Screening and Habituation of FES-Leg Cycle Ergometry for Individuals with Spinal Cord Injury: A Pilot Study

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Abstract

Objectives—To document the screening process and develop the habituation procedures prior to commencing a functional electrical stimulation leg cycle ergometry (FES-LCE) exercise program for individuals with spinal cord injury (SCI).

Design—This was a prospective descriptive study of screening and habituation for FES-LCE exercise for people with chronic (>1 year) SCI.

Setting—Tertiary rehabilitation centre.

Participants—Thirteen subjects with SCI (mean years since injury, 7; mean age, 34.8 years; injury range, C4 – T10; 7 male).

Interventions—Not applicable.

Main Outcome Measures—Time to attain target cycle speed for 30 continuous minutes.

Results—Six of the thirteen subjects were not eligible to start the FES-LCE habituation program because of previous fragility fracture, excessive spasticity, pain, autonomic dysreflexia, or lack of electrical stimulation response due to lower motor neuron damage in individuals with low thoracic injuries (T11-12). Time to attain target cycle speed for 30 continuous minutes ranged from 30 – 779 minutes (1 – 31 training sessions).

Conclusions—Almost half of the individuals interested in participating in the FES-LCE exercise program did not pass the screening phase. Although the habituation phase was time-consuming for most of the participants who were able to use the FES-LCE, all reported little adverse effects to using the device once they completed this phase of training.

Keywords

Spinal cord injury; rehabilitation; exercise; functional electrical stimulation; cycling; screening; habituation

INTRODUCTION

Although physical activity options for people with SCI are limited, one option for exercise is the functional electrical stimulation leg cycle ergometer (FES-LCE). It provides computerized electrical stimulation to hamstrings, gluteal, and quadriceps muscles to enable active leg cycling at a pre-set cadence (measured in pedal revolutions/minute; rpm). Previous literature highlighting the benefits of FES-LCE, includes increases in muscle mass,^{1, 2} improved cardiovascular fitness,³ and slower rate of bone density loss.⁴ Long term users report decreased pressure sores and pain, allowing them to remain in their wheelchair for extended periods of time.⁵ Furthermore, FES-LCE, like any other exercise, enhances self image, maintains a healthy appearance, and boosts energy levels.⁵

However, not all people with SCI can use the FES-LCE. Potential barriers include insufficient contractile response to electrical stimulation,⁶ intolerable pain in response to the FES, autonomic dysreflexia (AD),⁷ and excessive lower extremity spasticity.^{2, 8} To our knowledge, there has been no clear documentation of the screening procedures used to determine appropriate entry into an FES-LCE exercise program. Previous literature reports medical screening (general physical examinations, x-rays) prior to using the FES-LCE.^{2, 3} Though these tests are a necessary precautionary measure, they do not indicate successful response to the FES-LCE. Because FES-LCE use depends on both physiological health and successful response to the stimulation, a complete screening protocol requires two-steps, eliminating individuals who (a) have known contraindications to FES-LCE use and (b) do not successfully respond to the FES-LCE.

For those who can use FES-LCE regularly, the literature suggests an exercise duration of 30 minutes at a cycling cadence above 35 rpm.^{1, 5} However, many participants are initially unable to maintain 30 minutes of cycling at this speed. Consequently, the need for a pre-training period, or habituation (building tolerance to FES-LCE), has been documented.³ Despite this acknowledgement, the lack of detailed information regarding the procedures or time course of this habituation phase has been noted.¹

Previously documented habituation procedures vary from short preconditioning phases to electrically-induced knee extension training (Table 1). However, documentation is rarely thorough enough to allow replication of the procedure or prediction of the time-course required to attain the target exercise duration and speed. Consequently, there is no established protocol for FES-LCE habituation.

It would benefit clinicians and researchers to clearly document the step-wise process involved prior to initiating an FES-LCE exercise program. Such information could assist the knowledge translation of research findings into practice, thereby facilitating the implementation of this intervention. Therefore, our main objective was to document the

screening and habituation process used prior to a 3-month study of FES-LCE exercise for people with SCI. Specifically, we outlined i) the screening process used prior to trying the FES-LCE, and ii) the protocol used to attain target duration and cycle speed.

METHODS

Participants

All participants met the following criteria: (1) sustained a traumatic SCI, (2) chronic SCI (injury duration >1 year), and (3) able to communicate in English. We excluded participants who had: (1) other neurological conditions in addition to SCI, (2) known unstable cardiovascular disease [i.e., cardiac arrhythmia, high blood pressure (systolic blood pressure >140mmHg; diastolic blood pressure >90 mmHg), (3) unhealed wounds or pressure ulcers, (4) previous history of fragility fracture(s), and/or (5) abnormal bone formations which limited hip or knee range of motion (e.g. heterotropic ossification). No participants had previous experience using FES-LCE. Eligible participants gave written informed consent. The study was approved by local hospital and university research ethics board.

FES-LCE

The cycle training was performed using a computer controlled leg cycle ergometer (Ergys2, Version H.6, Therapeutic Alliances Inc., Ohio, U.S.A). This device provides electrical stimulation using six self-adhesive surface electrodes (Uni-Patch, Wabasha, MN, U.S.A) placed in three areas; (1) quadriceps, (2) hamstrings, and (3) gluteals (Figure 1). A small screen, visible to both the FES-LCE user and the attending researcher, displayed stimulation level, pedaling cadence, and elapsed time. FES-LCE boot pedals, designed to restrict sagittal and transverse plane movements at the ankle, were used by all participants.

The electrical stimulation was applied in a coordinated sequence of muscle contractions that resulted in cycling. The sinusoidal wave pulse was set to 500µsec duration and the stimulation frequency was set to 60 Hz - synchronized for each pair of electrodes. The ergometer was programmed to increase the stimulation current from 0 to 140 milliamps to achieve the desired pedaling cadence. The maximum stimulation current was set on an individual basis, depending on comfort. Threshold settings, used during warm-up and cool-down, were set to palpable muscle contraction in each participant.

Pedaling cadence (rpm) is a frequency range defined by pre-set upper maximum and lower minimum levels. If pedaling cadence approached the upper maximum, the stimulation current would decrease in order to slow down pedaling cadence. If stimulation was at its maximum current and pedal speed dropped below the pre-set lower minimum, the ergometer would automatically stop and go into cool-down mode.

Screening

Participants who met the inclusion and exclusion criteria started on the FES-LCE at the minimum upper and lower cadence levels (32 and 18 rpm, respectively). Participants who (1) did not respond to the FES; or (2) responded to the FES-LCE with: (i) intolerable pain; (ii) severe spasticity upon stimulation (stimulation at the lowest stimulation levels caused an

increase in muscle tone and extensor muscle spasms which prohibited the cycling motion); and/or (iii) severe AD, were excluded from the study. Pain was considered to be intolerable if participants required cessation of stimulation immediately upon use of the FES-LCE at the lowest stimulation levels. Severe AD was defined as that which caused (1) adverse symptoms (e.g. headache/sweating above the neurological level of injury) sufficient for participants to request the cessation of electrical stimulation; and/or (2) a rise in systolic blood pressure to 150 mmHg (or 40 mmHg above baseline). Blood pressure and heart rate were measured prior to exercise, on initial stimulation, and periodically during exercise.

Habituation

All participants were scheduled for three sessions per week at the local rehabilitation centre. Each session started with a one-minute passive warm-up. Stimulation was pulsed between 50% and 100% of the preset threshold setting and the participant manually kept the speed above the pre-set lower cadence by pushing alternately on his/her knees which turned the crankshaft. In cases of higher tetraplegia, the research assistant turned the crankshaft manually. Low stimulation during the passive (i.e. stimulation not sufficient to initiate/maintain leg movement) warm-up and cool down sessions was used to facilitate blood flow in the lower extremities in order to prevent blood pooling and potential hypotension. After the warm-up, stimulation of the leg muscles started and active FES-LCE training continued until the participant could no longer maintain a pedaling cadence above 18 rpm. Once the speed fell below 18 rpm, the working muscles were considered to be fatigued, and the FES-LCE began a two minute cool down mode automatically – in which the stimulation was pulsed between 50% and 100% of the threshold setting and the participant would again push alternatively on his/her knees or the research assistant turned the crankshaft manually to keep the pedaling frequency above the pre-set minimal cadence level. This was followed by a five minute rest period. This warm-up, training, cool-down, and rest cycle constituted one 'run'. The procedure was repeated to a maximum of five runs or 30 minutes of active FES-LCE. Once participants were able to complete 30 minutes of active cycling in one run for two consecutive sessions, the upper and lower bound speeds were increased to the next speed increment and the procedure repeated, until target cadence [maximum 49 rpm, minimum 35 rpm; 49/35 rpm], was reached. We used 4 pre-set increments on the Ergys2 to move from 35/18 rpm to 49/35 rpm (39/21, 42/25, 46/32, 49/35 rpm). If the subject was able to achieve a good muscle contraction with a moderate amount of current with no adverse effects on the first day, a range of speeds were attempted to ascertain the highest speed at which the participant could sustain active pedaling. Stimulation was stopped immediately upon reports of intolerable discomfort/pain or when systolic blood pressure increased more than 40 mmHg above baseline.

RESULTS

Screening

Thirteen people expressed interest in the study (Table 2). Participant 11 had a previous fragility fracture and was excluded; the remaining twelve participants met the initial inclusion criteria and were deemed safe to try the FES-LCE at minimal intensity. Five people were excluded because of insufficient and/or inappropriate response to the FES-LCE.

Participants 8 and 9 did not respond sufficiently to the FES-LCE in order to independently cycle the ergometer. Participant 8 obtained hamstrings and gluteal, but not a quadriceps, response to the stimulation, while Participant 9 had no palpable response to the FES and was unable to move the pedals. Participants 10 and 12 could not pedal the ergometer because the stimulation triggered extreme knee extensor muscle spasms which prevented knee flexion. Participant 12 also exhibited AD as displayed by a spike in systolic blood pressure to 210 mmHg and a severe headache. Participant 13 was unable to cycle because the stimulation caused AD which presented as intolerable head and whole body pain. Thus, seven participants began the habituation training (Figure 2).

Habituation

After one session of the habituation training (no adverse effects noted), Participant 7 withdrew because of the time commitment necessary to complete the exercise program (three sessions per week). The remaining six participants completed the habituation phase of FES-LCE training. Table 3 reports the time course of the exercise sessions (in exercise sessions and minutes), including the time to achieve: 1) 30 minutes of FES-LCE; and 2) 30 continuous minutes of FES-LCE at 35 rpm. A scatter-plot (Figure 3) highlights the positive relationship between length of time to achieve 30 continuous minutes and length of time to achieve 30 continuous minutes at the target cadence (49/35 rpm). The number of sessions to achieve 30 continuous minutes at 49/35 rpm ranged from one to 26 over a time-frame of one day to 23 weeks.

Adverse reactions to the FES-LCE were minimal for those participants who passed the screening phase and were included in the training study (Table 3). Two of the six participants did not experience any adverse reactions. Three participants experienced mild AD (i.e. subjective symptoms not accompanied by large increases in BP). For one, this presented as a mild headache, which subsided naturally as she became accustomed to using the ergometer. For the two others, AD was minimized with a gradual habituation process. In all cases, blood pressure was monitored and stimulation continued at participants' discretion. Participants were scheduled for 3 sessions per week. One subject was able to cycle for the 30 minute duration at 49/35 rpm on the first day, while the other five attended 1.3 – 2.7 times per week.

DISCUSSION

Screening

General Eligibility Criteria—We did not allow one participant to use the FES-LCE due to the presence of a prior fragility fracture. Previous literature has shown that the knee-joint torques during FES cycling may be large enough to produce a fracture in the compromised lower limbs of an individual with SCI⁹ and others have been equally conservative in their exclusion of participants due to a history of bone fracture and/or osteoporosis.^{8, 10, 11}

Response to the FES-LCE

(a) Insufficient response to the FES-LCE: Two of our participants did not respond to the FES sufficiently to independently cycle the ergometer. Successful stimulation of the muscle

for functional purposes requires an intact lower motor neuron (LMN). Although LMN damage is often associated with traumatic injuries occurring at or below the lower thoracic (T10-12) segments, many of these individuals show preserved LMN function.¹² In our study, one of three individuals with low thoracic injuries had a good response to the FES-LCE. Thus, response to the FES-LCE cannot be predicted solely by injury level and should be determined on an individual basis.

(b) Autonomic Dysreflexia: The AD resulting from the FES-LCE was severe enough to stop or modify training in four participants. For two, the presence of severe AD (escalating blood pressure and/or intolerable pain) was apparent within 30–60 seconds of electrical stimulation and required immediate cessation of the machine. Thus, AD prevented further FES-LCE use for these two individuals. For the two others, AD was not as extreme (BP did not reach 40mmHg above baseline and was not accompanied by pain) and subsided with gradual progression of stimulation intensity. These individuals were able to continue FES-LCE habituation with careful monitoring and progression. Thus, although AD does not necessarily prevent FES-LCE use, its presence cannot be ignored (regardless of subjective symptoms) and must be monitored closely.

Habituation

The time duration to reach 30 minutes at 35 rpm was variable between participants, but was as long as 31 sessions (778 minutes) over 23 weeks. This time frame, while similar to other habituation phases,^{16, 8, 13} was notably lengthy.

The major problem limiting exercise training, particularly when beginning FES, is rapid muscle fatigue. Though some state FES knee extension training is a necessary antecedent to FES-LCE due to limited lower extremity strength,⁶ others have found no relationship between this training and ability to obtain a continuous cycling motion on the FES-LCE.³ Muscle fatigue is experienced faster when pedaling the FES-LCE at a high cycling cadence (50rpm) than when pedaling at a slower cadence (15 rpm).¹⁴ Consequently, we started habituation at a low pedal cadence to facilitate longer exercise durations and gradually increased cadence once participants could sustain the cycling motion. In contrast, previous habituation procedures held cadence constant while increasing resistance. Because results from able-bodied individuals suggest that pedaling at higher cadences facilitates muscular endurance and cardiorespiratory fitness,¹⁵ we worked towards the faster target cadence of 35 rpm in order to maximize fitness gains.

Individual reasons contributed to differences in the time to reach the target duration and cadence. Though a previous study of FES-LCE exercise noted no correlation between habituation time and age, sex, or medical history,¹ it appeared that individuals with higher lesion levels required longer habituation phases in our study. Participants 5 and 6 (C4 Asia Impairment Scale (ASIA) B; injury duration: 2.5–3) required long habituation periods (>20 sessions). Other individuals required very gradual increments in stimulation intensity to overcome adverse effects (head-aches, pain at electrode sites). Thus, the habituation protocol should be an individualized process which addresses the needs and reactions of each participant.

The importance of adherence to the scheduled sessions cannot be overlooked. There was a marked division based on level/severity of SCI. Those requiring greater amounts of assistance for daily activities had lower attendance levels. The two individuals with tetraplegia in our study relied on care workers, modified vans, and government-operated accessible transportation service. These participants missed more sessions due to practical problems (transport, care attendant cancellations), sickness, and fatigue, than did the participants with paraplegia.

Feasibility of using the FES-LCE as a rehabilitation tool—Not all participants are able to use this exercise modality. Both clients and rehabilitation professionals should be aware of the time requirements associated with this program.

LIMITATIONS

Our subject pool was small and thus reduces the generalizability of the results. Participants were highly heterogeneous with respect to the duration and neurological classification of their injuries. Despite the small sample size and large diversity in participant demographics, our documented habituation procedures were successful (all subjects were able to complete 30 minutes of cycling at 49/35 rpm). However, a larger sample size would provide more data in order to determine relationships between other variables (e.g. injury duration) and time to habituation.

The low attendance of participants in the present study was not ideal, but represents “real world” barriers to people with SCI who want to participate in treatment interventions at an institution. Similar attendance levels have been noted during long-term studies of FES-LCE exercise.^{3,4,8,6} Although the FES-LCE is a costly purchase, using it as a home device, where transportation to a site is not required, may be a better option for some individuals. Our results show that habituation to the FES-LCE, using the above-mentioned procedures, is possible despite low adherence rates.

CONCLUSIONS

About half of the participants could not pass the screening phase of FES-LCE training, mostly due to inappropriate responses to the electrical stimulation. All individuals who meet the inclusion criteria for FES-LCE use would benefit from trying the device, as response to the stimulation cannot be determined by demographic information (i.e. ASIA classification, duration of injury etc.) The habituation phase can be a time-consuming process and requires individualized protocols to address differences in the response to electrical stimulation. Though mild AD and/or small increases in BP may be experienced by some participants, these issues can be ameliorated by gradual progression of the stimulation intensity, and are not necessarily prohibitive factors to FES-LCE use. The participants in this study reported little adverse effects to using the FES-LCE once they complete the habituation phase of training.

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Figure 1.
Electrode Placement

Figure 2.

Study flow chart. Thirteen individuals volunteered for the study and 6 completed the habituation program.

Figure 3.

Scatter-plot of the time to attain 30 continuous minutes of cycling the FES-LCE at low speed versus the time to attain 30 continuous minutes at the target speed of 49/35 RPM.

Table 1

Summary of previously documented habituation procedures.

Authors	Screening	Habituation
Arnold et al., 1992 ¹⁶	Physical examination including: <ul style="list-style-type: none"> • Radiographs • Spasticity and pressure sore examinations 	<p><u>Phase 1</u> (Leg extension, 1 week – 4 months)</p> <ul style="list-style-type: none"> • Knee extension practice until 45 leg extensions with 5lb ankle weights was completed. <p><u>Phase 2</u> (Cycle ergometer, 1 – 4 months)</p> <ul style="list-style-type: none"> • 1–2 minutes of cycling was gradually increased to 30 minutes cycling at 50 rpm.
Chilibeck et al. 1999 ²	<p><u>Exclusion criteria:</u></p> <ul style="list-style-type: none"> • Pacemakers or uncontrolled heart conditions • Current DVT or pulmonary emboli • Severe AD in response to FES • Less than 90° of hip or knee flexion • Severe lower limb spasticity 	Training began with 1 min, technician-assisted pedaling at 45 rpm. Sessions were unloaded at 50 rpm with a progressive increase in resistance over 8 weeks. Habituation protocol to reach 50 rpm was not reported.
Clark et al. 2006 ¹⁰	<p><u>Exclusion criteria:</u></p> <ul style="list-style-type: none"> • Deteriorating neurological condition • Known osteoporosis • Medical contraindications to exercise <p>Maximal intensity FES tests were performed at quadriceps femoris and anterior tibial motor points to ascertain whether a 30Hz frequency could evoke titanic muscle contractions.</p>	2 week pre-conditioning period. No other details noted.
Cramer et al. 2002 ¹⁷	All subjects had spastic paralysis.	Training was initially unloaded. Load increased by 6W after 15 min of uninterrupted cycling was completed in 2 consecutive sessions. Habituation protocol to attain 15 min of uninterrupted cycling was not described.
Faghri et al., 1989 ¹⁸	Medical examination included: <ul style="list-style-type: none"> • Neurological and psychological evaluations • ECG • Pulmonary function testing • Lower extremity radiographs 	<p><u>Phase 1</u> (Leg extension; 7 wks; 3×30 min sessions/wk)</p> <ul style="list-style-type: none"> • 5 knee extension-flexion cycles/min. Each cycle consisted of 3s concentric + 3s eccentric contraction + 6s rest. Load was increased in 0.5kg increments (from 1.5 to 7kg) once 15 mins of exercise was completed at previous resistance. <p><u>Phase 2</u> (Cycle ergometer; 3×15 min sessions/wk)</p> <ul style="list-style-type: none"> • Subjects pedaled against no resistance at 35–50rpm. Resistance increased by 6W after 15 mins of uninterrupted cycling at previous load.

Authors	Screening	Habituation
Faghri et al., 1992 ¹⁹	Medical examination included: <ul style="list-style-type: none"> Resting ECG (12-lead) and resting BP Chest and lower limb radiographs Fasting blood chemistry and urinalysis Physical and psychological assessments. 	Subjects trained unloaded for the first 3 sessions. Once 30 minutes of continuous exercise was completed in 3 consecutive sessions, load increased by 6W. Habituation protocol to attain 30 min continuous exercise not reported.
Formusek and Davis, 2004 ¹⁴	None noted	All subjects were regular FES-LCE users; thus, no habituation phase was required.
Gerrits et al., 2000 ¹¹	<u>Exclusion criteria:</u> <ul style="list-style-type: none"> Pacemaker or cardiac arrhythmia High BP: SBP>180mmHg; DBP>110mmHg Pressure ulcers Severely reduced hip and/or knee ROM Absence of spinal reflexes Previous bone fractures 	Training began with 1 min, technician-assisted warm-up. Active FES-LCE training ensued until 35 rpm could not be maintained (1 run). A 2 min, technician-assisted cool-down at 45 rpm and a 5 min rest period followed each run. This was repeated until 30 mins of active cycling or 5 runs were completed. Once 30 continuous mins of FES-LCE exercise at 90% of the programmed pedal resistance was completed, resistance increased by 6W.
Goss et al., 1992 ⁶	<u>Exclusion criteria:</u> <ul style="list-style-type: none"> No effective contractile response to FES Uncontrolled cardiovascular conditions Severe spasticity Significant osteoporosis Inadequate ROM in lower extremities 	<p><u>Phase 1</u> (Leg extension, 3–6 weeks, 3 sessions/week)</p> <ul style="list-style-type: none"> Knee extension practice until 30 leg extensions with 2.27kg ankle weights was completed. <p><u>Phase 2</u> (Cycle ergometer, 3 × 30 min session per week)</p> <ul style="list-style-type: none"> Training began with 2 min, technician-assisted warm-up with low stimulation. FES pedaling at 35 rpm ensued with 6W increases in resistance. If 35 rpm could not be maintained, resistance was decreased so 30 min could be completed.
Hooker et al., 1992 ³	Medical examination included: <ul style="list-style-type: none"> Resting ECG (12 lead) and resting BP Chest and lower limb radiographs Fasting blood chemistry and urinalysis Physical and psychological assessments. 	<ul style="list-style-type: none"> 7 subjects completed knee extension training and FES-LCE habituation. Neither protocol was reported. 11 subjects had minimal exposure to graded knee stimulation and FES-LCE habituation sessions. All subjects continued habituation until 5 mins of unloaded FES-LCE cycling was completed.
Mohr et al., 1997 ¹	None reported.	Baseline measurements were taken 5 mins of continuous exercise was sustained (time: 3–50 weeks). Habituation protocol not reported.
Mutton et al., 1997 ¹³	Medical examination included: <ul style="list-style-type: none"> 12-lead resting ECG 	Training began/ended with 2 min, technician-assisted pedalling. Unloaded FES pedaling ensued until 35rpm could not be maintained. 2 min rest periods were taken between exercise bouts. Exercise duration progressively increased until 2 30-min sessions of unloaded FES cycling was completed (8 weeks).

Authors	Screening	Habituation
	<ul style="list-style-type: none"> • Arm ergometer stress test with ECG • Blood chemistry and urinalysis • X-rays of the chest, spine, and lower limbs 	
Pollack et al., 1989 ²⁰	<p><u>Inclusion criteria:</u></p> <ul style="list-style-type: none"> • Neurologically stable, motor complete lesions • No joint deformities or severe osteoporosis (determined by radiographic examination) • Normal range of motion in knees and hips • Able to perform 5 consecutive FES leg lifts 	<p><u>Phase 1</u> (Leg extension)</p> <ul style="list-style-type: none"> • Knee extension practice until 45 leg extensions with 3lb ankle weights through 75% of available ROM <p><u>Phase 2</u> (Cycle ergometry)</p> <ul style="list-style-type: none"> • Cycling resistance alternated between 0W and 6W for 6 × (2 min exercise+2 min rest). This phase ended once 5 non-stop mins of unloaded pedaling was completed.
Scremin et al., 1999 ⁸	<p><u>Exclusion criteria:</u> (excluded 12 subjects)</p> <ul style="list-style-type: none"> • Pacemakers or cardiovascular disease • Unhealed leg fracture or extreme osteoporosis with history of fracture • History of hip/knee dislocation/subluxation • Presence of plates/screws/pins in femurs • Poorly controlled AD or active HO • Severe uncontrollable leg spasticity • Pressure sores in treatment areas • Acute medical intercurrent • Recent history of alcohol abuse • Moderate to severe pulmonary disease 	<p><u>Phase 1</u> (Leg extension, 7.5 weeks)</p> <ul style="list-style-type: none"> • Knee extension practice until 45 leg extensions with 3–5lb ankle weights. Treatment began without load and increased by 1lb after completion of 45 extensions in 2 consecutive sessions. <p><u>Phase 2</u> (Cycle ergometry, 8.9 weeks)</p> <ul style="list-style-type: none"> • Unloaded cycling sessions increased progressively until 30 continuous mins were achieved in 2 consecutive sessions.

(DVT-deep vein thrombosis; AD-autonomic dysreflexia; FES-functional electrical stimulation; ECG-electrocardiogram; SBP/DBP-systolic/diastolic blood pressure; ROM-range of motion; HO-heterotrophic ossification)

Demographic information for participants who undertook a screening assessment of the FES-LCE. There were no significant differences between those participants who were included and those who were excluded in this study. The table highlights the participants who were excluded prior to commencing the habituation phase (n=6).

TABLE 2

Participant #	Sex	Age	Injury Level	Years since injury	ASIA	Included in Study
1	F	29	T4	14	A	Yes
2	M	40	T10	8	A	Yes
3	M	29	T3	1.5	B	Yes
4	F	51	T7	16	C	Yes
5	F	19	C4	2.5	B	Yes
6	F	29	C4	3	B	Yes
7	M	37	C4	3	B	Yes
Reason for Exclusion						
8	M	26	T11	2.5	A	Insufficient response to FES
9	M	26	T11	5	B	Insufficient response to FES
10	M	51	T3	33	A	Muscle spasms
11	M	35	C5	15	B	Previous fragility fracture
12	F	47	C6	3.5	B	Autonomic dysreflexia and muscle spasms
13	F	34	C6	10	A	Autonomic dysreflexia (presenting as intolerable pain)

TABLE 3

Description of participants' response to FES-LCE.

Participant No.	Number of Sessions to 30 Continuous Minutes	Cumulative Time (in minutes) to 30 Continuous Minutes	Number of Sessions to 30 Continuous Minutes above 35 RPM	Cumulative Time (in minutes) to 30 Continuous Minutes above 35 RPM	Duration of Habituation *	Adverse Reactions to FES-cycle training
1	6	98	15	368	5.5 weeks	Mild headache on first 4 sessions
2	6	113	13	321	7 weeks	None
3	1	30	1	30	1 day	None
4	3	65	13	365	10 weeks	Pain at the site of the electrodes which was eliminated with a low current amplitude and a very gradual increase over the sessions
5	11	205	23	566	18 weeks	Experienced dysreflexia as mild sweating and uncomfortable sensations, but stable blood pressure. A very gradual habituation was required to minimize the dysreflexia
6	13	219	31	778	23 weeks	Mild hypotension following the last 6 sessions which had increased workload and had to rest for 10 minutes following the FES.

* Includes Cumulative Training and Non-training days.