

# Arm cycle ergometry in the ICU rehabilitation pilot study

<b>Submission date</b> 22/12/2025	<b>Recruitment status</b> Recruiting	<input checked="" type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
<b>Registration date</b> 31/12/2025	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 23/12/2025	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Plain English summary of protocol not provided at registration.

## Contact information

### Type(s)

Principal investigator, Public, Scientific

### Contact name

Dr Michelle Kho

### ORCID ID

<https://orcid.org/0000-0003-3170-031X>

### Contact details

School of Rehabilitation Science  
Institute for Applied Health Sciences Building  
1400 Main St W (AHS) Building - Room 403  
McMaster University  
Hamilton  
Canada  
L8S 1C7  
+1 2892370194  
khome@mcmaster.ca

## Additional identifiers

## Study information

Scientific Title

Arm cycle ergometry in the ICU (ACE-ICU) rehabilitation pilot: a pilot randomized controlled trial of arm cycle ergometry versus routine rehabilitation in mechanically ventilated patients

## **Acronym**

ACE-ICU Rehabilitation Pilot RCT

## **Study objectives**

Evaluate the feasibility of a multi-centre pilot RCT of arm cycling with MV patients:

1. Accrual - 1 to 2 patients/ month/ site
2. Protocol fidelity- >80% of study days
3. Outcome measures - >80% completed by blinded assessors at hospital discharge
4. Acceptability by patients, families, and healthcare workers

## **Ethics approval required**

Ethics approval required

## **Ethics approval(s)**

approved 25/09/2025, Hamilton Integrated Research Ethics Board / Clinical Trials Ontario (237 Barton Street East, Hamilton, L8L 2X2, Canada; +1 905 521-2100 Ext: 46243; inmanma@mcmaster.ca), ref: 5333

## **Primary study design**

Interventional

## **Allocation**

Randomized controlled trial

## **Masking**

Open (masking not used)

## **Control**

Active

## **Assignment**

Parallel

## **Purpose**

Treatment

## **Study type(s)**

## **Health condition(s) or problem(s) studied**

Mechanically ventilated ICU patients who independently used their arms for functional activities (e.g., eating, dressing) before their critical illness.

## **Interventions**

Usual ICU and Ward rehabilitation – Patients will receive routine rehabilitation (e.g., interventions from physiotherapists and occupational therapists) per current institutional practice. Routine physiotherapy includes activities to optimize airway clearance and respiratory function, and, based on the patient's alertness and medical stability, activities to maintain or

increase limb range of motion and strength, in- and out-of-bed mobility, and ambulation. Routine occupational therapy includes joint contracture prevention (e.g., splinting), equipment provision (e.g., wheelchairs), pressure injury prevention and treatment, and activities to help patients return to their roles in life (e.g., bathing, dressing).

Intervention description - Patients will be randomized to receive 10 minutes of arm cycling in addition to Usual ICU and ward rehabilitation, 5 days per week, for the duration of their ICU and hospital stay (to a maximum of 28 days). We will use a specialized arm cycle (e.g., RT300 supine cycle modified with arm attachments), which provides 3 possible cycling modes: passive (i.e., no patient initiation), active-assisted (i.e., partially patient-initiated), or active (i.e., fully patient-initiated). A patient's ability to perform arm cycling is not a requirement to join the trial because the ergometer can accommodate passive and active cycling.

We aim for participants to complete as much active cycling as possible during each session for a target of 10 minutes, based on pilot data and our systematic review. The therapist will place the participants' arms in the cycle ergometer, starting with passive cycling at 5 revolutions per minute (RPM) with no resistance. If patients initiate active cycling, the therapist will use standardized encouragement to promote active participation and muscle activation. Since ICU patients' level of consciousness may vary throughout their stay, we will allow patients to cycle at a self-selected RPM. If the patients stop cycling actively, the ergometer will revert to passive cycling. If patients restart active cycling, we will provide standardized encouragement as above.

## **Intervention Type**

Device

## **Phase**

Phase II

## **Drug/device/biological/vaccine name(s)**

Arm cycle ergometer

## **Primary outcome(s)**

1. Accrual (1-2 patients per month per site) measured using study data collection at the end of the study
2. Protocol fidelity (>80 % of study days) measured using study data collection at End of study

## **Key secondary outcome(s)**

1. Lower body strength and endurance measured using the number of repetitions in 30 seconds in the 30-second sit-to-stand test at ICU awakening, ICU discharge, hospital discharge (by assessors blinded to treatment group)
2. Global muscle strength measured using the Medical Research Council Sum Score standardized assessor rating of static strength in 6 muscle groups at ICU awakening, ICU discharge, hospital discharge (by assessors blinded to treatment group)
3. Hand grip strength measured using a hand grip dynamometer (kg) at ICU awakening, ICU discharge, hospital discharge (by assessors blinded to treatment group)

4. Physical function measured using the Physical Function ICU Test score out of 10 (higher scores, better function) at ICU awakening, ICU discharge, hospital discharge (by assessors blinded to treatment group)
5. Patient-centered function measured using the Patient-Specific Functional Scale (PSFS) for the ICU score out of 10 (higher scores, better function) at ICU discharge, hospital discharge
6. Quality of Life measured using the Euro-QoL 5D-5L at ICU Discharge, Hospital Discharge, 90-days post-randomization
7. Anxiety and depression measured using the Hospital Anxiety and Depression Scale at 90-days post-randomization

**Completion date**

15/10/2028

## Eligibility

**Key inclusion criteria**

1. Adults ( $\geq 18$  years old)
2. Who used their upper limbs for functional activities (e.g., dressing, bathing) before their critical illness
3. Within the first 7 days of their ICU stay
4. Received or are receiving mechanical ventilation (invasive or non-invasive) for  $>24$  hours
5. Within the first 4 days of starting mechanical ventilation

**Healthy volunteers allowed**

No

**Age group**

Mixed

**Lower age limit**

18 years

**Upper age limit**

100 years

**Sex**

All

**Total final enrolment**

0

**Key exclusion criteria**

1. Known shoulder pathology
2. Impaired shoulder range of motion
3. Any condition impairing patients' ability to cycle (e.g., arm fracture)
4. Proven or suspected neuromuscular weakness affecting the arms
5. Unable to follow commands pre-critical illness

6. Expected hospital mortality >90%
7. Body habitus unable to fit the bike, palliative goals of care
8. Persistent therapy exemptions in the first 4 days of ICU stay (e.g., cardiorespiratory instability, active major bleeding)

**Date of first enrolment**

15/04/2026

**Date of final enrolment**

15/04/2028

## Locations

**Countries of recruitment**

Australia

Canada

## Sponsor information

**Organisation**

McMaster University

**ROR**

<https://ror.org/02fa3aq29>

## Funder(s)

**Funder type****Funder Name**

Canadian Institutes of Health Research

**Alternative Name(s)**

Instituts de Recherche en Santé du Canada, The Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research (CIHR), Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

Canada

**Funder Name**

Research Institute of St. Joe's Hamilton

**Alternative Name(s)**

The Research Institute of St. Joe's Hamilton

**Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Research institutes and centers

**Location**

Canada

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Data sharing statement to be made available at a later date