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Arm cycle ergometry in the ICU rehabilitation pilot study

Submission date	Recruitment status	[X] Prospectively registered
22/12/2025	Recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
31/12/2025	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
23/12/2025	Injury, Occupational Diseases, Poisoning	[X] 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

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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 (>= 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