

ORIGINAL ARTICLE

Does regular standing improve bowel function in people with spinal cord injury? A randomised crossover trial

S Kwok^{1,2}, L Harvey^{1,2}, J Glinsky¹, JL Bowden¹, M Coggrave^{3,4} and D Tussler³**Study Design:** A randomised crossover trial.**Objectives:** To determine the effects of a 6-week standing programme on bowel function in people with spinal cord injury.**Setting:** Community, Australia and the United Kingdom.**Methods:** Twenty community-dwelling people with motor complete spinal cord injury above T8 participated in a 16-week trial. The trial consisted of a 6-week stand phase and a 6-week no-stand phase separated by a 4-week washout period. Participants were randomised to one of two treatment sequences. Participants allocated to the Treatment First group stood on a tilt table for 30 min per session, five times per week for 6 weeks and then did not stand for the next 10 weeks. Participants allocated to the Control First group did the opposite: they did not stand for 10 weeks and then stood for 6 weeks. Participants in both groups received routine bowel care throughout the 16-week trial. Assessments occurred at weeks 0, 7, 10 and 17 corresponding with pre and post stand and no-stand phases. The primary outcome was Time to First Stool. There were seven secondary outcomes reflecting other aspects of bowel function and spasticity.**Results:** There were three dropouts leaving complete data sets on 17 participants. The mean (95% confidence interval) between-intervention difference for Time to First Stool was 0 min (−7 to 7) indicating no effect of regular standing on Time to First Stool.**Conclusion:** Regular standing does not reduce Time to First Stool. Further trials are required to test the veracity of some commonly held assumptions about the benefits of regular standing for bowel function.*Spinal Cord* (2015) **53**, 36–41; doi:10.1038/sc.2014.189; published online 4 November 2014

INTRODUCTION

Neurogenic bowel dysfunction is common following spinal cord injury (SCI)¹ and often associated with constipation and faecal incontinence. The extent of dysfunction is primarily determined by the completeness and level of the lesion.² Bowel dysfunction is an important problem for people with SCI and can adversely affect physical, social and psychological wellbeing.^{1,3} It is therefore appropriate that attention be directed at determining effective interventions for improving bowel function.

Regular standing has been advocated for a long time as an effective way to improve bowel function.^{4–8} Partly for this reason, some people with extensive lower limb paralysis stand on a regular basis throughout their lives⁵ with the use of tilt tables, standing frames, standing wheelchairs, orthoses or other devices. However, there is little empirical evidence to indicate that regular standing improves bowel function. Two recent systematic reviews investigating management strategies for neurogenic bowel dysfunction failed to identify any randomised controlled trials which had examined this issue.^{9,10} Instead, claims about the effectiveness of regular standing on bowel function are based on survey reports, single case studies and anecdotal claims passed down through the years.^{4–8}

Standing is not only advocated because of its possible therapeutic effects on bowel function but also for other reasons. For example, it is

claimed that regular standing improves circulation,⁵ skin integrity,⁵ sleep,⁵ joint range of motion,^{4,6} digestion,⁵ bone mineral density¹¹ and bladder function.^{4–6} It is also believed to reduce pain and fatigue.⁵ All of these beliefs are plausible but none are supported by high-quality evidence. Of interest to this trial is not only the claim that regular standing improves bowel function but also that it reduces spasticity.^{4–6,8,12–14} It is believed that the stretch associated with standing dampens the reflex arc. There is some interim evidence to support this belief particularly from studies showing an immediate decrease in spasticity with one-off stretches. However, there is no high-quality trial demonstrating lasting effects of standing on spasticity.^{4–6,8,12–14}

It is important to clarify the therapeutic effects of standing because it is a time consuming and expensive intervention when continued on a regular basis over the course of an individual's life. The cost is not only associated with providing people with standing equipment, but more notably providing people with access to carers who can help them use the equipment. This trial did not investigate all the claimed therapeutic benefits of standing, but rather focused on the effects of standing on bowel function and spasticity. Therefore, the primary aim of this trial was to determine the effects of a 6-week programme of standing on Time to First Stool in people with SCI. The secondary aims were to determine the effects of standing on duration of bowel

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care and participants' perception of bowel dysfunction, constipation, incontinence and spasticity.

PATIENTS AND METHODS

A single-blind randomised crossover trial was conducted in Australia and the United Kingdom. The first and last participants were randomised on December 2011 and January 2014, respectively. The Australian participants stood in their homes and the UK participant stood in the physiotherapy department of a hospital. All assessments were conducted in participants' homes. A trial protocol was written prior to commencing the trial and nothing changed over the course of the trial including outcomes. The trial was registered with the Australian New Zealand Clinical Trials Registry (Ref no. ACTRN1261200003875). The registration does not include one of the secondary outcomes. This was an error. The omitted secondary outcome was part of the original protocol. The registration also did not acknowledge the second site in the United Kingdom which was added after registration. We certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed.

Participants

Twenty wheelchair-dependant people with SCI were recruited from a community-based sample of convenience and invited to participate in the trial. Participants were included if they were more than 18 years of age, had a traumatic or non-traumatic SCI with an American Spinal Injury Association Impairment Scale (AIS) of A or B, had a neurological level above T8, had sustained the SCI more than 1 year prior, had a stable bowel regime that was unlikely to change in the near future, were medically stable and had access to carer support to assist with transfers on and off the tilt table if necessary. Participants were excluded if they were pregnant, had a current or past history of bowel disease, had surgery of the bowel, had a stoma, were unwilling to comply with the standing regime, did not speak English or were already standing or walking on a regular basis (unless they were willing to stop standing for 2 months prior to the commencement of the trial). Those with a current or past history of osteoporosis and/or osteoporotic fracture(s) were also excluded unless clearance was obtained from a medical officer.

A computer-generated blocked random allocation schedule was compiled prior to commencement by a person not involved in the recruitment of participants. Each participant was randomly allocated to one of the two treatment sequences. Participants' allocations were placed in opaque, sequentially numbered and sealed envelopes which were held off-site by an independent person. Once a participant passed the screening process and completed the initial assessments, an envelope was opened and allocation revealed. The participant was considered to have entered the trial at this point.

Intervention

The trial was 16-weeks long with a 6-week stand phase and a 6-week no-stand phase separated by a 4-week washout period. Participants allocated to the Treatment First group stood 5 days a week for the first 6 weeks and participants allocated to the Control First group did the same for the last 6 weeks. All standing was done on a tilt table for 30 min with participants standing as upright as possible. All participants were assisted on and off the tilt table by either paid staff or family members. Compliance was self-reported in diaries. Participants did not stand for the 6 weeks during the no-stand phase. Participants continued their regular bowel routines throughout the trial.

Assessment

All assessments were conducted at the beginning and end of the stand and no-stand phases, at weeks 0, 7, 10 and 17. The primary outcome was Time to First Stool (assessor determined).¹⁵ The secondary outcomes were Time to Complete Bowel Care (assessor determined),¹⁵ Time to First Stool (self report),¹⁵ Time to Complete Bowel Care (self report)¹⁵ and four self-report assessments including the Neurogenic Bowel Dysfunction Score,¹⁶ Cleveland Clinic Constipation Score,¹⁷ St Mark's Incontinence Score¹⁸ and the Spinal Cord Injury Spasticity Evaluation tool.¹⁹ The Time to First Stool (assessor determined) and Time to Complete Bowel Care (assessor determined) were measured twice by a blinded assessor on 2 days in close succession at the

beginning and end of the stand and no-stand phases. The self-report assessments were also administered by a blinded assessor but only once at the beginning and end of each phase. The Time to First Stool (self report)¹⁵ and Time to Complete Bowel Care (self report) were determined by asking participants to record the times to first stool and to complete bowel care each day in diaries over the last 2 weeks of the stand and no-stand phases.¹⁵ In addition, participants were asked open-ended questions at the end of the stand phase about any perceived beneficial or deleterious effects of standing. Bowel regimes during all assessments and throughout the duration of the trial were carried out in accordance with the participants' usual routines and sometimes involved participants' carers.

The details of the outcome measures are as follows:

*Time to First Stool (assessor determined).*¹⁵ This outcome reflects the time from commencement of bowel regime to first stool. Commencement was defined by when the participant or participant's carer inserted rectal medication or any form of rectal stimulation. Time was recorded with a stopwatch by a blinded assessor. The mean time from the two assessments for each participant was derived and used for all analyses.

*Time to Complete Bowel Care (assessor determined).*¹⁵ This outcome reflects the time from commencement of bowel regime to completion of bowel regime. The mean time from the two assessments for each participant was derived and used for all analyses.

*Time to First Stool (self report).*¹⁵ This outcome was timed and recorded in diaries by participants and their carers on each bowel-care day over the last 2 weeks of each phase. The median time for each participant was derived and used for all analyses.

*Time to Complete Bowel Care (self report).*¹⁵ This outcome was also timed and recorded in diaries by participants and their carers on each bowel-care day over the last 2 weeks of each phase. The median time for each participant was derived and used for all analyses.

*Neurogenic Bowel Dysfunction (NBD) Score.*¹⁶ The NBD Score is based on a validated 10-item questionnaire about colorectal and anal dysfunction in people with SCI. The total score ranges from 0 (very minor neurogenic bowel dysfunction) to 47 (severe neurogenic bowel dysfunction).

*Cleveland Clinic Constipation Score.*¹⁷ The Cleveland Clinic Constipation Score is based on a validated eight-item questionnaire about constipation. The total score ranges from 0 (normal) to 30 (severe constipation).

*St Mark's Incontinence Score.*¹⁸ The St Mark's Incontinence Score is a self-report questionnaire which captures three domains of faecal incontinence. The total score ranges from 0 (perfect continence) to 24 (total incontinence).

*Spinal Cord Injury Spasticity Evaluation Tool (SCI-SET).*¹⁹ The SCI-SET is a validated 7-day recall self-report questionnaire of the impact of spasticity on the daily life in people with SCI, taking into account the problematic and useful effects of spasticity. It contains 35 items with each item's score ranging from -3 (extremely problematic) to +3 (extremely helpful). The tallied score ranges from -3.00 to +3.00 and is derived by summing the responses from all applicable items and dividing the sum by the number of applicable items.

Statistical analysis

A power calculation indicated that a sample size of 20 would provide a 95% probability of detecting a mean between-group difference of 10 min for the primary outcome: Time to First Stool. This 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 and was based on an estimated Time to First Stool of 30 min and s.d. of 25 min.²⁰

The difference between post and pre-data for each phase were compared using paired *t*-tests to determine differences between the stand and no-stand phases. The analysis did not address the possibility of an order or phase effect as any potential for an order effect was accounted for by the blocked randomisation schedule and any potential for a phase effect was accounted for by the 4-week-washout period. This approach is recommended by others for trials of this size.²¹ All data were analysed by 'intention-to-treat'.²² An unplanned interim analysis was performed after 15 participants because the lead author (SK) was conducting the trial as part of a postgraduate qualification and needed to submit a thesis with an analysis of data collected to date. However, there was never any intention of stopping the trial at this stage.

RESULTS

Flow of participants through the study

Twenty community-dwelling people with SCI above T8 were recruited in Sydney, Australia ($n = 19$) and the United Kingdom ($n = 1$). The flow of participants through the trial is shown in Figure 1. Three participants withdrew from the study due to personal and medical reasons; one at week 1, one at week 7 and one at week 8. One participant was from the Treatment First group and the other two were from the Control First group. The data from these three participants were excluded from all analyses. In addition, one participant from the Treatment First group had missing data at week 10 (pre no-stand phase) due to medical issues. Therefore, the participant's pre-stand data were imputed. Data were also missing for Time to First Stool (self report) and Time to Complete Bowel Care (self report) for three participants. None of the First Stool (self report) and Time to Complete Bowel Care (self report) data for these three participants were included in the analyses.

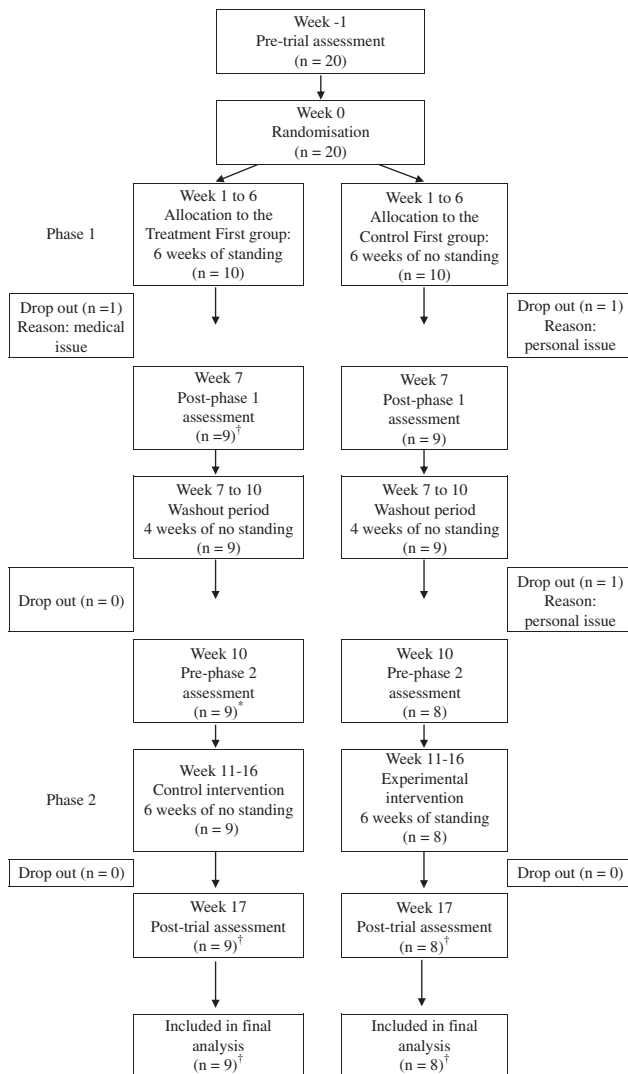


Figure 1 Flow of participants through the trial. *Data were missing for one participant in the Treatment First group. The participant's pre-stand phase were imputed. †Data from three participants were missing for Time to First Stool (self report) and Time to Complete Bowel Care (self report). No data for these two variables were included in the analyses for these participants.

Participant characteristics

The median (interquartile range) age and time since injury were 46 years (40–51) and 6 years (4–19), respectively. Participants had AIS A ($n = 13$) or AIS B ($n = 7$) lesions with neurological levels ranging from C2 to T1 and motor levels ranging from C5 to T7 as defined by the International Standards for Neurological Classification of Spinal Cord Injury (see Table 1). The groups were similar at baseline for most key prognostic factors except time since injury. The characteristics of the three participants who withdrew from the study were similar to the characteristics of the whole group. For example, the ages were 44, 43 and 78 years, time since injury were 4, 6 and 8 years and neurological levels were C6, T2 and T5.

Adherence to the protocol

The protocol dictated that participants stand for 30 min, five times a week for 6 weeks. In reality, they stood a median (interquartile range) of 30 min (30–40), five times a week (3–5) for 6 weeks (5–6). These data include one participant who required urgent surgery soon after commencing the standing phase so only stood for a median of 3.5 times a week for 2 weeks. The protocol also dictated that participants be tested before and after the 6-week stand and no-stand phases. The median (IQR) time between pre- and post-stand phase assessments were 7.4 weeks (7 to 8). The corresponding values for the no-stand phase assessments were 6.9 weeks (6.8–7.2). The variability was due to one participant who developed a pressure ulcer during the non-stand phase. The post non-stand phase assessment was delayed until the pressure ulcer was healed.

Treatment effect

The mean (95% confidence interval (CI)) between-intervention difference for Time to First Stool (assessor determined) was 0 min (95% CI, –7 to 7) indicating that regular standing had no effect on Time to First Stool (see Table 2). A cautious interpretation based on

Table 1 Characteristics of participants including age (years), gender, time since injury (years), motor level, ASIA impairment classification (n) and defecation method (n)

	Treatment first group, n = 10	Control first group, n = 10		
Age (years)	46 (39–55)	46 (42–51)		
Time (years) since injury	4 (3–11)	9 (6–20)		
Male: female participants, n	8:2	7:3		
<i>Motor level, n</i>				
C5 to C8	7	8		
T1 to T7	3	2		
<i>ASIA impairment scale, n</i>				
A	7	6		
B	3	4		
<i>Defecation method, n</i>	Primary	Secondary	Primary	Secondary
Straining/bearing down	0	0	0	0
Digital ano-rectal stimulation	1	4	1	5
Suppositories	3	0	1	0
Digital evacuation	0	2	0	3
Mini enema (clysma ≤ 150 ml)	6	1	6	1
Enema (clysma > 150 ml)	0	0	2	0

All data are reported as median (interquartile range) unless otherwise stated.

the 95% CI is that at best, standing may decrease time to first stool by 7 min and at worst, increase time to first stool by 7 min. The between-intervention differences for all the secondary outcomes are shown in Table 2. None indicated a treatment effect although all estimates were imprecise.

Perceived effect of standing and rate of inconvenience

The median (interquartile range) perceived change in bowel function after 6 weeks of training was 0/10 (0–3). Participants rated the inconvenience of the standing intervention as 5/10 (0–7). The results indicate that participants did not think that there was any change in their bowel function following 6 weeks of regular standing and did not think the standing regime was particularly onerous.

Adverse events and perceived benefits, and detrimental effects

There were no serious adverse events, although one participant experienced autonomic dysreflexia with standing. This was resolved by reducing the tilt, and placing pillows and padding to minimise the stretch on her ankles, knees, hips and lower back. Some of the perceived detrimental effects of standing included light-headedness (*n* = 2), increased blood pressure (*n* = 1), increased pressure on back and lower limb joints (*n* = 1) and increased pressure on an existing pressure ulcer on the foot (*n* = 1). Some of the perceived beneficial effects of standing included improved posture (*n* = 1), improved bowel function (*n* = 8), increased blood flow to legs (*n* = 1), increased bone density (*n* = 3), decreased spasticity (*n* = 1) and increased feelings of ‘wellbeing’ (*n* = 2). Some participants reported more than one perceived benefit.

DISCUSSION

This is the first randomised controlled trial to examine the effects of regular standing on bowel function in people with SCI. This study is important because regular standing is often advocated as a way to improve bowel function. However, the efficacy of regular standing for bowel function has never been examined. There is a theoretical basis to believe that standing may improve bowel function. For example, standing may stretch the colon and stimulate bowel movement. Studies in able-bodied individuals without bowel dysfunction show that food empties from the stomach best when individuals alternate between sitting and standing and worst when individuals just sit, stand or lie.²³ However, despite a sound rationale to believe that standing improves bowel function, this trial was unable to demonstrate any therapeutic effects.

The estimate for Time to First Stool was reasonably precise as indicated by the 95% CI (–7 to 7 min). This indicates that the sample size was sufficient to detect a treatment effect if there was one to be found assuming a minimally worthwhile treatment effect of 10 min. However, the minimally worthwhile treatment effect was based on data which suggested much longer Time to First Stool than seen in this study. This created problems for the interpretation of the results because it may be unreasonable to expect a treatment effect of 10 min in people with a mean (s.d.; range) initial Time to First Stool of 17 min (13; 2 to 46 min). This problem with interpretation is not specific to this trial. The interpretation of all trials relies on *a priori* definitions of minimally worthwhile treatment effect. This is difficult in new areas of research where little prior data exists. We could have chosen to express our data standardised to the s.d. by using Cohen’s *d* or similar. However, this does not overcome the underlying problem and makes it difficult for clinicians to interpret. A minimally worthwhile treatment effect was not set for the secondary outcomes. However, if one accepts an arbitrary cutoff equivalent to 10% of mean initial

Table 2 The intention-to-treat analysis

	Treatment First group				Control First group				Stand phase				No stand phase				Between intervention differences		
	Post stand		Pre control		Post control		Pre control		Post stand		Pre		Post		Pre			Post	
	Pre stand	Post stand	Pre control	Post control	Pre control	Post control	Pre stand	Post stand	Pre	Post	Pre	Post	Pre	Post	Pre	Post		Pre	Post
Time to First Stool (assessor determined) (min)	20.5 (20.1) (n=9)	14.1 (17.4) (n=9)	15.0 (14.9) (n=9)	14.1 (17.3) (n=9)	18.9 (11.5) (n=8)	14.3 (7.2) (n=8)	15.9 (7.9) (n=8)	17.7 (9.0) (n=8)	18.3 (15.3) (n=17)	15.8 (13.8) (n=17)	16.8 (13.2) (n=17)	14.2 (13.1) (n=17)	0.0 (–6.7 to 6.8) (n=17)						
Time to Complete Bowel Care (assessor determined) (min)	35.9 (22.1) (n=9)	30.6 (17.8) (n=9)	36.2 (19.5) (n=9)	37.5 (24.3) (n=9)	48.5 (21.1) (n=8)	41.9 (16.3) (n=8)	49.0 (27.7) (n=8)	51.5 (29.7) (n=8)	42.1 (25.0) (n=17)	40.4 (25.7) (n=17)	42.0 (20.6) (n=17)	39.6 (20.4) (n=17)	0.8 (–7.0 to 8.6) (n=17)						
Neurogenic Bowel Dysfunction Score (points/47)	13.2 (6.0) (n=9)	13.0 (7.2) (n=9)	10.3 (3.7) (n=9)	11.3 (3.7) (n=9)	14.1 (3.7) (n=8)	14.9 (2.6) (n=8)	16.3 (3.5) (n=8)	14.8 (5.4) (n=8)	14.6 (5.0) (n=17)	13.8 (6.2) (n=17)	12.1 (4.1) (n=17)	13.0 (3.6) (n=17)	–1.7 (–5.4 to 2.0) (n=17)						
Cleveland Clinic Constipation Score (points/30)	8.8 (2.6) (n=9)	8.9 (2.3) (n=9)	8.2 (1.3) (n=9)	9.0 (2.2) (n=9)	12.8 (4.6) (n=8)	12.5 (2.4) (n=8)	12.5 (2.2) (n=8)	11.1 (3.2) (n=8)	10.5 (3.0) (n=17)	9.9 (2.9) (n=17)	10.4 (3.9) (n=17)	10.6 (2.9) (n=17)	–0.9 (–2.9 to 1.1) (n=17)						
St. Mark’s Incontinence Score (points/24)	7.2 (2.2) (n=9)	7.0 (2.7) (n=9)	6.4 (2.3) (n=9)	7.4 (2.8) (n=9)	7.4 (3.3) (n=8)	6.9 (3.5) (n=8)	7.4 (3.5) (n=8)	6.6 (2.6) (n=8)	7.3 (2.8) (n=17)	6.8 (2.6) (n=17)	6.9 (2.8) (n=17)	7.2 (3.1) (n=17)	–0.8 (–2.5 to 0.9) (n=17)						
Spinal Cord Injury Spasticity Evaluation Tool (points –3 to 3)	–0.3 (0.5) (n=9)	–0.2 (0.2) (n=9)	–0.2 (0.2) (n=9)	–0.1 (0.2) (n=9)	–0.4 (0.4) (n=8)	–0.4 (0.4) (n=8)	–0.3 (0.3) (n=8)	–0.4 (0.5) (n=8)	–0.3 (0.4) (n=17)	–0.3 (0.4) (n=17)	–0.3 (0.3) (n=17)	–0.2 (0.3) (n=17)	–0.1 (–0.3 to 0.2) (n=17)						
Time to First Stool (self report) (min)	NA	8.1 (6.0) (n=7)	NA	10.6 (9.1) (n=7)	NA	15.0 (9.2) (n=7)	NA	13.9 (7.3) (n=7)	NA	11.0 (7.1) (n=14)	NA	12.8 (9.0) (n=14)	1.8 (–2.1 to 5.7) (n=14)						
Time to Complete Bowel Care (self report) (min)	NA	22.4 (9.5) (n=7)	NA	28.4 (13.9) (n=7)	NA	53.0 (25.1) (n=7)	NA	47.1 (28.8) (n=7)	NA	34.8 (24.2) (n=14)	NA	40.7 (23.3) (n=14)	5.9 (–0.1 to 11.9) (n=14)						

Abbreviation: NA, not applicable. Mean (s.d.) of interventions, and mean (95% CI) between-intervention differences. The data are expressed by order and by phase.

values, then all the results for the secondary outcomes are inconclusive and fail to rule in or out a treatment effect.

There are various factors that may have contributed to the imprecise estimates for the outcome measures. The most likely explanation is that the effect of standing on bowel function is highly variable and different subgroups of people with SCI respond differently. For example, the response to standing may be affected by neurological status, time since injury, lifestyle, diet, activity levels and health conditions. We tried to increase the precision of estimates by restricting the inclusion criterion. For example, we restricted the inclusion to those with AIS A and AIS B lesions above T8. Coincidentally, 75% ($n=15$) of the participants had neurological levels above T1, and 75% ($n=15$) were more than 40 years old, with eight participants over 50 years old. The small sample size of the study precluded exploring the possibility that different subgroups of patients responded differently to the standing protocol with *post hoc* analyses.

Bowel function is notoriously difficult to quantify. The best available outcomes were used in an attempt to increase the precision of the estimates. Different aspects of bowel function were captured with a variety of outcomes. For example, the trial not only looked at the Time to Complete Bowel Care but the bowel care pattern, characteristics of faecal incontinence and constipation. In addition, duplicate measures of Time to First Stool and Time to Complete Bowel Care were taken. One set of measures was collected by a blinded assessor and the other set was measured by the participants themselves. The blinded assessor took the measures of Time to First Stool and Time to Complete Bowel Care on two different occasions for both pre and post assessments of each phase (that is, eight occasions). The other set of measures were collected on each bowel-care day by the participants themselves in diaries for the last 2 weeks of each phase. The data from the diaries were included because we were concerned that the Time to First Stool and the Time to Complete Bowel Care may be highly variable even within the same person over successive bowel-care days. Ideally, we would have liked to have sent a blinded assessor into people's homes over many successive days at the beginning and end of each stand and no-stand phase to minimise variability and reduce bias. However, this was not economically feasible and overly intrusive. We therefore chose to collect self-report data as a secondary outcome with the aim of examining these data more closely if our estimates for our primary outcomes were highly variable.

Adherence to the standing protocol was reasonably good and participants were regularly encouraged to stand. This level of encouragement cannot be provided on an ongoing basis. A few participants had interruptions because of illness or busy schedules but nonetheless, we probably achieved better adherence than what is typically achieved when these standing programs are rolled out over the span of people's lives. Therefore, our estimates of treatment effectiveness may be overly optimistic. The real effect of the type and extent of standing that typically occurs in the community may be considerably smaller. Of course it is possible that standing may be more effective if adherence can be increased and if people can be encouraged to stand for more than 30 min a day. Similarly, perhaps regular standing is more effective if performed just prior to bowel care each day, or if done for more than 6 weeks. All these possibilities require further investigation, although healthcare professionals need to be careful about placing too many demands on people with SCI. We should not expect people with SCI to devote too much of their time to these and various other interventions advocated by different healthcare professionals unless they make a notable difference to quality of life.

Standing is also advocated on the basis that it decreases spasticity. However, beliefs about the therapeutic effects of standing on spasticity are primarily based on the results of surveys, case series and case reports.^{4-6,8,12-14} There are as yet no high-quality trials that have provided convincing evidence that standing decreases spasticity. We therefore included spasticity as a secondary outcome to further explore this issue. However, participants were not selected on the basis of spasticity and as it eventuated few participants had notable spasticity with a mean (s.d.; range) initial SCI-SET score of -0.3 point ($0.3; -1.25$ to 0.1) on a -3 to $+3$ scale. It is therefore not surprising that standing had little effect on spasticity with a mean between-group difference of only -0.1 point (95% CI, -0.3 to 0.2). The effectiveness of standing on spasticity is therefore still unclear. The issue will only be resolved with future high quality and large trials which capture objective measures of spasticity as well as participants' perceptions about spasticity.

Although no therapeutic effects of standing were found on any of the objective measures, participants perceived that they benefitted from regular standing with eight participants stating that standing improved bowel function. Some of the participants also reported less abdominal distention and decreased muscle tone or benefits in other areas not captured in the objective measures. For example, they reported improved posture in their wheelchairs and a sense of achievement. They also invariably believed that standing was good for them often citing its beneficial effects on blood pressure, bone mineral density and joint mobility. It is not clear whether these perceptions and beliefs reflect real benefits that we were not able to detect with our outcome measures or whether they merely reflect participants' exposure to the widely articulated beliefs of others about regular standing.

It is possible that while standing does not have a clear effect on Time to First Stool, it may reduce colonic transit times. Colorectal emptying at defecation is reduced and colonic transit times are prolonged in people with SCI.²⁴ However, colonic transit times were not measured in this study because this would have required participants to ingest radio opaque markers followed by multiple abdominal X-rays. In addition, we reasoned that Time to First Stool is probably the most meaningful outcome measure to people with SCI and that the three standardised bowel questionnaires should capture any clinically important changes in colonic transit times.

A cautious interpretation of the results is that at best, standing may decrease Time to First Stool by 7 min but few would consider this sufficient to justify the time and cost associated with regular standing. However, further research is required to clarify other possible therapeutic effects of standing. Importantly, the results of this study should encourage questioning of long-held assumptions about standing and other similar interventions which have been passed down through the years and have become entrenched in clinical practise without a clear evidence base.

DATA ARCHIVING

There were no data to deposit.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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- 1 Emmanuel A. Managing neurogenic bowel dysfunction. *Clin Rehabil* 2010; **24**: 483–488.
- 2 Emmanuel AV, Chung EA, Kamm MA, Middleton F. Relationship between gut-specific autonomic testing and bowel dysfunction in spinal cord injury patients. *Spinal Cord* 2009; **47**: 623–627.
- 3 Lynch AC, Wong C, Anthony A, Dobbs BR, Frizelle FA. Bowel dysfunction following spinal cord injury: a description of bowel function in a spinal cord-injured population and comparison with age and gender matched controls. *Spinal Cord* 2000; **38**: 717–723.
- 4 Dunn RB, Walter JS, Lucero Y, Weaver F, Langbein E, Fehr L *et al*. Follow-up assessment of standing mobility device users. *Assist Technol* 1998; **10**: 84–93.
- 5 Eng JJ, Levins SM, Townson AF, Mah-Jones D, Bremner J, Huston G. Use of prolonged standing for individuals with spinal cord injuries. *Phys Ther* 2001; **81**: 1392–1399.
- 6 Walter JS, Sola PG, Sacks J, Lucero Y, Langbein E, Weaver F. Indications for a home standing program for individuals with spinal cord injury. *J Spinal Cord Med* 1999; **22**: 152–158.
- 7 Hoenig H, Murphy T, Galbraith J, Zolkewitz M. Case study to evaluate a standing table for managing constipation. *SCI Nurs* 2001; **18**: 74–77.
- 8 Shields RK, Dudley-Javoroski S. Monitoring standing wheelchair use after spinal cord injury: a case report. *Disabil Rehabil* 2005; **27**: 142–146.
- 9 Krassioukov A, Eng JJ, Claxton G, Sakakibara BM, Shum S. Neurogenic bowel management after spinal cord injury: a systematic review of the evidence. *Spinal Cord* 2010; **48**: 718–733.
- 10 Coggrave M, Wiesel PH, Norton C. Management of faecal incontinence and constipation in adults with central neurological diseases. *Cochrane Database Syst Rev* 2006; **19**: CD002115.
- 11 De Bruin ED, Frey-Rindova P, Herzog RE, Dietz V, Dambacher MA, Stüssi E. Changes of tibia bone properties after spinal cord injury: Effects of early intervention. *Arch Phys Med Rehabil* 1999; **80**: 214–220.
- 12 Kunkel CF, Scremin AME, Eisenberg B, Garcia JF, Roberts S, Martinez S. Effect of 'standing' on spasticity, contracture, and osteoporosis in paralyzed males. *Arch Phys Med Rehabil* 1993; **74**: 73–78.
- 13 Bohannon RW. Tilt table standing for reducing spasticity after spinal cord injury. *Arch Phys Med Rehabil* 1993; **74**: 1121–1122.
- 14 Boutilier G, Sawatzky BJ, Grant C, Wiefelspuett S, Finlayson H. Spasticity changes in SCI following a dynamic standing program using the Segway. *Spinal Cord* 2012; **50**: 595–598.
- 15 Coggrave MJ, Norton C. The need for manual evacuation and oral laxatives in the management of neurogenic bowel dysfunction after spinal cord injury: a randomized controlled trial of a stepwise protocol. *Spinal Cord* 2010; **48**: 504–510.
- 16 Krogh K, Christensen P, Sabroe S, Laurberg S. Neurogenic bowel dysfunction score. *Spinal Cord* 2006; **44**: 625–631.
- 17 Agachan F, Chen T, Pfeifer J, Reissman P, Wexner SD. A constipation scoring system to simplify evaluation and management of constipated patients. *Dis Colon Rectum* 1996; **39**: 681–685.
- 18 Vaizey CJ, Carapeti E, Cahill JA, Kamm MA. Prospective comparison of faecal incontinence grading systems. *Gut* 1999; **44**: 77–80.
- 19 Adams MM, Ginis KA, Hicks AL. The spinal cord injury spasticity evaluation tool: development and evaluation. *Arch Phys Med Rehabil* 2007; **88**: 1185–1192.
- 20 Korsten MA, Fajardo NR, Rosman AS, Creasey GH, Spungen AM, Bauman WA. Difficulty with evacuation after spinal cord injury: Colonic motility during sleep and effects of abdominal wall stimulation. *J Rehabil Res Dev* 2004; **41**: 95–99.
- 21 Senn S. *Cross-Over Trials in Clinical Research*. 2nd edn, Chichester, UK: J. Wiley, 2002.
- 22 Pocock SJ. *Clinical Trials: A Practical Approach*. Chichester, UK: Wiley, 1983.
- 23 Moore JG, Datz FL, Christian PE, Greenberg E, Alazraki N. Effect of body posture on radionuclide measurements of gastric emptying. *Dig Dis Sci* 1988; **33**: 1592–1595.
- 24 Rasmussen MM, Krogh K, Clemmensen D, Bluhme H, Rawashdeh Y, Christensen P. Colorectal transport during defecation in subjects with supraconal spinal cord injury. *Spinal Cord* 2013; **51**: 683–687.