-week training period. A stopwatch was used to record the actual time spent performing the exercises, as opposed to the time spent on conversing or setting up. Details about each participant's exercise programme were recorded.

Outcome measures

Outcome measures were obtained at the beginning and end of the 6-week training period by blinded assessors. Participants were asked not to discuss their training or group allocation with the assessors. The success of blinding was recorded after each participant's final assessment.

Primary outcomes

There were four primary outcome measures: the performance component of the Canadian Occupational Performance Measure (COPM), the Upper Body Sway test (total length component), the Maximal Balance Range test and the T-shirt test. These tests of unsupported sitting have proven reliability and validity in SCI.[7]

The performance component of the COPM measured the participants' self-rated perceptions about their abilities to complete self-selected activities.[8] The participants identified three purposeful activities that they had difficulties in performing because of poor sitting ability. The participants rated their current ability to perform each activity (COPM performance component) on a one-to-ten scale. At the same time, they rated each activity for importance (COPM importance component) and level of satisfaction (COPM satisfaction component); these latter two measures were secondary outcome measures. It was decided *a priori* that only those activities that scored >5 on the importance component would be analysed.

The Upper Body Sway test measured the participants' abilities to sit unsupported and remain as still as possible for 30 s.[7] The test used the Lord swaymeter,[9] which inscribed the sway path of the participants' bodies. The total length of the path (number of square mm traversed) was recorded. The test was performed three times and the mean derived.

The Maximal Balance Range test assessed the participants' abilities to lean as far forward and backward as possible without falling.[7] Maximal anterior–posterior distance traversed normalized to trunk length (mm) was recorded with the Lord swaymeter. The better of two attempts was analysed.

The T-shirt test measured the time taken by the participants to don and then doff a T-shirt.[7] The test was repeated twice with the mean total time (s) calculated.

Secondary outcomes

There were eleven secondary outcome measures comprising six physical tests and five self-reported tests. The physical tests of unsupported sitting included the Alternating Reach test (supported and unsupported), Seated Reach test 45° to the right, Coordinated Stability test (version A) and Upper Body Sway test (lateral and antero-posterior components).[7]

The self-reported tests included the importance and satisfaction components of the COPM (described above), an adapted Falls Efficacy Scale-International (FES-I), and a self-rated falls and balance questionnaire. The FES-I measured people's perceived fears of falling.[10] The scale was adapted with specific wording for people in wheelchairs and consisted of 16 items related to activities of daily living. It has been named the Spinal Cord Injury-Falls Efficacy Scale (SCI-FES). The participants were asked how concerned they were about falling when performing each activity. Responses were rated on a 4-point scale, in which a score of 1 reflected 'not at all concerned' and a score of 4 reflected 'very concerned'. Scores on each item were summed. The self-rated falls and balance questionnaire consisted of three questions about the ability to sit and fear of falling. The participants responded to each question on a 5-point scale. In addition, the participants recorded the number of falls they had experienced in the previous 6-weeks. In addition, participants in the training group were asked at the end of the trial to rate the difficulty and usefulness of the training exercises on 5- and 4-point Likert scales, respectively.

Sample size

There were insufficient data to accurately perform power calculations. The best available evidence indicated that a sample size of 30 would be sufficient to provide an 80% probability of detecting a clinically meaningful between-group difference on each primary outcome with an alpha of 0.05. The clinically meaningful between-group differences were set *a priori* at 10% of mean initial values for all outcomes except the COPM. This was set at two points as recommended by others (20% of the maximal attainable score).[11] The likely standard deviations (s.d.) for each outcome were derived from preliminary data collected on 30 participants.[7]

Data analysis

Data were analysed using analysis of covariance with a linear regression approach.[12] ASIA sensory scores were used as a covariate rather than ASIA motor scores because they provide a more sensitive indication of trunk muscle paralysis. The treatment effect size was reflected by the between-group mean difference and corresponding 95% confidence intervals (CIs). The participants' data were analysed in the group to which they were allocated in accordance with the principles of intention-to-treat.[13] An alpha level of <0.05 was considered significant.

Results

The participants' characteristics were similar at initial assessment (Table 1). No participant withdrew from the trial

and all outcome measures were obtained for all participants. The trial protocol dictated that the participants received 18 training sessions over 6 weeks, however, two participants received less than this. One received 11 sessions over 7 weeks because of a sacral pressure area (unrelated to training). The other was non-compliant and received 15 training sessions over 7 weeks. In all, the mean number of training sessions received by the participants was 16 (s.d. = 2) over 6 weeks with a mean of 52 min (s.d. = 8) devoted to actual training per session. The mean number of exercises performed each session was nine (s.d. = 2). Forty per cent of exercises were performed at a basic level, 46% at an intermediate level and 14% at an advanced level. Participants felt that the exercises were of 'average difficulty' and 'moderately useful' in improving unsupported sitting. No adverse effects were reported.

Table 1 Characteristics of participants in the control and training groups at the commencement of the trial

Characteristics	*Control group (n = 15)*	*Training group (n = 15)*
Age in years	48 (14)	42 (11)
Years since injury	19 (13)	10 (10)
Gender ratio male:female (%)	12:3 (80:20)	13:2 (87:13)
ASIA motor score	51 (1)	50 (1)
ASIA sensory score	129 (42)	105 (28)
ASIA classification ratio A:B:C (%)	12:3:0 (80:20:0)	13:2:0 (87:13:0)

Abbreviation: ASIA, American Spinal Injury Association.
All data expressed as mean (s.d.) unless indicated.

Primary outcomes

Initial and final data for both groups and the between-group mean differences (95% CI) are presented in Table 2. On average, there were improvements in all primary outcome measures for both control and experimental participants, although, on average, the improvements were greater for the training participants. The between-group mean differences for the COPM and the Upper Body Sway, Maximal Balance Range and T-shirt tests were 1.0 point (95% CI, −0.1 to 2.1; $P = 0.148$), 39 mm (95% CI, −65 to 143; $P = 0.458$), 64 mm (95% CI, 20–108; $P = 0.006$), and 3.7 s (95% CI, −2.0 to 9.4; $P = 0.205$), respectively.

Secondary outcomes

On average, participants in the training and control groups improved on all secondary outcome measures. The between-group mean differences for the unsupported Alternating Reach was 1.7 s (95% CI, 0.6–2.7; $P = 0.003$) and for the Seated Reach distance 45° to the right tests was 8% (95% CI, 3–13; $P = 0.006$). Results for the remainder of the secondary outcomes are presented in Table 2.

Discussion

The purpose of this trial was to determine the effectiveness of a 6-week training programme on the abilities of people with chronic SCI to sit unsupported. The training programme used the principles of task-specific training in which individuals repeatedly practised purposeful activities while

Table 2 Mean (s.d.) initial and final scores for all outcomes in both control and training groups and their corresponding between-group mean difference (95% confidence interval)

Outcome	*Control*		*Training*		*Between-group mean difference*	*Minimally worthwhile treatment effect*
	Initial	*Final*	*Initial*	*Final*		
Primary measure						
COPM performance (score/10)	6 (2)	7 (1)	5 (2)	7 (2)	1.0 (−0.1 to 2.1)	2.0
Upper body sway total length (mm)[a]	113 (109)	73 (61)	174 (215)	96 (69)	39 (−65 to 143)	14
Maximal balance range (mm)	301 (168)	283 (165)	201 (75)	247 (106)	64 (20 to 108)[b]	25
T-shirt (s)[a]	18 (12)	17 (16)	20 (12)	15 (9)	3.7 (−2.0 to 9.4)	1.9
Secondary measure						
Alternating reach unsupported (s)[a]	4.9 (1.2)	4.5 (1.6)	6.1 (1.7)	4.1 (1.3)	1.7 (0.6–2.7)[b]	0.6
Alternating reach supported (s)[a]	5.5 (1.2)	4.3 (1.0)	5.5 (1.6)	4.1 (0.9)	0.2 (−0.6 to 0.9)	0.5
Seated reach distance 45° to the right (% arms length)	102 (17)	102 (16)	96 (9)	104 (14)	8 (3–13)[b]	10
Coordinated stability (error score)[a]	25 (21)	22 (19)	48 (38)	30 (26)	15 (−5 to 34)	3.6
Upper body sway lateral (mm)[a]	16 (11)	16 (9)	21 (15)	16 (7)	4 (−4 to 12)	2
Upper body sway AP (mm)[a]	22 (16)	18 (11)	25 (18)	22 (11)	−1 (−11 to 9)	2
SCI–FES (score/64)[a]	29 (11)	27 (9)	27 (13)	25 (7)	0.3 (−4.6 to 5.2)	2.8
Self-rated falls and balance questionnaire (score/15)[a]	7 (3)	5 (2)	8 (2)	5 (3)	0.6 (−2.2 to 2.3)	0.8
Number of falls in previous 6 weeks[a]	3 (10)	1 (3)	1 (1)	0 (1)	−1.2 (−5.1 to 2.7)	0.4
COPM importance (score/10)	9 (1)	8 (1)	8 (1)	9 (1)	0.6 (−0.2 to 1.4)	2.0
COPM satisfaction (score/10)	6 (2)	7 (2)	5 (2)	6 (2)	0.8 (−1.0 to 2.6)	2.0

Abbreviation: COPM, Canadian Occupational Performance Measure; SCI–FES, Spinal Cord Injury–Falls Efficacy Scale.
The minimally worthwhile treatment effect for each outcome is also indicated as articulated before the commencement of the trial.
[a]A low score indicates a better outcome. In addition, for these measures the signs have been reversed for the between-group mean differences to indicate either a positive or negative treatment effect.
[b]Indicates significance at the level of $P < 0.05$.

sitting without support. Until now, this widely used training strategy has not been evaluated within a clinical trial in SCI. Results provide initial support for this training approach in people with chronic SCI, although there is uncertainty around some of the estimates of treatment effectiveness, and it is unclear whether the size of some of the treatment effects would be considered worthwhile (Table 2).

The results of this trial only reflect the response of people with chronic SCI to the training intervention. There may have been a more convincing treatment effect had people with recent SCI been included. Inclusion was restricted to people with chronic SCI to reduce data variability and increase statistical power. Poor statistical power resulting in inconclusive findings is a common problem for clinical trials in SCI,[14] particularly those involving people with recent SCI and neurological improvement.

Despite using a relatively homogeneous participant group, there was still considerable data variability, reflected in the wide 95% CI associated with the between-group mean differences. For example, the 95% CI of the between-group mean differences for the Maximal Balance Range test was 20–108 mm. This variability is most likely due to differences in the way participants responded to training, with certain subgroups responding to the intervention better than others. The types of factors likely to influence the response of participants to training include initial sitting ability, time since injury, neurological level and degree of impairment. *Post-hoc* subgroup analysis was not undertaken to explore these issues because of small sample size. However, this warrants future investigation.

Some of the outcome measures had floor and/or ceiling effects that might have masked treatment effects. For instance, some participants performed the T-shirt test in <10 s at the beginning of the trial leaving little room for improvement. Future trials could overcome these problems by refining the outcome measures or further restricting the inclusion criteria.

The COPM outcome reflects the participants' perceptions about their improved abilities to perform activities important to them. Participants did not perceive any significant change in performance of their nominated activities on the COPM. However, this did not correspond with the participants' responses after training when they consistently reported an improved ability to sit unsupported. In some respects, these types of outcomes are the most meaningful. However, they need to be interpreted with caution because participants were not blinded and positive responses may partly reflect their expectations of treatment effectiveness.

Improvements occurred in both training and control groups over the 6-week trial period. Improvement in the control group may have been due to various factors, but was most likely due to repeated exposure to the assessments. These results highlight the importance of restricting conclusions to between-group differences, even in trials using people with apparently stable and chronic SCI.

The underlying mechanisms explaining the participants' improved abilities to sit unsupported are unclear. The most likely explanation is that participants learnt new 'compensatory' strategies to effectively position their centre of mass over their base of support. One strategy the participants may have learnt was to move their non-paralysed arms and heads in subtle (or even not so subtle) ways.[1,15] Alternatively, the training programme may have induced changes in the sensorimotor pathways, which in turn improved the strength and control of trunk muscles. This may or may not have been accompanied by changes in the spinal cord or brain. Such changes have been reported to occur following upper limb[16] and treadmill training[17,18] and are commonly cited as evidence of neural plasticity after SCI. However, activity-dependent plasticity needs to be considered in the context that a change in performance of any motor task is evidence of the underlying changes in neural networks whether it is in people with SCI or in highly trained able-bodied athletes.[19,20] That is, neural plasticity underlies skill acquisition whether the spinal cord is or is not damaged.

The results of this trial provide preliminary support for the use of task-specific training of unsupported sitting in people with chronic SCI. However, the clinical and real-life implications of the observed treatment effects are yet to be clarified. Future trials could also be directed at identifying the types of patients who are most likely to benefit from this type of training and the optimal length and duration of training.

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