McMaster University HEALTH SCIENCES

CYCLE

CCCTG Canadian Critical Care Trials Group

RESEARCH QUESTION:

Among critically ill, mechanically ventilated adults, does early in-bed cycling and routine PT compared to routine PT alone improve physical function at 3 days after ICU discharge?

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CIHR IRSC

Rationale for CYCLE

- Patients developing muscle weakness in the ICU are at a higher risk of death and disability
- Muscle weakness begins within the 1st 7 days of bed rest
- Exercise started within 1.5 days of mechanical ventilation improved patients' function at hospital discharge
- Cycling started 2 weeks after ICU admission improved patients' 6-minute walk at hospital discharge
- Can cycling start earlier in a patient's ICU stay and will it improve patients' function at 3 days post ICU?

CYCLE RCT
Main Inclusion and Exclusion Criteria

Inclusion Criteria

- Adults ≥ 18 years old
- Invasively mechanically ventilated ≤ 4 days
- Expected additional 2 Day ICU stay
- Ambulated independently (with or without gait aid) pre-hospital admission
- ICU LOS ≤ 7 days

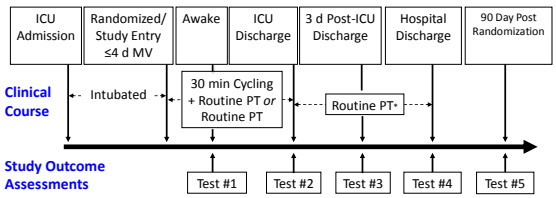
Exclusion Criteria

- Acute condition impairing ability to cycle (e.g., leg fracture)
- Proven or suspected neuromuscular weakness affecting the legs (e.g., stroke, Guillain Barre)
- Inability to follow commands in local language pre-ICU
- Severe cognitive impairment pre-ICU
- Temporary pacemaker
- Pregnancy (or suspected pregnancy)
- Expected hospital mortality >90%
- Body habitus unable to fit the bike
- Palliative goals of care
- Able to march on spot at the time of screening
- Cycling exemption not resolved during 1st 4 days of mechanical ventilation

Cycling / Routine PT Exemptions

- Increase in vasopressor/ inotrope within last 2 hours
- Active MI, or unstable/ uncontrolled arrhythmia per ICU team
- MAP<60 or >110 mmHg or per treating team within the last 2 hours
- Heart Rate <40 or >140 bpm within the last 2 hours
- Persistent SpO_2 <88% or per treating team within the last 2 hours
- Neuromuscular blocker within last 4 hours
- Severe agitation (RASS>2 [or equivalent]) within last 2 hours
- Uncontrolled pain
- Change in goals to palliative care
- Team perception that in-bed cycling or therapy is not appropriate for other new reasons (e.g., acute peritonitis, new incision/wound, known/suspected muscle inflammation (e.g., rhabdomyolysis)
- Patient or proxy refusal

RCT Study Schema



- **Intervention:** 30 minutes cycling/ day + routine PT **or** routine PT alone during their ICU stay (5 d/ week, excluding statutory holidays, maximum 28 days)
  - Once a patient can march on the spot, cycling in the ICU will be discontinued
- **Assessments:** ICU awakening, ICU discharge, 3 days post-ICU discharge & Hospital discharge, 90 days post randomization

As of July 26, 2018

Questions?

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Thank you!

This study is approved by the Hamilton Integrated Research Ethics Board CTO #1345