Critical Care Cycling to Improve Lower Extremity Strength

Michelle Kho, PT, PhD on behalf of

the CYCLE Investigators and

the Canadian Critical Care Trials Group

October 10, 2024

ACT RFA 1 Competition

McMaster University | School of Rehabilitation Science | CCCTG Canadian Critical Care Trials Group | CIHR IRSC Canadian Institutes of Health Research / Instituts de recherche en santé du Canada | Canada Research Chairs / Chaires de recherche du Canada | INNOVATION Canada Foundation for Innovation / Fondation canadienne pour l'innovation | ACT AEC Accelerating Clinical Trials / Accélérer les Essais Cliniques

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McMaster University HEALTH SCIENCES

CIHR IRSC
Canadian Institutes of Health Research
Instituts de recherche en santé du Canada

Chaires de recherche du Canada
Canada Research Chairs
Canada

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INNOVATION
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ACT AEC
Accelerating Clinical Trials
Accélérer les Essais Cliniques

Additional CYCLE Pilot RCT Funding:

CRRN RCRR
Canadian Respiratory Research Network
Réseau canadien de recherche respiratoire

Canadian Frailty Network

THE LUNG ASSOCIATION™
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CYCLE RCT Investigators

CCCTG Canadian Critical Care Trials Group

Methods Centre

Data Safety and Monitoring Committee

CYCLE International Steering Committee Member

CYCLE


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Melbourne

Misak. Am J Respir Crit Care Med 2011;183:845-6.

In an ICU survivor's words...

"It is hard to convey just how debilitated one is after an insult of intensive care magnitude.

When I was finally weaned (from mechanical ventilation), sitting in a chair was impossible….

There was a remarkably persistent and overwhelming generalized weakness and fatigue."

2012 - Clinical inspiration for CYCLE

- Sedation and invasive mechanical ventilation barriers to starting early rehabilitation
- Patients could cycle actively, even while sedated

CYCLE

Critical Care Cycling to Improve Lower Extremity Strength

Research Question:

In medical-surgical ICU patients, does 30 minutes of in-bed cycling and usual PT started within the first 4 days of mechanical ventilation, compared to usual PT alone, improve patient function at 3 days post-ICU?

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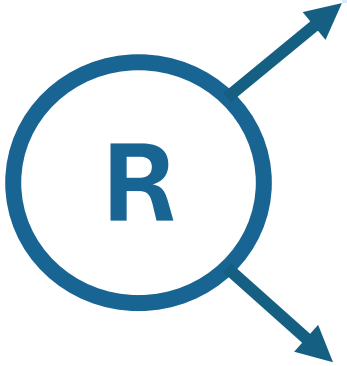
CYCLE RCT

Critically ill, mechanically ventilated adults

n=360



30 min in-bed Cycling + Usual ICU physiotherapy, 5 days/week

Usual ICU physiotherapy alone

Led by existing ICU physiotherapists at each site

Primary Outcome

Physical Function 3-days after ICU d/c

Physical Function in ICU test-scored (PFIT-s)

Measured by assessors blinded to randomized group

Baseline Characteristics

	Cycling + Usual Physiotherapy n=178	Usual Physiotherapy n=182
Age (years)	61.8 ± 15.4	61.2 ± 15.8
Female sex	75 (42.1%)	80 (44.0%)
APACHE II	24.8 ± 8.9	23.1 ± 8.1
Living at home independently	154 (86.5%)	159 (87.4%)
Clinical Frailty Scale Score	3.1 ± 1.3	3.2 ± 1.3
Charlson Comorbidity Index	1 (0 to 3)	1 (0 to 3)

Primary outcome

	Cycling + Usual Physiotherapy	Usual Physiotherapy	Difference (95% CI)
Physical Function ICU Test-scored at 3-days after ICU d/c	**7.7 ±1.7**	**7.5 ±1.8**	0.23 (-0.19 to 0.65) p=0.287

Outcomes in Survivors at Hospital Discharge

	Cycling + Usual Physiotherapy	Usual Physiotherapy
ICU-Acquired weakness*	10 (9.6%)	13 (12.1%)
Clinical Frailty Scale Score*	4.5 ±1.5	4.9 ±1.6

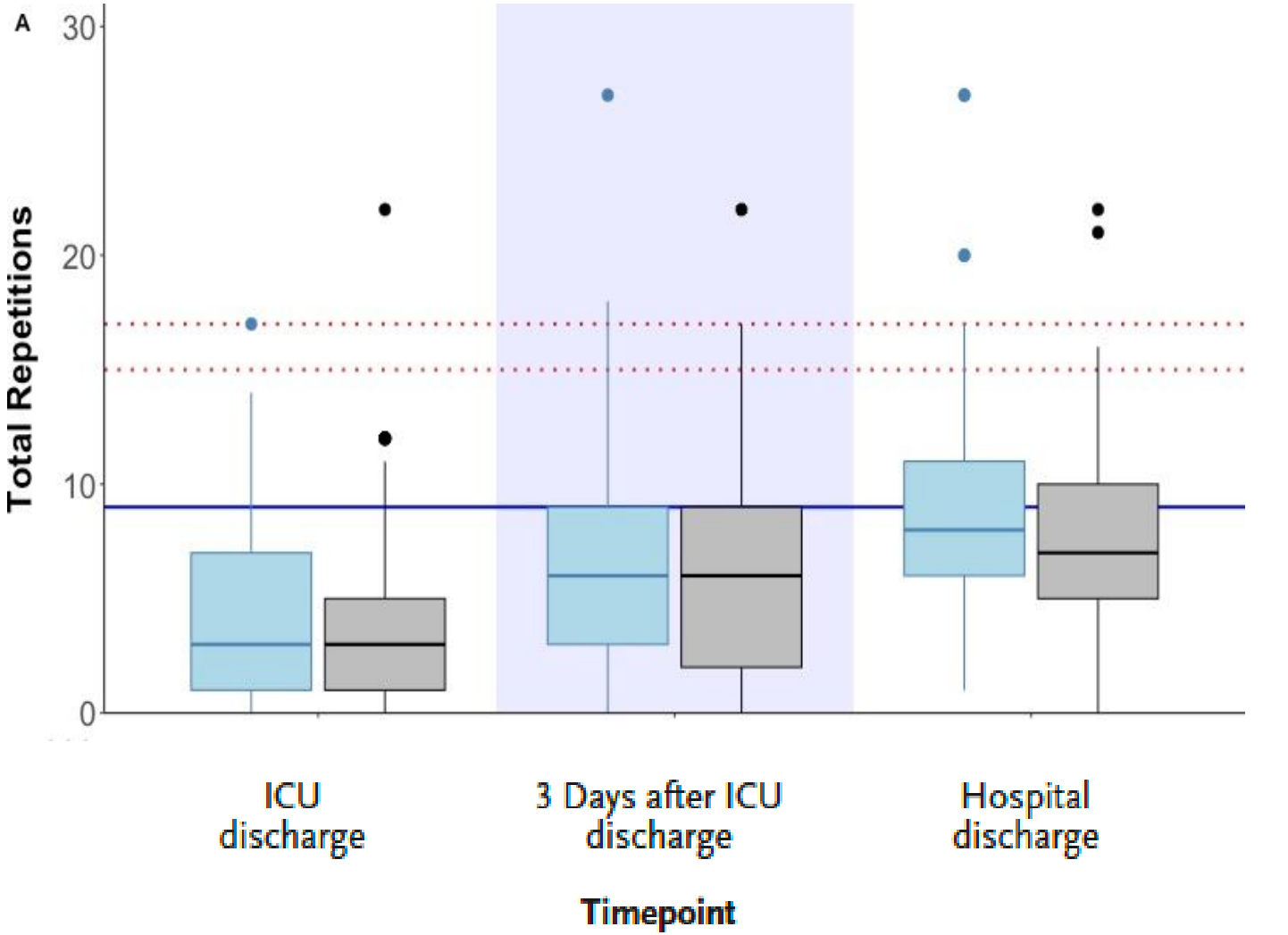
*ICU-Acquired weakness & frailty: Lower numbers = better

Outcomes in Survivors at Hospital Discharge

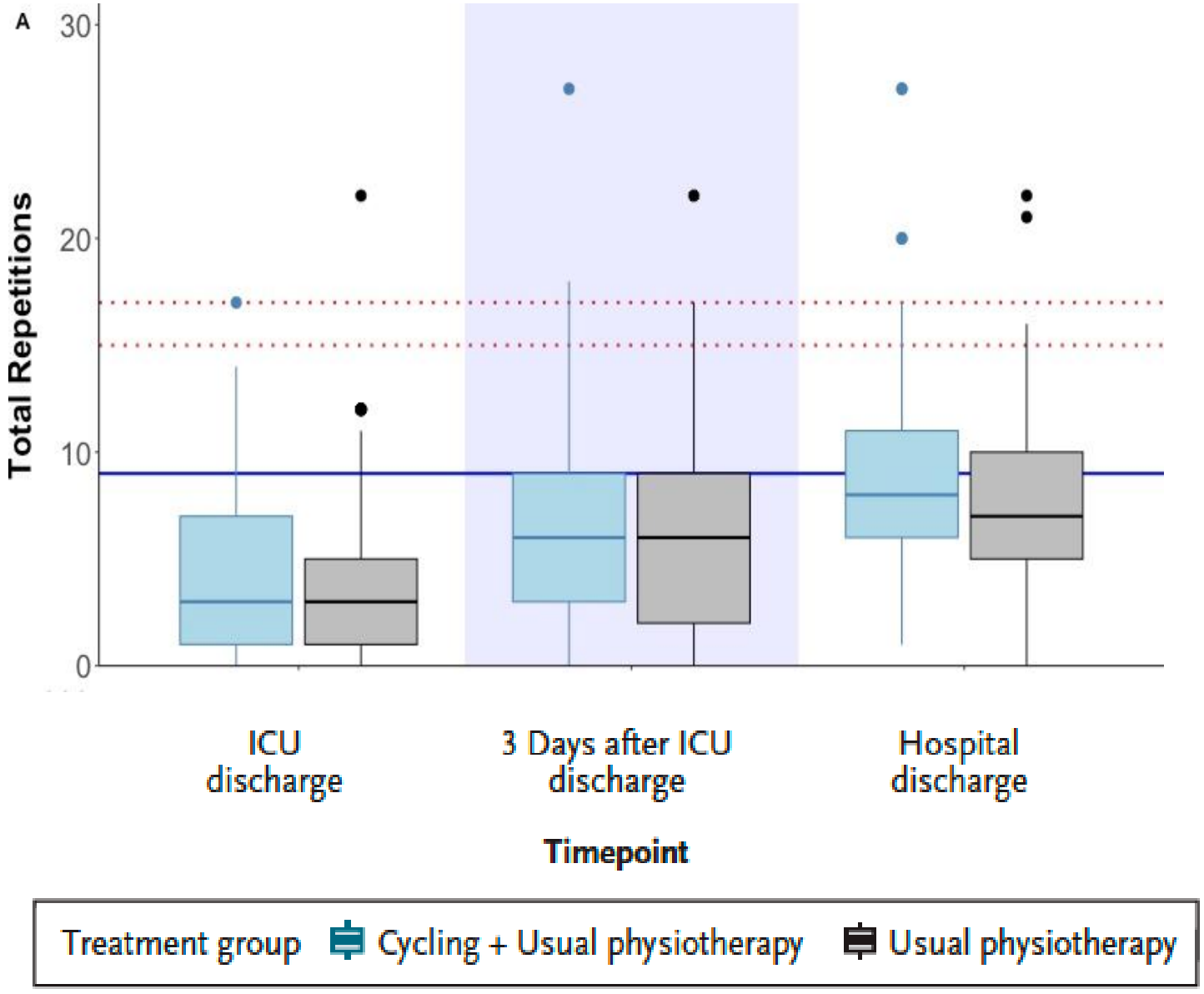
	Cycling + Usual Physiotherapy	Usual Physiotherapy
ICU-Acquired weakness*	10 (9.6%)	13 (12.1%)
Clinical Frailty Scale Score*	4.5 ±1.5	4.9 ±1.6
Patient-Reported Functional Score for ICU	8.2 (5.8 to 9.0)	7.5 (4.8 to 9.0)
2-minute walk test distance (metres)	73.2 (52.0 to 107.0)	67.0 (45.0 to 96.0)
Residence at hospital d/c ≥ baseline	83/138 (60.1%)	84/142 (59.2%)

*ICU-Acquired weakness & frailty: Lower numbers = better

Physical function: 30-second Sit to Stand



Physical function: 30-second Sit to Stand



Men 60-64: 17 reps

Women 60-64: 15 reps

Age- and sex- cohort norms

Men & Women 90-94: 9 reps

Closest functional norms

At hospital discharge, this cohort of ~61 year old survivors had scores comparable to 90-year olds

NEJM Evidence

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ORIGINAL ARTICLE | CRITICAL CARE REVIEWS MEETING 2024

Early In-Bed Cycle Ergometry in Mechanically Ventilated Patients

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Leg Cycle Ergometry in Critically Ill Patients: An updated systematic review and meta-analysis

Presented by: Heather O'Grady, PhD

On behalf of: Hibaa Hasan, BSc, Alyson Takaoka, MSc, Rucha Utgikar, MD, Julie Reid, PT, PhD, Bram Rochwerg, MD, Deborah Cook, MD, Michelle Kho, PT, PhD







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CYCLE

ACT AEC Accelerating Clinical Trials / Accélérer les Essais Cliniques

St. Joseph's Healthcare Hamilton

The Research Institute of St. Joe's Hamilton

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Methods: Inclusion Criteria for RCTs

Population

Adults admitted to any ICU for ≥ 24 hours, with or without mechanical ventilation

Intervention

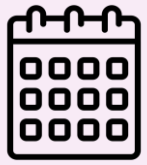
Any - must include cycling, started in ICU, alone or with other strategies

Comparator

Any – strategies must not include cycling

Outcomes

Physical Function

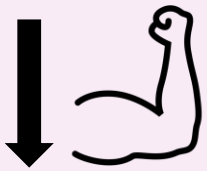


Length of Stay

Safety

Mortality

Muscle Strength



ICU-Acquired Weakness

Duration of MV

Quality of Life

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Results: Study Characteristics

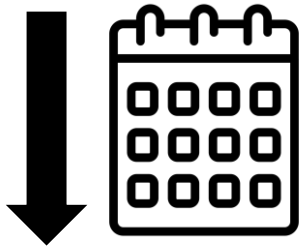
	n=33 studies
Sample Size	
Median no. per study (1st, 3rd quartiles)	74 (40, 135)
Range per study	19-363
Centers	
Median no. per study (1st, 3rd quartiles)	1 (1, 1)
Range per study	1-16
ICU Type, no. (%) studies	
Mixed	9 (27%)
Cardiac	6 (18%)
General	2 (6%)
Respiratory, Medical, COVID	3 (9%)
Not specified	13 (39%)

In this systematic review and meta-analysis of 33 trials and 3,274 patients, in-bed cycling as part of ICU rehabilitation...

Improved physical function at ICU discharge and post-hospital

Patients get a head start on their recovery journey

Decreased ICU LOS by 1 day and hospital LOS by 1.5 days



Patients get home faster

Was associated with rare adverse events

Cycling can be safely incorporated into ICU rehabilitation

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NEJM Evidence

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Leg Cycle Ergometry in Critically Ill Patients — An Updated Systematic Review and Meta-Analysis

Heather K. O'Grady, Ph.D.,[1] Hibaa Hasan, B.Sc.,[1] Bram Rochwerg, M.D., M.Sc.,[2,3] Deborah J. Cook, M.D., M.Sc.,[2,3,4] Alyson Takaoka, M.Sc.,[5] Rucha Utgikar, M.D., M.Sc.,[4,6] Julie C. Reid, P.T., Ph.D.,[2,4] and Michelle E. Kho, P.T., Ph.D.[1,4,7]