Early Exercise in Critically Ill Youth and Children, a Preliminary Evaluation: The wEECYCLE Pilot Trial

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Objectives: To determine the feasibility of conducting a full trial evaluating the efficacy of early mobilization using in-bed cycling as an adjunct to physiotherapy, on functional outcomes in critically ill children.

Design: Single center, pilot, randomized controlled trial.

Setting: Twelve-bed tertiary care, medical-surgical PICU at McMaster Children's Hospital, Hamilton, ON, Canada.

Patients: Children 3–17 years old who were limited to bed-rest with an expected PICU stay of at least 48 hours. Patients were excluded if they were at their baseline level of function, already mobilizing out of bed or expected to do so within 24 hours.

Interventions: Patients were randomized in a 2:1 ratio to early mobilization using in-bed cycling in addition to usual care physiotherapy (cycling arm) or to usual care physiotherapy alone (control). Usual care was according to institutional practice guidelines. The primary outcome was feasibility and safety.

Measurements and Main Results: Thirty patients were enrolled (20 to the cycling and 10 to control) over a 12-month period, at a 93.7% consent rate. The median (interquartile range) time from PICU admission to mobilization was 1.5 days (1–3) in the cycling arm and 2.5 days (2–7) in the control arm. Total duration of mobilization therapy in PICU was 210 (152–380) and 136 minutes (42–314 min) in cycling and control arms, respectively. Total number of PICU days mobilized was 5.0 (3–6) with cycling and 2.5 (2–4.8) with usual care. No adverse events occurred in either arm. The main threat to feasibility of mobilization was the availability of physiotherapists or research personnel.

Conclusions: Early mobilization is safe and feasible in the PICU. In-bed cycling may facilitate greater duration and intensity of mobilization, in critically ill children. A full-scale randomized controlled trial is warranted to evaluate the efficacy of this intervention on PICU-acquired morbidities and functional outcomes in this population. (*Pediatr Crit Care Med* 2017; XX:00–00)

Key Words: critical illness; early mobilization; in-bed cycling; pediatrics; rehabilitation

Critically ill patients are often confined to bed and immobilized for concerns of safety and severity of illness (1). The combination of critical illness and immobility can result in significant muscle wasting due to potential synergistic effects of systemic inflammation, and the interventions imposed during critical illness such as sedatives, corticosteroids, and neuromuscular blocking agents (2). Prolonged immobility increases the risk of critical illness-acquired morbidities such as ICU-acquired weakness, delirium and sedation withdrawal, which in turn negatively impact on a patient's duration of mechanical ventilatory support, length of stay, and even mortality (3).These sequelae can adversely affect a child's functional outcome and health-related quality of life long after they leave the PICU (4, 5).

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Current evidence suggests that early mobility-based rehabilitation in critically ill adults can attenuate the complications of immobility and critical illness-acquired morbidities (6, 7). Early mobilization (EM) may reduce the risk of delirium, improve functional recovery, and reduce overall resource utilization in adult ICUs (8). To date, there are prospective studies demonstrating that EM is feasible and safe (9); however, it remains unclear whether this intervention is effective in improving PICU and longer term functional outcomes in critically ill children. The objective of this pilot randomized controlled trial (RCT) was to evaluate the feasibility of conducting a full trial evaluating the efficacy of EM using in-bed cycling as an adjunct to physiotherapy, on functional recovery in critically ill children. We hypothesized the following: (1) institutional guidelines for mobilizing critically ill children facilitates safe, early mobility-based rehabilitation and (2) in-bed cycling can enhance mobilization in critically ill children. The rationale for evaluating these hypotheses in a pilot RCT was to determine the feasibility of enrolling and adhering to a research protocol for the control and cycling arms in an open-label trial.

METHODS

Setting

This single center, pilot RCT was conducted from September 2015 to October 2016, in the PICU at McMaster Children's Hospital, Hamilton, ON, Canada. The trial protocol was approved by the Hamilton Integrated Research Ethics Board. Participants were screened by research personnel, and informed consent and assent where appropriate was obtained from the participants or their substituted decision-makers. This study was registered at ClinicalTrials.gov prior to patient enrollment (NCT02358577).

Participants

Children 3–17 years old were eligible if they were limited to bedrest or not being mobilized at the time of screening, and expected to stay in the PICU for an additional 48 hours. Patients were excluded if they were at their baseline level of function, already mobilizing out of bed, or expected to do so within the next 24 hours. Those in whom death was imminent (i.e., expected in the next 72 hr as judged by the PICU consultant) were excluded. Children were also excluded if there were physical or anatomical restrictions to fitting the cycle ergometer (e.g., due to limb length, amputation, musculoskeletal injuries, or fixed or spastic deformities in the limbs). Patients with clinical contraindications to mobilization present at time of screening (**Supplemental Appendix**, Supplemental Digital Content 1, http://links.lww.com/PCC/A529) continued to be screened daily until the contraindications resolved. We limited enrollment in this pilot RCT to one participant at a time, given the availability of only one cycle ergometer and limited research personnel.

Intervention

Using a computer-generated sequence, participants were randomly assigned in a 2:1 ratio, to the in-bed cycling arm in addition to usual care physiotherapy (cycling arm) or to usual care physiotherapy alone (control). The rationale for the higher assignment into the cycling arm was to assess the feasibility of cycling in accordance to our stated primary objective, without hindering the ability to deliver usual care physiotherapy in both arms. Although allocation was concealed, because of the nature of the intervention, the investigators, healthcare providers, participants, and substitute decision-makers were aware of the study-group assignments. Both treatment arms received usual medical and nursing care in PICU as deemed appropriate.

Usual Care–EM Guidelines

Participants in both arms were assessed as possible after PICU admission, and mobilized as deemed appropriate by the PICU physiotherapist and occupational therapist, in accordance with our institutional practice guidelines (Supplemental Appendix, Supplemental Digital Content 1, http://links.lww.com/PCC/A529). These guidelines clearly outline what therapies constitute mobilization and are based on the consensus (10). EM was defined as mobility therapy that occurred as soon as it was safe in the absence of contraindications, according to systems-based clinical criteria (Supplemental Appendix, Supplemental Digital Content 1, http://links.lww.com/PCC/A529). Contraindications to mobilization limited activity to bed repositioning, passive range of motion and chest physiotherapy (i.e., nonmobility therapies) only. In the absence of contraindications, participants were mobilized at increasing levels, according to individualized daily goals, the level of assistance required, and the presence or absence of precautions, to achieve functional mobility (10). Functional mobility for each child was determined by the physiotherapist and/or occupational therapist. Both arms observed the following predetermined safety criteria for interrupting or aborting mobilization activities: (1) cardiorespiratory instability, defined by persistent desaturation less than 88% despite increase in F_{IO_2}, persistent tachycardia, bradycardia, or hypotension for age (11), 25% increase in mean blood pressure from baseline, or new onset arrhythmia; (2) increase work of breathing: new onset/increase in accessory muscle use, air entry, stridor, or wheezing tachypnea (e.g., Pediatric Respiratory Assessment Measure score increase by more than two points from baseline); (3) pain or discomfort that cannot be resolved with concurrent administration of analgesia; and (4) patient refusal.

Cycling Arm

In-bed cycling was applied 5 days a week (on weekdays) using a cycle ergometer (RT300 Supine Cycle Ergometer; Restorative Therapies, Baltimore, MD). This cycle ergometer is designed for pediatric use and can be applied to facilitate lower or upper limb cycling. Cycling could be instituted passively or actively. Following consent, each participant was assessed by the physiotherapist to ensure the appropriate fit and prescription of in-bed cycling for each individual patient. The cycle ergometer was applied by a trained physiotherapist (H.C.) and/or investigator (K.C., S.A., A.K.). Lower limb cycling was the preference,

unless there is a contraindication to using the lower limbs, in which case, the upper limbs were used. Cycling was applied for 30 minutes a day, 5 days a week (during weekdays) in addition to usual care physical therapy, until the physiotherapist determined that the patient was ready for an increased level of mobility beyond the bed, and/or the patient achieved functional mobility for 2 consecutive days, or a maximum of 7 days of cycling was completed.

Outcomes of Interest

The primary outcome for this pilot study was feasibility as defined by (1) the ability to enroll at least 75% of eligible patients, (2) an accrual rate of one to two patients per month, and (3) a 30-day follow-up rate of over 75%. Coprimary outcomes included the time to mobilization and adverse events related to mobilization. Secondary outcomes of interest included the following: (1) Clinical outcomes: risk of PICU-acquired morbidities (e.g., PICU-acquired weakness, pressure ulceration, delirium; and joint contractures), duration of mechanical ventilation, length of PICU and hospital stay, PICU and 30-day mortality. (2) Functional outcome as measured by the Pediatric Evaluation of Disability Inventory-Computer Adaptive Test (PEDI-CAT) Speedy version (12), at enrollment time (preadmission function), PICU discharge, and 1 month post PICU discharge. The PEDI-CAT is an interview administered, valid, and responsive outcome functional outcome measure that can be used from birth through 20 years old. It measures functional skills in four domains: daily activities, mobility, social/cognitive ability, and responsibility (13). The Speedy (Precision) version provides an efficient CAT score while maintaining precision. The PEDI-CAT takes 10–20 minutes to complete and was administered by the same trained research assistance at each time point, through parent-proxy and/or patient interview where possible.

Sample Size

The sample size was based on feasibility considerations (14). Using basic rules of thumb recommended for justifying sample sizes for pilot studies (15), we estimated that a minimum of 30 participants (i.e., 20 participants in the cycling arm and 10 participants in the control arm) were necessary to inform our feasibility and safety objectives and to inform the future sample size of a larger trial.

Data Analysis

The reporting of the pilot trial is done in accordance with the recommended CONSORT extension guideline for pilot trials (16). Data were analyzed using the intention-to-treat principle.

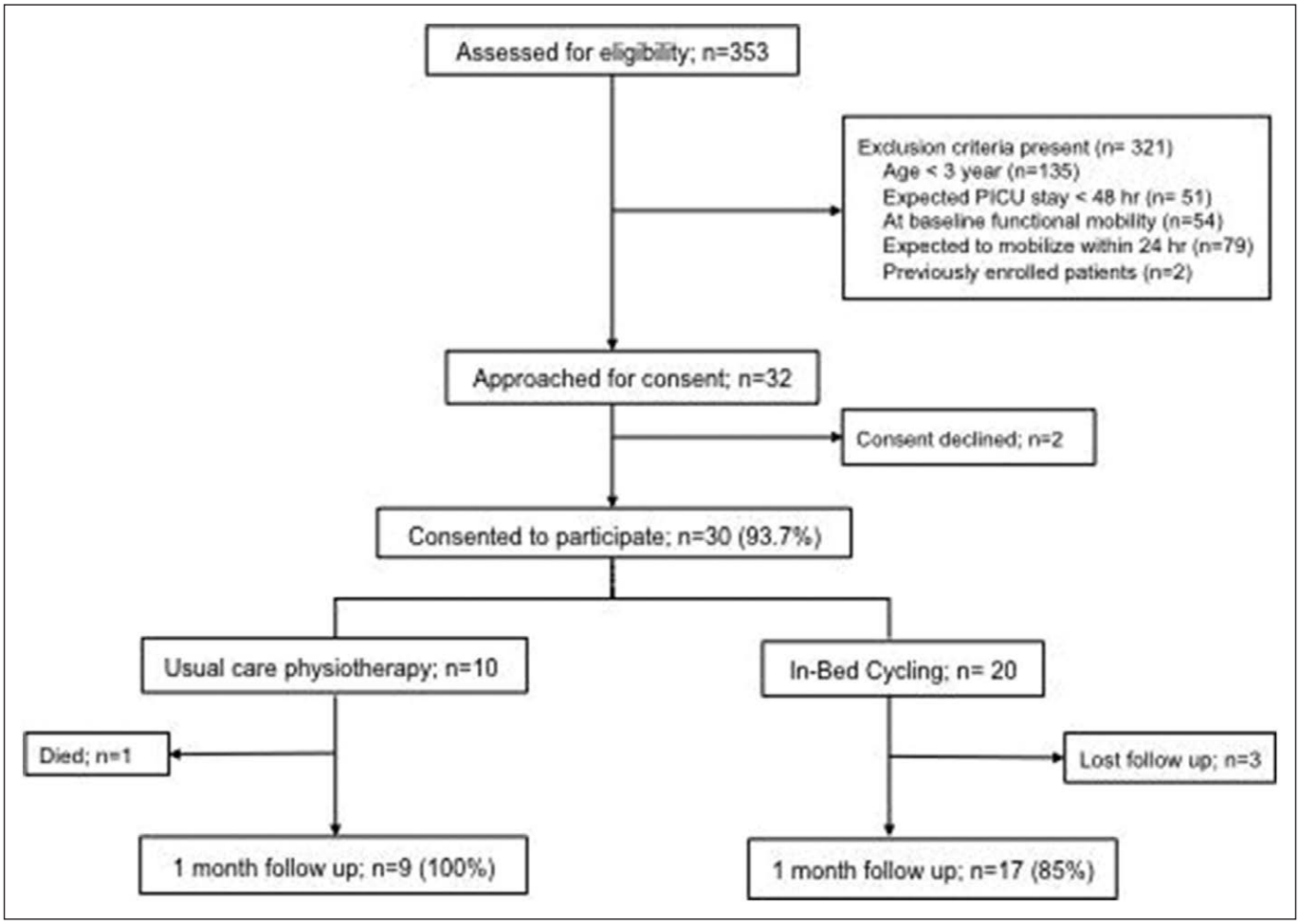

Figure 1. Flow diagram of patient enrollment, randomization, and follow-up.

TABLE 1. Baseline Demographics

Demographic Variable	Usual Care ($n = 10$)	In-Bed Cycling ($n = 20$)
Age (yr)	9 (6–11)	8 (5–14)
Weight (kg)	27.5 (17.1–34.0)	23.8 (20.4–46.8)
Primary reason for admission, *n* (%)		
Respiratory failure (including respiratory tract infections)	4 (40)	13 (65)
Sepsis/septic shock	2 (20)	
Surgery	2 (20)	2 (10)
Neurologic	1 (10)	1 (5)
Trauma		1 (5)
Cardiac		1 (5)
Other[a]	1 (10)	2 (10)
Severity of illness scores at admission		
Pediatric Risk of Mortality III[b]	10 (7–16)	8 (6–13)
Pediatric Logistic Organ Dysfunction score[c]	5 (3–6)	3 (0–7)
Pediatric Cerebral Performance Category score[d]	2 (1–3)	1 (1–3)
Pediatric Overall Performance Category score[d]	2 (1–3)	1 (1–2)
Baseline function (Pediatric Evaluation of Disability Inventory-Computer Adaptive Test[e] score prior to critical illness)		
Daily activities	57 (51–60)	56 (49–62)
Mobility	64 (54–68)	63 (48–67)
Social/cognitive ability	65 (62–69)	64 (58–71)
Responsibility	48 (41–52)	48 (36–56)

All results are presented as median (interquartile range) unless otherwise indicated.

[a]Other: endocrine, renal failure, malignancy.

[b]Pediatric Risk of Mortality Score, third generation; based on the first 12 hr of PICU stay (range, 0–74) (41).

[c]Pediatric Logistic Organ Dysfunction-2 score (range, 0–33) (42).

[d]Range for Pediatric Overall Performance Category and Pediatric Cerebral Performance Category scores are 1–7 from 1 = normal, increasing scores indicating increasing disability, 6 = brain death, or 7 = cardiorespiratory death (43).

[e]Pediatric Evaluation of Disability Inventory-Computer Adaptive Test, Scaled score (12, 17–19).

Descriptive statistics were used for reporting baseline characteristics and feasibility outcomes, using count (%) for dichotomous variables and the mean (SD) or median (interquartile range [IQR] [first quartile (Q1) to third quartile (Q3)]) as appropriate for continuous variables. The period of time that the patient was mobilized per day in each study arm was measured in minutes. We agreed a priori not to explore comparisons on outcomes between groups in this pilot RCT.

RESULTS

A total of 30 patients were enrolled into this RCT between October 2015 and October 2016, 20 in the cycling arm and 10 in the control arm (**Fig. 1**). Our consent rate was 93.7%, and the overall 1-month follow-up rate was 86.7%. The baseline demographics of the participants are presented in **Table 1**. Twenty-one (70%) of patients had a preexisting chronic condition. The median (IQR) time from PICU admission to randomization was 2 days (1–4 d).

Feasibility of EM and In-Bed Cycling

The median (IQR) time from PICU admission to mobilization in the entire cohort was 2 days (1–4 d), 2.5 days (2–7 d) in the control arm and 1.5 days (1–3 d) in the cycling arm. The median time from randomization to applying mobility physiotherapy and in-bed cycling was 2.3 (1–20) and 2.5 hours (0.9–11 hr), respectively; 23 patients (77%) were mobilized within 72 hours of admission, six (60%) in the control and 17 (85%) in the cycling arm. The remaining seven patients (23%) could not be mobilized early because of the presence of contraindications, in accordance with the guidelines. **Figure 2** displays patients mobilizing in both the control and cycling arms. The feasibility of mobilization and reasons why mobilization could not occur during the study period are outlined in **Table 2**. In both arms, 39% of planned physiotherapy and cycling sessions, respectively, were not conducted most commonly because of unavailability of the physiotherapist, or research personnel to apply the cycle ergometer, due to workload. Patients or parents refused a total of three physiotherapy (3%) and eight cycling sessions (22.8%). In the cycling arm, parent refusals were related to emotional distress (one parent upset as approached for tracheostomy and another was upset that the child required escalation in respiratory support) and concern that the child was tired due to a lack of sleep ($n = 1$). Parents refused physiotherapy because of emotional distress ($n = 1$) and perception that their child was in pain ($n = 1$). Patients declined cycling because of concurrent pain ($n = 4$), or no reason given ($n = 1$), and declined physiotherapy because of delirium ($n = 1$). Of a total of 340 planned physiotherapy and cycling sessions, mobilization was withheld in 24 (7%), due to contraindications. **Figure 3** displays the duration of mobilization in each study arm on each PICU stay. The duration of mobilization during the PICU stay is presented in Table 2. Median cycle ergometer set up time was 16.5 minutes (10–26.5 min). Participants in the cycling arm cycled for a median of 2 days (min 1, max 6 d). The main reason that cycling intervention was discontinued was that functional mobility was achieved for 2 consecutive days, per protocol. Cycling was conducted beyond the PICU in only one patient. There were no interruptions to mobilization or cycling for safety criteria, nor were there any adverse events

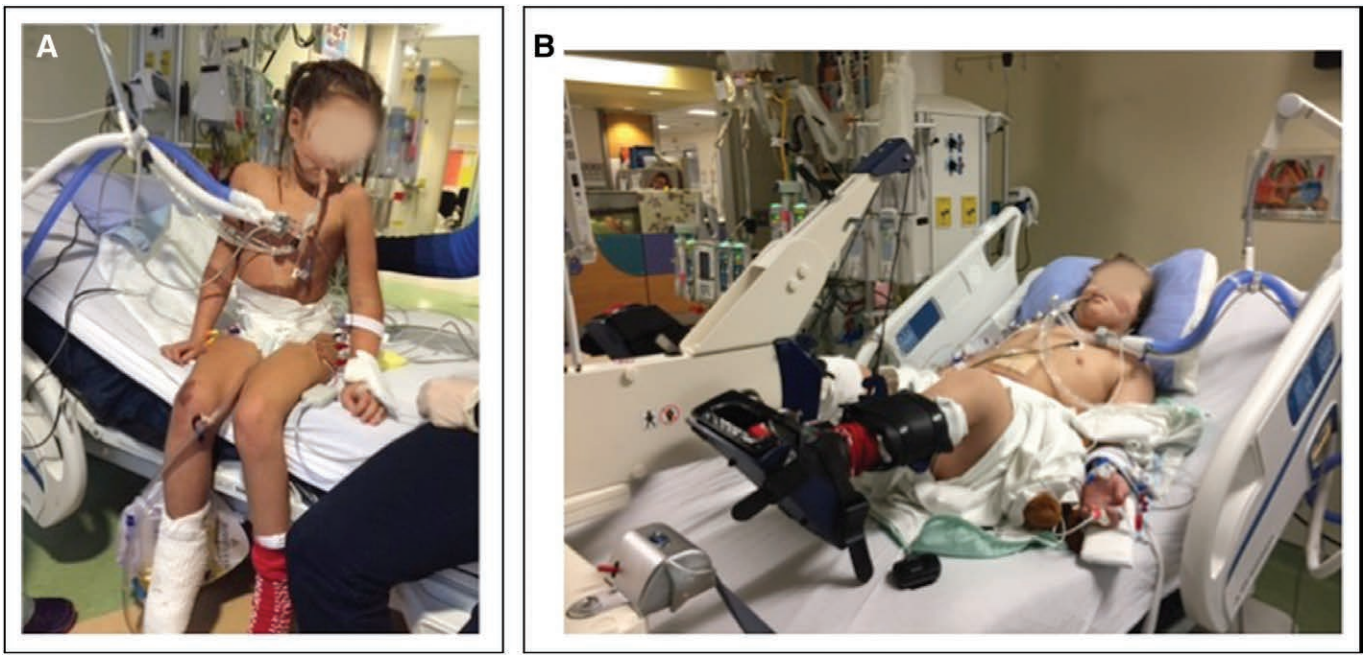

Figure 2. (**A**) Mobilization, usual care arm. (**B**) In-bed cycling (RT300, pediatric version; Restorative Therapies, Baltimore, MD). Images have been provided with patient/substitute decision-maker's consent.

TABLE 2. Feasibility and Duration of Mobilization

Feasibility of Mobilization	Mobility Physical Therapy (Both Arms)	In-Bed Cycling
Total no. of planned sessions	249	91
No. of missed sessions, *n* (% of planned sessions)	97 (38.9)	35 (38.5)
Reasons of missed sessions, *n* (%)		
Physiotherapist/research personnel	80 (82.5)	17 (48.5)
Not available		
Contraindications present, *n* (%)	14 (14.4)	10 (28.5)
Parent refusal	2 (2)	3 (8.5)
Patient refusal	1 (1)	5 (14.5)

Mobilization	Usual Care (*n* = 10)	In-Bed Cycling (*n* = 20)	Mean Difference (95% CI)
Duration of mobilization (min), median (Q1, Q3)			
Total during PICU stay	136 (42, 314)	210 (152, 380)	73 (–116 to 262)
Per day of PICU stay	18 (5, 31)	26 (17, 50)	6 (–28 to 40)
Total no. of PICU days patient was mobilized	2.5 (2.0–4.8)	5.0 (3–6)	1.4 (–0.2 to 3.0)
Proportion of PICU days patient was mobilized[a]	0.4 (0.3–0.6)	0.6 (0.4–0.7)	0.17 (–0.01 to 0.36)

Concurrent Interventions, *n* (%)	Total, *n* = 6 (60%)	Total, *n* = 20 (100%)
Invasive ventilation	2 (20)	8 (40)
Noninvasive ventilation	3 (30)	13 (65)
Vasoactive infusions	1 (10)	3 (15)
Sedative/analgesic infusions	2 (20)	11 (55)
Neuromuscular blockade	0	3 (15)
Continuous renal replacement therapy	0	1 (3.4)

[a]Number of days patient was mobilized divided by number of days in PICU.

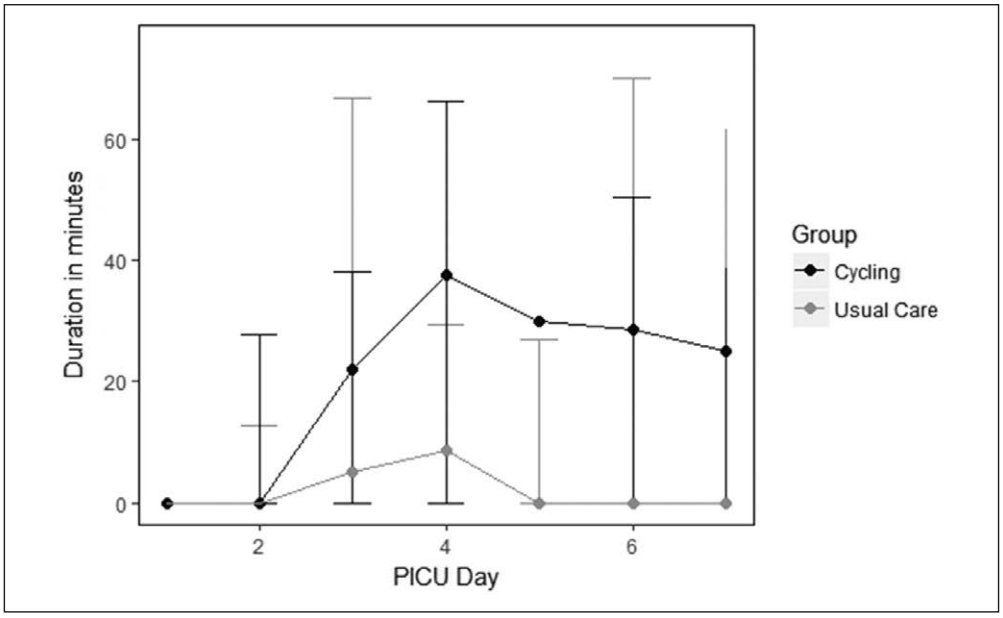

Figure 3. Duration of mobilization in cycling and control arms (median, interquartile range).

during usual care physiotherapy in either arm. Cycling was discontinued prior to 30 minutes in four cases, due to uncooperative patients ($n = 2$, 4 and 5 yr old), pain at chest tube site ($n = 1$), abdominal discomfort attributable to constipation ($n = 1$).

Secondary Outcomes

The clinical and functional outcomes for the entire cohort are presented in **Table 3**. Twenty-four patients (80%) developed newly acquired functional deterioration at PICU discharge, as measured by the PEDI-CAT; seven (70%) in the usual care arm and 17 (85%) in the cycling arm. **Figure 4** displays the functional outcome trajectory from baseline to PICU discharge and at 1-month follow-up. Only three (10%) of patients achieved full functional recovery in all domains at 1 month. Mobility seemed to be more affected than the other functional domains and slowest to recover in this cohort (Table 3).

DISCUSSION

This pilot RCT is the first to our knowledge to prospectively evaluate the use of in-bed cycling to facilitate EM in critically ill children. Our successful enrollment and retention rates at follow-up, and our ability to apply the intervention in addition

TABLE 3. Secondary Clinical Outcomes

Clinical Outcomes	Whole Cohort ($n = 30$)	
Ventilator-free days at day 30	24.5 (18.0–28.0)	
Duration of mechanical ventilatory support (invasive and/or noninvasive)	6 (2.0–13.0)	
Mortality, *n* (%)		
PICU	1 (3)	
Hospital	1 (3)	
Length of PICU stay	8.0 (5.0–13.8)	
Length of hospital stay	17.5 (8.2–29)	
PICU-acquired morbidities, *n* (%)		
PICU-acquired weakness	1 (3)	
Pressure ulcer (grade ≥ 2)	4 (13)	
Delirium	6 (20)	
Functional outcome (Pediatric Evaluation of Disability Inventory-Computer Adaptive Test[a] mean change scores: 95% CI)	**PICU discharge**	**1 mo**
Daily activities	−5.7 (−8.6 to −2.7)	0.1 (−2.1 to 2.3)
Mobility	−12.0 (−18.0 to −6.1)	−3.1(−6.8 to 0.7)
Social/cognitive ability	−2.3 (−3.8 to −0.7)	0.3 (−1.0 to 1.5)
Responsibility	−2.9 (−5.1 to −0.6)	0.4 (−2.8 to 3.3)

Data are presented in median (interquartile range) unless otherwise indicated.

[a]Pediatric Evaluation of Disability Inventory-Computer Adaptive Test (12), mean change in scaled score from time point to baseline.

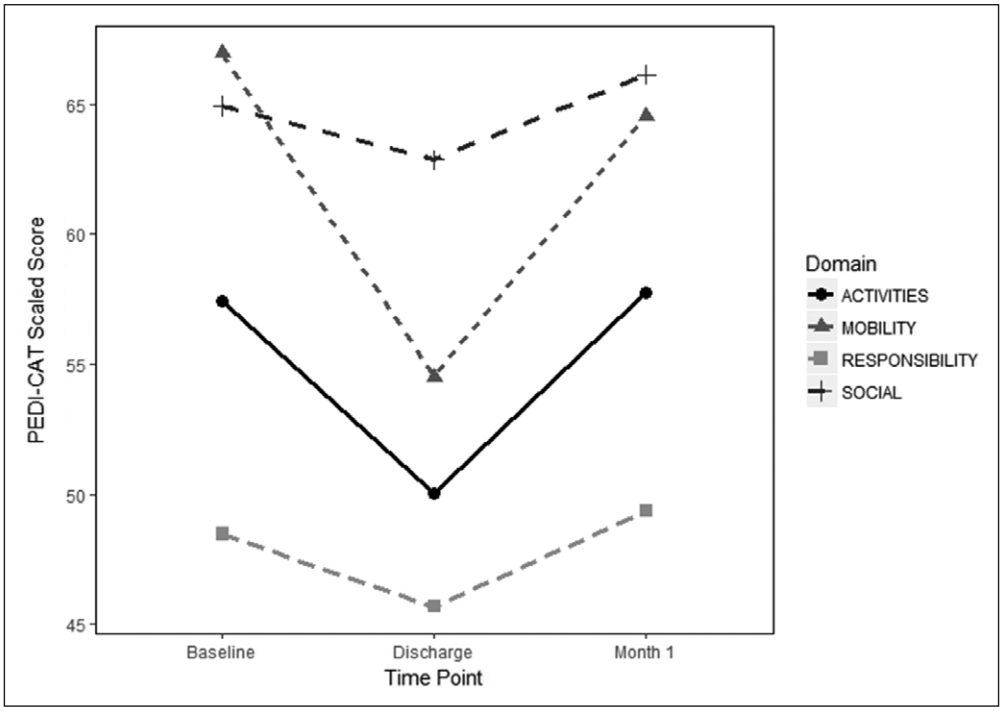

Figure 4. Functional outcomes of participants at baseline, PICU discharge, and 1 mo post PICU discharge. PEDI-CAT = Pediatric Evaluation of Disability Inventory-Computer Adaptive Test.

to usual care physiotherapy, confirm the feasibility of this trial design. We demonstrated that mobilizing critically ill children was safe and feasible with in-bed cycling and physiotherapy, using institutional practice guidelines, and can be executed in the majority of patients within 2 days of PICU admission. Delays in mobilization occurred most commonly for safety reasons, due to the presence of contraindications.

Immobilization during critical illness is common and harmful in both adults and children (20, 21). The associated adverse impact on short-term clinical outcomes, and perhaps more importantly, long-term functional recovery, has let to great interest in mobility-based rehabilitation strategies in critically ill patients (3, 22). There are now at least 14 clinical trials and six systematic reviews on EM in the adult literature (6, 7, 23–26). Earlier reviews suggest that EM decreases length of stay and improves physical function and quality of life (7, 23); however, more recent trials have added controversy due to conflicting results (27, 28). The most recent meta-analysis by Tipping et al (6) found that ICU-based mobilization and rehabilitation improves body function and activity at discharge, improves participation, and may improve quality of life at 6 months. It does not, however, appear to have any effect on patient mortality. The existing evidence in pediatrics is presently limited to a handful of prospective cohort studies which demonstrates that EM is safe and feasible (9, 29, 30). There is therefore a clear need for more pediatric specific evidence.

Our objective for a future trial is to evaluate the efficacy of in-bed cycling as an potential adjunct to rehabilitation. Therefore in this pilot, we chose not to compare early to "late" mobilization given clear evidence of harm in the latter (3, 31), but to institute a best possible standard in both arms, by implementing practice recommendations for EM in critically ill children (10). A coprimary objective of this pilot therefore was to evaluate our ability to safely implement EM. We were able to demonstrate that a minority of mobilization could not be conducted due to contraindications, and that mobilization can occur safely in critically ill children even in the presence of precautions and cointerventions. These data demonstrate that institutional practice guidelines can facilitate timely patient assessments and enables safe mobilization as early as possible in the majority critically ill children—77% our cohort was mobilized within the first 3 days of PICU admission. This is an important finding as the most important barrier to mobilizing critically ill children as reported by clinicians is the lack of institutional practice guidelines (1). These results are similar to the study by Wieczorek et al (32), where 76% children engaged in mobilization by PICU day 3, following implementation of a quality improvement intervention focused on early rehabilitation. This is in great contrast to rehabilitation practices in a multicenter retrospective study published in 2014, where only 9.5% of PICU patients were mobilized early (20). The most appropriate timing to initiate mobility-based rehabilitation in critically ill patients remains unclear. As muscle wasting occurs early and rapidly in critical illness (33), it has been suggested that the benefits of mobilization may be greater with early introduction (7). However, mobilization initiated too early within 24 hours of stroke onset in adults may, in fact, be harmful (34). The adult literature remains vague on the appropriate definition for EM (6). We therefore chose to define early using clinical criteria focused on safety and individualized to patient condition (10), rather than a predefined time, and evaluate the time to mobilization in this pilot in order to inform the design of a future trial.

Current evidence suggests that both the intensity and duration of physical activity are beneficial in healthy children as well as those with chronic health conditions (35). Although 60 minutes of moderate to vigorous activity is recommended in healthy children, the Canadian Pediatric Society recommends a more cautious, individualized approach given the increased risk of injury and exacerbation of illness in children with underlying disease (36, 37). Evidence in critically ill adults suggest that higher dose rehabilitation (i.e., ≥ 30 min a day) may lead to improved quality of life at 6 months within the physical and emotional domains (6). The rationale for in-bed cycling

as an adjunctive method of mobilization in this trial is to optimize the duration and intensity of the delivered intervention. Mobilizing critically ill children is extremely challenging as the majority may not be able to comply with mobilization due to sedation, level of consciousness, or baseline cognitive ability (20, 38); 70% of our cohort had a preexisting chronic condition. In-bed cycling may therefore facilitate mobilization in either a passive or an active manner, leaving the physiotherapist and occupational therapist free to focus on other functional therapies and strengthening exercises for the patient. We selected 30 minutes of cycling in the protocol, based on previous studies of this nature (39); however, in order to be pragmatic, we left the duration of mobilization physiotherapy to the discretion of the physiotherapist.

Strengths and Limitations

The strengths of this trial include (1) it is the first RCT in children designed to test the feasibility of EM and the use of in-bed cycling to facilitate mobilization; (2) it allowed us to evaluate the trial design as well as the resources required to execute what may be considered a complex intervention; and (3) we were able to demonstrate that in-bed cycling may enhance mobilization without impacting on usual care. While allocation was concealed, limitations of this trial include (1) the inability to blind the intervention; (2) the intervention is limited to children large enough to apply cycling, hence excluding toddlers and infants from our study; (3) usual care in this study is not generalizable—we did not compare EM to "late" or what may be considered "usual care" elsewhere, given that usual care in this single-center study is based on institutional guidelines. As a result, we did not feel it was ethical to randomize patients to delayed or reduced mobilization; and (4) finally, our follow-up was limited to 1-month post discharge due to funding limitations. However, we have previously demonstrated the feasibility of longer term follow-up for functional outcome measurements (22).

Approximately a third of planned mobilization sessions were missed due to the unavailability of a physiotherapist or research personnel. Missed cycling sessions were primarily due to the workload of the research personnel—full time clinical fellows and a physiotherapist who volunteered to conduct this trial. Unavailability of physiotherapists for mobilization was not attributed to nonadherence to the research protocol, but due to pragmatic reasons, given that the physiotherapist is not funded by this study and prioritizes her workload according to the needs of the entire 12-bed PICU. McMaster PICU has one full time-equivalent physiotherapist from 8 AM to 4 PM on weekdays only. This may be an argument for either more resources, using alternative means of facilitating mobilization in the PICU, and engaging other interprofessional team members and family caregivers in the rehabilitation process (11). In-bed cycling may therefore be an appropriate adjunct to facilitating mobility-based rehabilitation in critically ill patients provided there are trained personnel to execute and oversee the intervention. Assessment for appropriateness for cycling and the initial "prescription" should be performed by a trained physiotherapist or occupational therapist, but subsequent sessions may be overseen by the therapist and conducted by other trained personnel as evidenced by this study. This frees the physiotherapist to conduct other important aspects of physiotherapy, which may account for why mobilization appears greater in the cycling arm. Cycling intervention therefore did not impact on the physiotherapist's workload. Patient or parent refusals accounted for a total of 8% of missed therapy sessions. This appears lower than the 10–19% patient rate reported in the adult critical care literature (40, 41). Patient refusals are not infrequent despite best efforts and are an acknowledged barrier to mobilizing critically ill patients (42). Future qualitative evidence will improve our understanding of patients, parents, and healthcare provider perceptions and experience with mobilization in critically ill children (43).

CONCLUSIONS

This pilot trial confirms that EM is safe and feasible, and in-bed cycling may be an appropriate adjunct to optimizing mobilization duration and intensity, in previously healthy children as well as those with underlying preexisting conditions and functional limitations. The efficacy of this intervention, and the impact of mobilization and rehabilitation on PICU-acquired morbidities and functional outcomes in this population deserves further investigation in a full-scale RCT.

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