

Cycle Pilot Rct: A Multicenter Feasibility Study Of Early In-Bed Cycling Versus Routine Physiotherapy In Medical-Surgical Ventilated Patients

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Rationale: Acute rehabilitation in critically ill patients can improve physical function. A single-center, 90-patient randomized control trial (RCT) of in-bed cycling started 2 weeks after intensive care unit (ICU) admission improved patients' 6-minute walk test at hospital discharge. The effects of starting in-bed cycling earlier in a patient's ICU stay are unknown.

Methods: We conducted a pilot RCT in 7 Canadian medical-surgical ICUs to determine the feasibility of a future large trial. We included patients within the first 4 days of invasive mechanical ventilation who could ambulate independently before ICU admission. We engaged over 35 front-line ICU physiotherapists to conduct in-bed cycling sessions. Following informed consent, patients underwent concealed randomization to either 30 minutes of in-bed cycling and routine physiotherapy or routine physiotherapy alone for 5 days per week, until ICU discharge. Feasibility outcomes included: 1) Accrual of 1-2 patients/month/site; 2) >80% cycling protocol delivery; 3) \geq 80% outcomes measured; 4) \geq 80% outcome measures blinded at hospital discharge. For items (3) and (4), we report our candidate primary outcome for the main trial (Physical Function ICU Test-scored [PFIT-s]). Clinicaltrials.gov: NCT02377830. Protocol: BMJ Open.2016.6:e011659.

Results: Between 3/2015 and 6/2016, we randomized 66 patients (36 to cycling). Our consent rate was 84.6% (66/78). Patients were 39.4% (n=26) female, had a mean (SD) APACHE II score of 23.5 (8.6) and 78.8% (n=52) had a medical ICU admission diagnosis. The time to first cycling was 3.6 (1.9) days, and 94.4% (34/36) of patients received at least 1 cycling session. The aggregate median (interquartile range) ICU and hospital length of stay was 11.5 (8-25) and 25.5 (15-46) days, respectively. The overall mortality in ICU and hospital was 25.8%(17/66) and 33.3% (22/66), respectively. Feasibility outcomes: 1) Mean patient accrual was 1.0 (0.3) patients/month/site, however sites reported missed opportunities to enroll patients due to limited physiotherapist capacity to manage multiple clinical trial patients concurrently. 2) Cycling occurred in 73.7% (146/198) of eligible sessions. Persistent tachycardia resulted in early termination of 1 cycling session. No control patients underwent cycling. 3) For patients alive at hospital discharge, the PFIT-s occurred in 86.4% (38/44). 4) Of these measures, assessors conducted 81.6% (31/38) outcomes blinded to treatment allocation.

Conclusions: In 7 Canadian ICUs, we documented the feasibility of conducting an RCT of early in-bed cycling led by ICU physiotherapists. Before embarking on a larger trial of in-bed cycling, augmented or additional strategies are needed to optimize recruitment and cycling delivery.

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