

## **CYCLE RCT:** An international, multi-centre, randomized clinical trial of early in-bed cycling for mechanically ventilated patients

**Background:** Patients in the ICU are the sickest patients in hospital, and need advanced life-support. ICU survivors are typically very weak and disabled. Over half of these patients have severe leg weakness impairing their quality of life for up to 5 years after ICU discharge. In-bed cycling uses special equipment that attaches to a patient's hospital bed, allowing them to gently exercise their legs in the ICU.

**Objectives:** The main goal of this research program is to see if patients who need a breathing machine recover faster if they receive in-bed cycling than those who do not. We will also determine whether in-bed cycling is a cost-effective intervention.

**Design**: 360-patient international, multi-centre RCT. Following informed consent, patients will be randomized to receive either:

- 1. 30 minutes of in-bed leg cycling within the first 4 days of MV, in addition to routine PT, 5 days per week, for the duration of their ICU stay (up to 28 days), or
- 2. Routine PT alone

**Outcomes:** We will assess strength and physical function at multiple time points throughout the patient's stay and at hospital discharge. We will also perform assessments to determine the effects of early in-bed cycling on quality of life, self-reported function, psychological distress, and healthcare utilization.

**Relevance:** To-date, no researchers have studied the use of early in-bed cycling in the ICU and how it affects issues important to patients (e.g., walking, quality of life). We hope the information learned from this study will help critically ill patients who need breathing machines in the ICU to regain strength and recover as quickly as possible.

## Impact on daily ICU care:

- On weekdays, we will review your patient for physiotherapy
- If there are better times in the day for your patient to receive physiotherapy, please let us know (e.g., scheduled tests, procedures)
- Our ICU PTs will conduct all cycling or routine PT sessions

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