Challenges of a Longitudinal Clinical Study on Early FES Cycling After Acute Spinal Cord Injury

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BACKGROUND

Functional Electrical Stimulation (FES) cycling is an activity-based therapy that can promote neurorecovery[1-3] and reverse muscle atrophy[4] in individuals with chronic spinal cord injury (SCI; ≥ 1-year post-injury), but little is known about its effects in acute SCI (< 1-year post-injury)[5-9].

OBJECTIVES

To determine the optimal study design for a future clinical trial, investigating the effect of early FES cycling and to evaluate the feasibility of retaining participants for a 6-month study.

METHODS: PARTICIPANTS

INCLUSION CRITERIA

- 18 - 80 years old
- Traumatic or non-traumatic SCI with acute onset
- Able to start FES Cycling 14-21 days post SCI
- At any neurological level of injury: para-, tetraplegia
- Complete or incomplete: American Spinal Injury Association Impairment Scale (AIS) A, B, C, D
- Medically stable

EXCLUSION CRITERIA

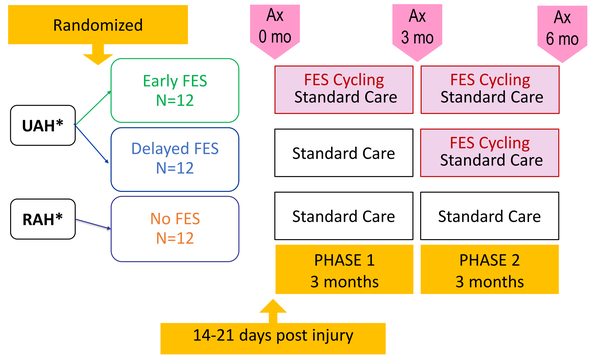
- Lower motor neuron injury with no contraction with FES
- AIS D who can walk without assistive device
- Unstable fractures (spine, lower extremities, pelvis)
- Pregnancy
- Unable to give consent

MAIN OUTCOME MEASURES

1. Clinical Assessment ➲ Neurorecovery & Neuromuscular preservation
   [Muscle strength & Sensation; Leg circumferences & skinfolds; Spasticity (modified Ashworth scale); Pain assessment (International SCI Pain Basic Data Set); Walking (6-min & 10-meter walking test, & Walking Index for SCI-2]
2. Electrophysiology ➲ Neurorecovery & Neuromuscular preservation
   [Corticospinal excitability; Spinal excitability; Spasticity]
3. Imaging (CT scan) ➲ Neuromuscular preservation
   [Muscle/Fat cross sectional area (calf, thigh, buttocks & abdomen; Bone density]

STUDY DESIGN

- Randomized design with 2 phases: 0-3 and 3-6 months after enrollment.
- Participants are randomly allocated into 3 groups: control, early and delayed FES group.



Standard Care: Physical, Occupational & Recreational therapy provided at the hospital.

Figure 1: Experimental design. Abbreviations: UAH, University of Alberta Hospital; RAH, Royal Alexandra Hospital; Ax, Assessment; mo, months.

INTERVENTION: FES CYCLING

- RT300 Supine (Fig. 2) or SLSA bike (Fig. 3) (Restorative Therapies, Baltimore, MD, USA)
- Stimulating 3-5 leg muscle groups
- 15-45 min/session
- 3 days/week
- Pulse width: ≥ 300 µs; Frequency: 40 Hz
- Stimulation amplitude: As tolerated and deemed appropriate for level of recovery

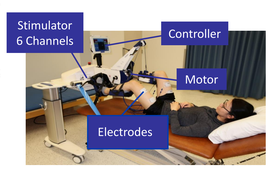


Figure 3. RT300 SLSA FES Bike

Figure 2. RT300 Supine FES Bike

RESULTS

- 39 participants (47.8±17.7 years old) were consented and allocated to a group.
- Two were approached but declined consent because they were overwhelmed.
- Eight out of 15 who completed the study were AIS A, while 14 out of 21 who dropped out were AIS C or D.
- Five participants with AIS D dropped out of the delayed-FES group and are willing to stay as controls, as their motor function at 3 months had improved substantially.
- Only one participants was willing to be assigned to a control.

AIS	A	B	C	D	Total N
Control	0	0	0	1	1
Early FES	7	3	7	2	19
Delayed FES	8	1	3	7	19

Table 1: Overview of participants group allocations based on the AIS classification.

AIS	A	B	C	D	Total N
Completed 6M	8	3	1	3	15
Drop Out	5	1	9	4	19
Switch to Control	1	0	0	5 (2 drop out)	6 (2 drop out)

Table 2: Overview of study completion and group allocation switch based on the AIS classification

Timeline	0M	3M	6M
Control	7	6	5
Early FES	17	14	8
Delayed FES	11	9	6
Drop Out	4	10 (4+6)	19 (4+6+9)
In Progress	0	0	1

Table 3: Completion of the project based on phases.

Reasons for Drop Out (N=19)	
Medical issues	4
Medically unstable	1
Language barrier	1
Lost interest	1
Can't reach	4
Lives too far	7
Can't come to the lab	1
Reasons for Switching to Control (N=6)	
Medically unstable (Early → Control)	1
Significant Functional improvement (Delayed → Control)	5

Table 4: Reason for leaving the project and group switch.

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CONCLUSION

Individuals must be motivated and have a good support system to come in for FES cycling 3x/week after discharge from hospital. Most people refused to be assigned to the control group. Starting FES cycling at an early stage of injury can pose challenges for some participants due to their acute medical condition and emotional state. Retaining individuals with AIS C and D for a 6-month study proved challenging.