Functional electrical stimulation cycling has no clear effect on urine output, lower limb swelling, and spasticity in people with spinal cord injury: a randomised cross-over trial

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Question: Does functional electrical stimulation (FES) cycling increase urine output and decrease lower limb swelling and spasticity in people with recent spinal cord injury? Design: Randomised cross-over trial. Participants: Fourteen participants with a recent motor complete spinal cord injury were consecutively recruited from two spinal cord injury units in Sydney. Intervention: Participants were randomised to an experimental phase followed by a control phase or vice versa, with a 1-week washout period in between. The experimental phase involved FES cycling four times a week for two weeks and the control phase involved standard rehabilitation for two weeks. Assessments by a blinded assessor occurred at the beginning and end of each phase. Allocation was concealed and an intention-to-treat analysis was performed. Outcome measures: The primary outcome was urine output (mL/hr) and the secondary outcomes were lower limb circumference, and spasticity using the Ashworth Scale, and the Patient Reported Impact of Spasticity Measure (PRISM). In addition, participants were asked open-ended questions to explore their perceptions about treatment effectiveness. Results: All participants completed the study. The mean between-group difference (95% CI) for urine output was 82 mL/hr (–35 to 199). The mean between-group differences (95% CI) for lower limb swelling, spasticity (Ashworth), and PRISM were –0.1 cm (–1.5 to 1.2), –1.9 points (–4.9 to 1.2) and –5 points (–13 to 2), respectively. All point estimates of treatment effects favoured FES cycling. Participants reported many benefits from FES cycling. Conclusion: There were no clear effects of FES cycling on urine output, swelling and spasticity even though all point estimates of treatment effects favoured FES cycling and participants perceived therapeutic effects. Trial registration: ACTRN12611000923965. [Ralston KE, Harvey LA, Batty J, Lee BB, Ben M, Cusmiani R, Bennett J (2013) Functional electrical stimulation cycling has no clear effect on urine output, lower limb swelling, and spasticity in people with spinal cord injury: a randomised cross-over trial. Journal of Physiotherapy 59: 237–243]

Key words: Spinal cord injury, Functional electrical stimulation cycling, Physical therapy

Introduction

Functional electrical stimulation (FES) cycling is commonly prescribed for people with spinal cord injury for a variety of reasons (Carlson et al 2009, Hicks et al 2011). Some of the proposed benefits of FES cycling include increased urine output, decreased lower limb swelling and decreased spasticity (Elokda et al 2000, Faghri and Yount 2002, Krause et al 2008, Sampson et al 2000, Skold et al 2002, van der Salm et al 2006). It is important to investigate the therapeutic effects of FES cycling on these variables because: increased urine output is associated with a reduced incidence of urinary tract infection (Wilde and Carrigan 2003); decreased lower limb swelling makes it easier for people with spinal cord injury to lift their legs and reduces incidence of pressure ulcers (Consortium for Spinal Cord Medicine Clinical Practice Guidelines 2001); and decreased spasticity has various functional and health benefits (Adams and Hicks 2005).

Anecdotal evidence suggests that FES cycling affects renal function causing an increase in urine output and decrease in lower limb swelling (Man et al 2003). It is hypothesised that the cyclic muscle contractions associated with FES cycling compress the lower limb vasculature thereby improving venous return and decreasing lower limb swelling (Elokda et al 2000, Faghri and Yount 2002, Man et al 2003, Sampson et al 2000). It is also claimed that the increased venous return associated with FES cycling stretches the myocardium of the right atrium stimulating the expression of atrial natriuretic peptide. This peptide is known to have an excitatory effect on the kidneys, which increases urine excretion (Dunn and Donnelly 2007) and

What is already known on this topic: Functional electrical stimulation of paralysed legs in people with spinal cord injury increases venous return which may increase urine output and decrease lower limb swelling. Functional electrical stimulation may also have short-term effects on spasticity.

What this study adds: This study provides unbiased point estimates of the effect of functional electrical stimulation on urine output, venous return and spasticity. These estimates indicate that our current confidence in the effectiveness of functional electrical stimulation on these outcomes is not yet justified.
potentially decreases lower limb swelling. However, it is not known whether FES cycling is a sufficiently potent stimulus to influence urine output or lower limb swelling. This has not been tested in a randomised controlled trial.

FES cycling is also advocated as a way to reduce spasticity (Elbasiouny et al 2010, Krause et al 2008, Skold et al 2002, van der Salm et al 2006). Various theories exist on how this may occur. One theory is that repeated electrical stimulation (ES)-evoked contractions lead to muscle fatigue (Skold et al 2002). Another hypothesis is that the excitation of the cutaneous afferents decreases the excitability of the propriospinal interneurons and motoneurons (Elbasiouny et al 2010), while others argue that ES applied to antagonistic muscles augments reciprocal inhibition of agonistic spastic muscles (van der Salm et al 2006). However, similar to the beliefs about FES cycling on urine output and lower limb swelling, it is not yet clear whether FES cycling affects spasticity. There are some studies indicating an immediate dampening of spasticity from one-off episodes of ES but these studies are vulnerable to bias and do not provide convincing evidence of the effects of FES cycling on spasticity (Krause et al 2008, Skold et al 2002, van der Salm et al 2006). Therefore, the research question for this study was:

Does a two-week FES cycling program increase urine output and decrease lower limb swelling and spasticity in people with recent spinal cord injury?

Method

Design

A 5-week cross-over randomised trial was undertaken, where participants received both experimental and control phases. Each participant underwent the 2-week control phase and the 2-week experimental phase. During the experimental phase, participants received FES cycling for 2 weeks. During the control phase, participants did not receive any FES cycling. The order of the two phases was randomised with a 1-week washout period in between. Participants continued to receive other usual care throughout the trial.

A blocked randomisation allocation schedule was computer-generated by an independent person to ensure equal numbers of participants commenced with the FES cycling phase and control phase (Schulz et al 2010). Each participant’s allocation was placed in a sealed, opaque and sequentially numbered envelope and kept at an off-site location. Once a participant passed the initial screening process, an independent person was contacted, an envelope opened and allocation revealed. The participant was deemed to have entered the trial at this point.

Participants

Fourteen participants with an upper motor neuron lesion following recent spinal cord injury were consecutively recruited from two Sydney spinal cord injury units over an 18-month period commencing July 2011. Participants were included if they: had sustained a spinal cord injury (traumatic or non-traumatic) within the preceding six months; were currently receiving inpatient rehabilitation; were over 16 years of age; were diagnosed with an American Spinal Cord Injury Association Impairment Scale (AIS) of A, B or C with less than 5/50 lower limb strength according to the International Standards for Neurological Classification of Spinal Cord Injury; and could tolerate FES cycling for at least 20 minutes within a one-hour period. Participants were excluded if: they had participated in a FES cycling program in the preceding two weeks; ES was medically contraindicated; or they had a limited ability to comply. All participants were deemed medically fit to participate by their treating medical consultant.

Intervention

Participants in the experimental phase received a progressive, individualised FES cycling program performed four times a week for two weeks. The aim was to provide participants with 30 to 45 minutes of FES driven leg cycling within a one-hour session with the option of participants building up to this time from 20 minutes. However, all participants tolerated at least 30 minutes from the start. Three muscle groups were stimulated for each leg; quadriceps, hamstrings, and gluteals. Electrodes were placed over two points on each muscle to provide a maximal contraction. One participant did not tolerate stimulation of the quadriceps; therefore the gastrocnemius was stimulated instead. FES cycling was performed using a leg FES cycling system, with participants seated in their wheelchairs. A FES protocol based on that recommended by others (Krause et al 2008) was used with the following parameters: frequency 33Hz, wavelength 350, and stimulation amplitude of up to 140mA according to participants’ tolerance to ES. Resistance was set at the highest level that still enabled participants to cycle for at least 30 minutes. The initial sessions for each participant were supervised on a one-to-one basis by a physiotherapist with at least four years of experience in the management of spinal cord injury. Later sessions for participants were sometimes supervised by a physiotherapist aide working under the guidance of a physiotherapist.

The usual care that was provided during both intervention phases of the study consisted of standard inpatient physiotherapy and occupational therapy that is typically provided to patients during their initial rehabilitation following spinal cord injury. This includes interventions directed at impairments such as poor strength, restricted joint mobility, limited fitness, reduced dexterity, and pain. It also includes a strong focus on training of functional skills such as dressing, walking, transferring, using the hands, and pushing a wheelchair.

Outcome measures

All assessments were conducted at the beginning (baseline) and end of each two-week phase by trained assessors who were blinded to group allocation. The success of blinding was determined by asking assessors at the completion of each participant’s last assessment whether they had been unblinded.

The primary outcome was urine output. Secondary outcomes were lower limb swelling measured as lower leg circumference, and spasticity measured using the Ashworth Scale and the Patient Reported Impact of Spasticity Measure (PRISM). An additional secondary outcome measure, Global Impression of Change, was collected at the completion of the trial.

Baseline urine output was measured prior to the commencement of each trial phase with the participant sitting quietly and avoiding any activity. Urine output was again measured at the end of both experimental and control phases, however at the end of experimental phase urine output was measured while participants simultaneously...
performed FES cycling. Urine output was measured each time over a one-hour period. Prior to all one-hour collection periods, participants’ bladders were emptied via a catheter. If intermittent self-catheterisations were used for bladder management, an indwelling catheter was temporarily inserted to ensure consistency between measurements. In addition, fluid intake was restricted for three hours prior to the collection period according to normal recommended daily intake for weight (Spinal Cord Medicine Consortium 1998). Where possible, participants’ bladder management remained constant throughout the trial although two participants changed bladder management from indwelling catheters – one to a suprapubic catheter and the other to intermittent self-catheterisations – for reasons unrelated to the trial.

Spasticity was measured before and after the experimental and control phases of the trial using the Ashworth Scale (Cardenas et al 2007). Measurements were performed in the supine position for quadriceps, hamstrings, plantarflexors, and hip adductor muscles (0–4). Scores for each muscle group of the left and right legs were tallied and treated as one overall measure of lower limb spasticity (0–32) as recommended by others (Hobbelen et al 2012).

Lower limb swelling was measured before and after the two phases of the trial using the ‘Leg-o-meter’, a reliable and valid tool that uses a tape measure to quantify leg circumference (Berard and Zuccarelli 2000). Circumferential measures were taken 13 cm from the base of the heel, directly posterior to the medial malleoli.

Participants were asked to complete the Patient Reported Impact of Spasticity Measure (PRISM) questionnaire before and after the control and experimental phases. The questionnaire explores participants’ experiences of abnormal muscle control or involuntary muscle movement over the preceding week. It asks participants to rate their abnormal muscle control or involuntary movement for 41 scenarios on a 5-point scale ranging from 0 (‘never true for me’) to 4 (‘very often true for me’) with a maximal possible score of 164 reflecting severe spasticity. Its reliability has been established (Cook et al 2007).

At the end of the trial, participants were asked to rate their perceptions about the overall effects of FES cycling using a 15-point Global Impression of Change Scale anchored at –7 by ‘markedly worse’ and at +7 by ‘markedly better’ (Schneider et al 1997). In addition, they were also asked to rate the inconvenience of the FES cycling phase of the trial on a 10-cm Visual Analogue Scale anchored at one end with 0 reflecting ‘not at all inconvenient’ and at the other end with 10 reflecting ‘extremely inconvenient’. Participants were also asked open-ended questions to explore any perceived deleterious or beneficial effects of the FES cycling.

Data analysis

Change data (pre to post difference) for each phase were used to derive point estimates of the differences between the experimental and control 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 minimised by the 1-week washout period. This approach is recommended by others (Senn 2002). Power calculations were not conducted because there were no previous studies upon which to base a sensible estimate of the likely SD for urine output or with which to set a minimally worthwhile treatment effect. Therefore, a pragmatic approach to determining the sample size was adopted. That is, we selected a sample size that was realistically achievable within a 2-year recruitment period even though ultimately we recruited within a 1.5-year period. We reasoned that an estimate of treatment effect even if imprecise from a trial with minimal bias would progress knowledge in this area and help sample size calculations for future trials.

Results

Flow of participants through the study

Fourteen participants entered and completed the study. Their median (interquartile range) age was 25 years (22 to 32) and time since injury was 118 days (64 to 135). All participants had motor complete lesions (AIS A, B) with neurological levels ranging from C4 to T10, as presented in Table 1. Figure 1 demonstrates the flow of participants through the trial.

Compliance with the trial method

Primary and secondary outcomes were attained for every participant with no drop outs. The assessors remained blind for all aspects of the trial. Participants received a median of 8 FES cycling sessions (IQR 8 to 9) over a mean of 2 weeks (SD 0.5). There was some variation because the FES cycling was continued until the assessment at the end of the 2-week FES cycling phase could be completed. These assessments were sometimes delayed for a day or more because of difficulties with scheduling.

### Table 1. Baseline characteristics of participants.

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Randomised (n = 14)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (yr), median (IQR)</td>
<td>25 (22 to 32)</td>
</tr>
<tr>
<td>Time since injury (d), median (IQR)</td>
<td>118 (64 to 135)</td>
</tr>
<tr>
<td>Gender, n (%) male</td>
<td>11 (79)</td>
</tr>
<tr>
<td>AIS, n</td>
<td></td>
</tr>
<tr>
<td>A</td>
<td>13</td>
</tr>
<tr>
<td>B</td>
<td>1</td>
</tr>
<tr>
<td>C</td>
<td>0</td>
</tr>
<tr>
<td>Neurological level, n</td>
<td></td>
</tr>
<tr>
<td>C4</td>
<td>3</td>
</tr>
<tr>
<td>C5</td>
<td>2</td>
</tr>
<tr>
<td>C6</td>
<td>1</td>
</tr>
<tr>
<td>C7</td>
<td>2</td>
</tr>
<tr>
<td>T3</td>
<td>1</td>
</tr>
<tr>
<td>T4</td>
<td>2</td>
</tr>
<tr>
<td>T6</td>
<td>1</td>
</tr>
<tr>
<td>T8</td>
<td>1</td>
</tr>
<tr>
<td>T10</td>
<td>1</td>
</tr>
<tr>
<td>Bladder management, n</td>
<td></td>
</tr>
<tr>
<td>IDC</td>
<td>3</td>
</tr>
<tr>
<td>SPC</td>
<td>3</td>
</tr>
<tr>
<td>ISC</td>
<td>8</td>
</tr>
</tbody>
</table>

AIS = American Spinal Injury Association (ASIA) Impairment Scale, IDC = indwelling catheter, SPC = suprapubic catheter, ISC = intermittent self-catheterisation.
People with spinal cord injury admitted to spinal injury units (n = 104)

Excluded (n = 90)
• major lower limb pathology/injury (n = 8)
• non-compliant with rehabilitation (n = 7)
• > 5/50 lower limb motor power (n = 30)
• LMN lesion/did not tolerate ES (n = 14)
• medically unfit/cognitive impairment (n = 19)
• non-English-speaking background (n = 5)
• < 8 weeks before discharge (n = 5)
• declined to participate (n = 2)

Eligible (n = 14)

Day 0
Measured urine output, swelling, spasticity and impact of spasticity
Randomised (n = 14)
(n = 7) (n = 7)

Experimental intervention
• FES cycling
• usual rehabilitation

Control intervention
• usual rehabilitation

Day 14
Measured urine output, swelling, spasticity and impact of spasticity
(n = 7) (n = 7)

Washout period

Day 22
Measured urine output, swelling, spasticity and impact of spasticity
(n = 7) (n = 7)

Control intervention

Experimental intervention

Day 36
Measured urine output, swelling, spasticity, impact of spasticity,
global impression of change and inconvenience
(n = 7) (n = 7)

Effect of intervention
The results for all outcomes are presented in Table 2, with individual participant data presented in Table 3 (see eAddenda for Table 3). The mean between-group difference for urine output was 82 mL (95% CI –35 to 199), where a positive value favours the experimental intervention because it indicates an increase in urine output with FES cycling. The other mean between-group differences were –0.1 cm (95% CI –1.5 to 1.2) for lower limb swelling, –1.9 points (95% CI –4.9 to 1.2) on the 32-point Ashworth Scale, and –5 points (95% CI –13 to 2) on the 164-point PRISM. Here, negative values favour the experimental intervention because they indicate a decrease in swelling and spasticity with FES cycling.

All but two participants reported improvements with the FES cycling on the Global Impression of Change Scale with
a median improvement of 3 points (IQR 3 to 4) on the scale from –7 to +7. The median perception of inconvenience of the FES cycling was 0.3 points (IQR 0 to 3.8) on the 10-point Visual Analogue Scale. There were two reports of adverse effects. One related to an increase in spasticity and the other related to precipitation of a bowel accident. All but two participants cited one or more of the following therapeutic effects: decreases in swelling or spasticity; improvements in circulation, urine output, bowel activity or ‘muscle tone’; and increased feelings of general wellbeing including improvements in ability to breathe, a sense of making progress with physical activity and psychological benefits from seeing their legs move.

**Discussion**

Despite widespread beliefs about the benefits of FES cycling on urine output, lower limb swelling and spasticity, we were unable to detect a convincing treatment effect on any of these variables. However, our results cannot be interpreted as evidence of no treatment effect because this interpretation relies on defining a minimally worthwhile treatment effect and it is not clear what size treatment effect clinicians and people with spinal cord injury would consider sufficient to justify the time and cost associated with FES cycling. If people with spinal cord injury would consider a treatment effect equivalent to 10% of mean initial values then our results could be used to indicate that FES cycling has no effect on lower limb swelling. Regardless, our results provide valuable data for future meta-analyses which may be the only way of answering questions about the effectiveness of FES cycling on these parameters in people with spinal cord injury. Our results and protocol also provide useful information for future trials.

Our point estimates of treatment effects for some variables were imprecise as reflected in the wide 95% CI associated with the between-group differences. This was particularly a problem for urine output. To increase the precision of our point estimates we needed a larger sample size and/or tighter inclusion criteria. We tried to minimise the need for a large sample size by using a cross-over design. Our research question was appropriate for a cross-over design because any effects of FES cycling on urine output are probably short lived. We could have tightened our inclusion criteria. For example, those with AIS A lesions may respond better and more consistently to FES cycling than those with AIS B, C or D lesions because they tolerate higher levels of stimulation. However, by restricting the inclusion criteria we would have also restricted the ability to generalise the results to a broad population. Setting the inclusion criterion of clinical trials is always a balance between these competing considerations.

There are no other studies investigating the effect of FES cycling on urine output against which to compare our results. At least one study provides indirect evidence to support the theory that FES cycling reduces swelling via its therapeutic effects on venous return. This study examined the effect of ES contractions on lower limb swelling during static standing on a tilt table in able-bodied individuals (Man et al 2003). The authors reported a notable between-group difference in lower limb swelling measured via water volumetry, with a mean between-group difference of 39 mL (95% CI 17 to 61 – estimated from provided data). There are obvious limitations of extrapolating the indirect evidence from this study. Nonetheless, along with studies demonstrating an effect of ES cycling on venous return (Elokd et al 2000, Faghi and Yount 2002, Sampson et al 2000), the study by Man and colleagues indicates some basis for the rationale that FES cycling in people with spinal cord injury influences venous return and lower limb swelling; a

### Table 2. Mean (SD) of measures before and after the experimental and control interventions, mean (SD) difference within interventions, and mean (95% CI) difference between interventions, except Global Impression of Change and perception of inconvenience, which are presented as median with interquartile range. Small numerical anomalies are due to the effects of rounding.

<table>
<thead>
<tr>
<th>Outcomes</th>
<th>Pre</th>
<th>Intervention</th>
<th>Post</th>
<th>Difference within interventions</th>
<th>Difference between interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Urine output (mL)</td>
<td>Exp (n = 14)</td>
<td>Con (n = 14)</td>
<td>Exp (n = 14)</td>
<td>Con (n = 14)</td>
<td>Exp minus Con</td>
</tr>
<tr>
<td></td>
<td>97 (72)</td>
<td>123 (91)</td>
<td>163 (136)</td>
<td>106 (68)</td>
<td>66 (127)</td>
</tr>
<tr>
<td>Leg circumference (cm)</td>
<td>49.2 (4.3)</td>
<td>49.6 (3.7)</td>
<td>49.3 (4.6)</td>
<td>49.8 (4.1)</td>
<td>0.1 (2.0)</td>
</tr>
<tr>
<td>Ashworth (0 to 32)</td>
<td>5.6 (4.6)</td>
<td>6.1 (5.7)</td>
<td>2.8 (2.3)</td>
<td>5.1 (4.6)</td>
<td>–2.9 (3.9)</td>
</tr>
<tr>
<td>PRISM (0 to 164)</td>
<td>24 (11)</td>
<td>23 (10)</td>
<td>22 (9)</td>
<td>26 (20)</td>
<td>–2 (4)</td>
</tr>
<tr>
<td>Global Impression of Change</td>
<td>3 (3 to 4)</td>
<td></td>
<td></td>
<td></td>
<td>0.3 (0 to 3.8)</td>
</tr>
<tr>
<td>Perception of inconvenience</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3 (3 to 4)</td>
</tr>
</tbody>
</table>

Exp = experimental phase = Functional Electrical Stimulation (FES) cycling, Con = control phase = usual care, PRISM = Patient Reported Impact of Spasticity Measure. *A positive number favours FES cycling indicating an increase in urine output. †A negative number favours FES cycling indicating a decrease in swelling or spasticity.
The results from the small number of studies examining the effects of FES cycling on spasticity are similar to ours with no clear indication of therapeutic effect (Krause et al 2008, Skold et al 2002, van der Salm et al 2006).

The potential effect of FES cycling on urine output may have been missed because we only measured urine output over a one-hour period immediately after FES cycling. One hour may be too short. However this seems unlikely because naturetic peptide has an immediate effect on the kidneys (Dunn and Donnelly 2007). If the release of naturetic peptide in response to an increase in venous return is the main mechanism by which FES cycling increases urine output, then our time frame for measurements of urine output should have been sufficient. Another possible explanation for our failure to find a convincing treatment effect is our use of a short intervention period, namely two weeks. A longer training period may have increased participants’ muscle bulk and stimulated strength (Baldi et al 1998) thereby enhancing the muscle pump effect and venous return. Venous return may have been further increased by the stimulation of additional lower limb muscles however stimulation of more than three muscle groups is problematic as this requires additional expensive equipment not routinely available in the clinical setting. Future studies could manipulate some of these variables to determine their effect on urine output.

Only the immediate effects of FES cycling were investigated and only at the impairment level. We acknowledge that urine output, lower limb swelling and spasticity are surrogate measures for what is important to people with spinal cord injury, and clearly immediate effects are of little interest unless they are sustained. We however restricted the trial in this way to increase statistical power. In addition, it is potentially wasteful of resources looking for sustained effects of interventions on global measures of participation without first demonstrating immediate effects on surrogate measures.

Importantly, FES cycling is advocated in people with motor complete lesions for reasons other than its effect on urine output, lower limb swelling and spasticity. For example, it is advocated on the basis that it increases cardiovascular fitness, muscle bulk and lean muscle mass. There is also some evidence to suggest that FES cycling prevents bone loss and contractures, and decreases adipose tissue and the risk of diabetes (Carlson et al 2009, Hicks et al 2011). We did not look at any of these variables because they were unlikely to be influenced by two weeks of FES cycling.

Interestingly, all but two participants when asked to rate change from the FES cycling on the Global Impression of Change Scale stated that it made them ‘somewhat’ to ‘moderately’ better, as reflected by a median score of 3 points (IQR 3 to 4). Some argue that even a 1-point change on the Global Impression of Change Scale should be considered clinically significant by definition (Schneider et al 1998). Yet we do not fully agree with this interpretation of clinical significance, it does indicate that some may interpret our results as convincing evidence of treatment effectiveness. When asked open-ended questions about the beneficial or detrimental effects of FES cycling, most participants stated only beneficial effects including improvements in urine output and reductions in lower limb swelling and spasms. It is difficult to explain the discrepancy between participants’ reports of treatment efficacy and the results of the objective measures. The most likely explanation is that participants were not blinded and therefore had expectations about treatment effectiveness.

These expectations may have been due to preconceived ideas regarding the therapeutic benefits of FES cycling. However, the same effectiveness of FES cycling on spasticity was not reflected in the PRISM results; an assessment of spasticity that also relies on self-report. This may be because the PRISM is structured and participants are asked to focus specifically on the implications of their spasticity over the last week. This may minimise bias. Of course, the discrepancy between participants’ reports of treatment efficacy and the results of the objective measures may reflect participants’ ability to sense changes that our measures were incapable of detecting.

In all, a cautious interpretation of our results is that two weeks of FES cycling does not have clear beneficial effects on urine output, lower limb swelling, or spasticity in people with recent spinal cord injury, and that our confidence in the therapeutic effects of FES cycling on these variables is not yet justified. It is therefore not clear whether FES cycling should be prescribed for these purposes.

Footnotes: *RT300 cycle, Restorative Therapies, USA.

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

Ethics: The Ethics Committees of the University of Sydney, University of Wollongong and Royal Rehabilitation Centre Sydney approved this study. All participants gave written informed consent before data collection began. All applicable governmental and institutional ethical regulations regarding the use of human volunteers were followed during the trial.

Competing interests: None declared.

Support: Prince of Wales Hospital Foundation.

Acknowledgments: We thank the patients, and physiotherapy, medical, and nursing staff of the Spinal Units at the Royal Rehabilitation Centre Sydney and the Prince of Wales Hospital, Sydney.

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