# Early Rehab in ICU: TEAM Trial

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Michelle Kho, PT, PhD February 10, 2023 12 pm ET khome@mcmaster.ca



Description of the TEAM trial and results

# Overview of today's talk



You choose: areas for further discussion



#### Test your knowledge

Improving long-term outcomes after discharge from intensive care 2012 unit: Report from a stakeholders' conference Needham et al., Crit Care Med 2012; 40. **Post-intensive** Post Intensive care syndrome Care Syndrome (PICS) Family Survivor (PICS-F) (PICS) Mental Health Mental Health **Cognitive Impairments** Physical **Executive Function** Anxiety/ASD Impairments Anxiety/ASD Memory PTSD Pulmonary PTSD Attention Neuromuscular Depression Visuo-spatial Depression **Physical Function Complicated Grief** Mental Processing Speed

#### ORIGINAL ARTICLE

# Early Active Mobilization during Mechanical Ventilation in the ICU

The TEAM Study Investigators and the ANZICS Clinical Trials Group\*

N Engl J Med 2022; 387:1747-1758

DOI: 10.1056/NEJMoa22 09083 **Research Question:** In mechanically ventilated adults, does early, goal-directed mobilization compared to usual care improve # days alive and out of hospital by day 180?

### PICOS

- **Population**: Mechanically ventilated adults in ICU who were expected to undergo at least 1 additional day of mechanical ventilation
- Intervention (unblinded): Minimization of sedation as required, daily
  physiotherapy (7 days per week), individually tailored to achieve the highest
  possible level of mobilization provided for as long as possible before a
  step-down to lower levels of activity if the patient became fatigued
- Comparison (unblinded): Usual Care
- Outcome: # days alive and out of hospital by day 180
- Study design: Randomized controlled trial in 49 centres and 6 countries



Figure 1. Early goal-directed mobilization algorithm. Once randomized and physiological stability is achieved, the mobility tearn assessed the ICU mobility scale (IMS) and targeted exercise at the highest possible level of the IMS for as long as possible.



# Results

# Characteristics of Included Patients (Table 1)

Table 1. Characteristics of the Patients at Baseline.*		
Characteristic	Early Mobilization (N=371)	Usual Care (N=370)
Age — yr	60.5±14.8	59.5±15.2
Female sex — no. (%)	128 (34.5)	146 (39.5)
Body-mass index†	29.9±7.9	30.4±7.8
Frailty and function		
Median score on Clinical Frailty Scale (IQR)‡	3 (2 to 4)	3 (2 to 4)
Median score on Functional Comorbidity Index (IQR)§	2 (1 to 3)	2 (1 to 3)
Median score on WHODAS 2.0 (IQR)¶	10.4 (2.1 to 25.0)	8.7 (2.1 to 22.7)
Highest score on the ICU Mobility Scale in wk before ICU admission	9.9±0.6	9.8±0.7
Median interval from hospital admission to randomization (IQR) — hr	88.3 (50.5 to 137.0)	81.6 (48.2 to 147.0)
Median interval from ICU admission to randomization (IQR) — hr	60.1 (35 to 92.3)	61.3 (33.8 to 96.1)
ICU admission type — no. (%)		
Planned ICU admission after elective surgery	68 (18.3)	58 (15.7)
Unplanned ICU admission	303 (81.7)	312 (84.3)
Median RASS score at randomization (IQR)**	-3 (-4 to -2)	-3 (-4 to -2)
Measurements and interventions at randomization††		
Positive end-expiratory pressure — cm of water	8.9±3.0	8.8±3.1
Pao,:Fio,	226±79.1	230±85.2
Receipt of vasopressors by infusion — no. (%)	228 (61.5)	231 (62.4)
Receipt of renal-replacement therapy — no. (%)	82 (22.1)	79 (21.4)
APACHE II score‡‡	18.2±6.8	18±6.9
Diagnosis subgroup — no. (%)∬		
Sepsis	246 (66.3)	245 (66.2)
Trauma	15 (4.0)	14 (3.8)
Covid-19	7 (1.9)	10 (2.7)

- 10.5% / 11.9% with Frailty (CFS >4)
- 3.6/ 3.4 days from hospital admission to randomization
- 2.5/ 2.6 days from ICU admission to randomization
- Median RASS @ randomization = -3

• APACHE II = 18.2 / 18.0

# Characteristics of included patients (Table S5)

Table S5. Additional characteristics of the patients at baseline: physiology and ICU treatment.					
Characteristic	Early Mobilization (n=371)	Usual Care (n=370)			
GCS, median [IQR] *	15 [14-15]	15 [14-15]			
Serum creatinine, median [IQR]	106 [72-166]	97 [69-160]			
PaO <sub>2</sub> – mmHg †	83.6 ±31.2	84.1±23.9			
Agitation and delirium					
RASS score, median [IQR] ‡	-3 [-4 to -2]	-3 [-4 to -2]			
CAM-ICU positive, no. (%)	16 (4.3)	15 (4.1)			
ICU supports and therapies, no. (%)					
Sedatives via continuous infusion	363 (97.8)	360 (97.3)			
Vasopressors via continuous infusion	228 (61.5)	231 (62.4)			
Renal replacement therapy	82 (22.1)	79 (21.4)			
Corticosteroids	169 (45.6)	167 (45.1)			

Plus-minus values are mean ±SD

\* GCS data were available for 736 patients (369 in the early mobilization group and 367 in the usual care group)

† PaO2 data were available for 737 patients (369 in the early mobilization group and 368 in the usual care group) ‡ RASS data were available for 715 patients (358 in the early mobilization group and 357 in the usual care group)

Abbreviations: CAM-ICU: Confusion Assessment Method for the ICU; GCS: Glasgow Coma Score; ICU: intensive care unit; IQR: interquartile range; no: number; PaO<sub>2</sub>: arterial partial pressure of oxygen; RASS: Richmond Agitation Sedation Scale; SD: standard deviation; µmol: A micromole is a unit of measure defined as 10<sup>-6</sup> (one-millionth) of a mole.

# Mobilization in ICU (Table 2)

Table 2. Mobilization in the ICU.*			
Characteristic	Early Mobilization (N = 371)	Usual Care (N = 370)	Between-Group Difference (95% CI)†
Patients who were assessed by a physiotherapist on day of randomization — no./total no. (%)	320/370 (86.5)	265/363 (73.0)	13.5 (6.7 to 20.3)
No. of days per patient when physiotherapy assessment oc- curred	0.94±0.11	0.81±0.24	0.14 (0.12 to 0.16)
No. of minutes of active mobilization per day	20.8±14.6	8.8±9.0	12.0 (10.4 to 13.6)
Mobilization milestones‡			
IMS 3 or higher			
Patients — no. (%)	331 (89.2)	330 (89.2)	0 (-4.3 to 4.3)
Median no. of days since randomization (IQR)	3 (1 to 6)	4 (2 to 7)	-1 (-2.2 to -0.2)
IMS 4 or higher			
Patients — no. (%)	287 (77.4)	286 (77.3)	0.1 (-6.0 to 6.1)
Median no. of days since randomization (IQR)	3 (2 to 7)	5 (3 to 8)	-2 (-3.4 to -0.6)
IMS 7 or higher			
Patients — no. (%)	176 (47.4)	150 (40.5)	6.9 (-0.2 to 14.0)
Median no. of days since randomization (IQR)	5 (3 to 8)	7 (4 to 13)	-2 (-3.4 to -0.7)
Median peak IMS (IQR)	6 (4 to 8)	6 (4 to 8)	0 (-1 to 1)

86.5%/ 73% assessments occurred w/ median RASS = -3

- 5.5/ 6.6 days from ICU admission to sit @ EOB or higher
- 5.5 / 7.6 days from ICU admission to stand or higher
- 7.5 / 9.6 from ICU admission to walk or higher

# Outcomes (Table 3, part 1)

Table 3. Primary Outcome, Key Secondary Outcomes, and Adverse Events.*						
Outcome	Early Mobilization (N=371)	Usual Care (N=370)	Difference or Odds Ratio (95% CI)†	P Value		
Primary outcome						
Days alive and out of hospital at day 180‡						
Median no. (IQR)	143 (21 to 161)	145 (51 to 164)	-2.0 (-10 to 6)	0.62		
Key secondary outcomes	and the second second second	and the second	and the second sec			
Death at day 180						
Patients — no. (%)	83/369 (22.5)	71/364 (19.5)	1.15 (0.81–1.65)§			
Median no. of days since randomization (IQR)	17 (9 to 41)	19 (12 to 50)	-2.0 (-12.0 to 8.0)			
Median no. of ventilator-free days at day 28 (IQR)	21 (8 to 25)	21 (11 to 25)	0.0 (-1.4 to 1.4)			
Median no. of ICU-free days at day 28 (IQR)	16 (0 to 21)	17 (3 to 22)	-1.0 (-3.1 to 1.1)			
Functional outcomes in survivors at day 180¶						
Score on EQ-5D-5L utility score	0.7±0.3	0.7±0.3	0.0 (-0.0 to 0.1)			
Score on EQ Visual Analogue Scale**	70.2±19.7	69.0±20.1	2.0 (-5.7 to 9.7)			
Median score on Barthel Index of ADL (IQR) ††	100 (100 to 100)	100 (95 to 100)	0			
Median score on IADL (IQR) ‡‡	8.0 (7.0 to 8.0)	8.0 (6.0 to 8.0)	0.2 (-0.9 to 1.3)			
Median score on WHODAS 2.0 (IQR)∬	12.5 (2.1 to 33.3)	14.6 (4.2 to 38.9)	-1.8 (-6.9 to 3.4)			

## Secondary Outcomes (Table S13)

Table S13. Additional Secondary	Outcome measu	ures.			
	Early Mobilization (n=371)	Usual Care (n=370)	Between- Group Difference**	Hazard Ratio**	
Day 28 mortality, no. (%)	58 (15.6)	42 (11.4)	4.3 (-0.2 to 8.8)		28-day mortality: 15.6% / 11.4%
Median no. of coma and delirium- free days to day 28	24 (17-26)	24 (18-26)	0 (-1.2 to 1.2)		
Day 180 functional outcomes *					
MoCA Blind Score † Median HADS Score [IQR] ±	18 (16-20)	18.5 (16-20)	0 (-0.9 to 0.9)		
Anxiety symptoms score Depression symptoms score	4 [2-7] 3 [1-6]	4 [2-8] 3 [1-7]	-0.2 (-2.6 to 2.2) -0.6 (-2.4 to 1.2)		
Date in hospital rehabilitation or a	7.0 [1.5-19.5]	7.5 [2.8-20.2]	-0 (-2.0 to 2.0)		
nursing home to day 180, median	25 [13-45]	25 [13-49]	0.0 (-4.4 to 4.4)		
Patients who survived, median [IQR]	28 [16-50]	27 [14-52]	0.9 (-3.7 to 5.6)		
Patients who survived, geometric mean (95% CI)	28.2 (24.5-32.4)	27.7 (24.1-31.9)			
Patients who died, median [IQR]	16 [7-29]	17 [11-47]	-1 (-10.2 to 8.2)		
Patients who died, geometric mean (95% CI)	15.7 (12.3-20)	21 (16.2-27.4)			
Days from randomization to ICU discharge, median [IQR]	7.9 [4.3-15.1]	8.4 [4.9-15.1]		0.91 (0.78-1.06)	Days from randomization to ICU discharge: 7.9 / 8.4
Patients who survived, median [IQR]	7.9 [4.3-15.1]	8.2 [4.9-14.3]			
Patients who survived, geometric mean (95% CI)	8.5 (7.4-9.6)	8.5 (7.5-9.6)			
Patients who died, median [IQR]	9.1 [4.1-16.2]	11.9 [7.2-20.7]			
Patients who died, geometric mean (95% CI)	8.4 (6.3-11.1)	12 (8.6-16.7)			Dave from readenization to be writed discharges $17/170$
Days from randomization to hospital discharge, median [IQR]	17 [9.8-28.9]	17.9 [10.2-32.0]		0.95 (0.81-1.11)	Days from randomization to hospital discharge: 17/17.9
Patients who survived, median [IOR]	19 [10.9-30.9]	19 [10.2-31.9]			
Patients who survived, geometric mean (95% CI)	19 (16.8-21.5)	18.7 (16.6-21.1)			
Patients who died, median [IQR]	10.6 [5.2-18.4]	14.5 [9.5-34.8]			
Patients who died, geometric mean (95% CI)	10.5 (8.1-13.7)	15.6 (11.8-20.6)			

# Conclusions (authors)

- No difference in number of days alive and out of hospital @ 180 days between early goal-directed mobilization than usual care
- Intervention associated with increased adverse events

# Strengths

- ✓ Largest ICU rehabilitation study in the field 750 patients!
- ✓ Multi-centre, multi-national
- ✓ High consent rate 91%
- ✓ 7 days per week physiotherapy (intervention)
- ✓ 6-month follow-up for physical function, cognition, psychological distress
- ✓ Patient-reported outcomes blinded

### Interpretation

- 1. Current state of the field
  - "Unique hypotheses"
- 2. How is early mobility defined in this trial?
  - Usual care
- 3. Is early mobility <u>safe</u>?
  - Dependent on duration of exposure and types of activities
  - Serious adverse events are very rare
  - Adverse events are rare; Total number of sessions per group unclear
- 4. How does this study fit in the literature?

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- Researchers design studies to answer unique hypotheses
- Early mobilization compared to usual level of mobilization in ICU
  - Does usual care reflect current practice in other hospitals?
  - High frequency of early mobilization in usual care group
  - 94% ICU days PT assessment intervention vs. 81% usual care
- # days alive and out of hospital may require larger sample sizes to detect meaningful differences
- Future ICU studies need to ID appropriate comparison group

## Interpretation

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# Intervention and Usual Care



Hodgson et al., Crit Care Med. 2016 Jun;44(6):1145-52. Figure 1. Early goal-directed mobilization algorithm. Once randomized and physiological stability is achieved, the mobility team assessed the ICU mobility scale (IMS) and targeted exercise at the highest possible level of the IMS for as long as possible.

# Comparison: Usual Care

 Usual care from physiotherapy staff not involved in delivering the intervention, whenever feasible

# Early Mobility Scale

#### Table 1

ICU Mobility Scale.

	Classification	Definition
0	Nothing (lying in bed)	Passively rolled or passively exercised by staff, but not actively moving
1	Sitting in bed, exercises in bed	Any activity in bed, including rolling, bridging, active exercises, cycle ergometry and active assisted exercises; not moving out of bed or over the edge of the bed
2	Passively moved to chair (no standing)	Hoist, passive lift or slide transfer to the chair, with no standing or sitting on the edge of the bed
3	Sitting over edge of bed	May be assisted by staff, but involves actively sitting over the side of the bed with some trunk control
4	Standing	Weight bearing through the feet in the standing position, with or without assistance. This may include use of a standing lifter device or tilt table
5	Transferring bed to chair	Able to step or shuffle through standing to the chair. This involves actively transferring weight from one leg to another to move to the chair. If the patient has been stood with the assistance of a medical device, they must step to the chair (not included if the patient is wheeled in a standing lifter device)
6	Marching on spot (at bedside)	Able to walk on the spot by lifting alternate feet (must be able to step at least 4 times, twice on each foot), with or without assistance
7	Walking with assistance of 2 or more people	Walking away from the bed/chair by at least 5 m (5 yards) assisted by 2 or more people
8	Walking with assistance of 1 person	Walking away from the bed/chair by at least 5 m (5 yards) assisted by 1 person
9	Walking independently with a gait aid	Walking away from the bed/chair by at least 5 m (5 yards) with a gait aid, but no assistance from another person. In a wheelchair bound person, this activity level includes wheeling the chair independently 5 m (5 years) away from the bed/chair
10	Walking independently without a gait aid	Walking away from the bed/chair by at least 5 m (5 yards) without a gait aid or assistance from another person

Hodgson et al., Heart & Lung 43 (2014) 19e24



# Duration of mobilization time (Fig S1)







#### Patients assessed (Fig S2)

Patients mobilized (Fig S1)

## Barriers to mobilization out of bed (Fig S4)





### More adverse events?





#### **Consider:**

- What was the Adverse event?
- A-priori (Severe adverse • events) or other (adverse events)?
- When did events occur? •
- Risks of reporting bias in an • open-label trial

...

#### Research

#### Serious adverse events in academic critical care research

Deborah Cook MD, François Lauzier MD, Marcelo G. Rocha MD, Mary Jane Sayles RN, Simon Finfer MD



Figure 1: Possible relationships between the condition on admission, a patient's critical illness, the study drug, serious adverse events and death in academic trials of drugs in common use in critical care.

CMAJ. 2008. 178(9): 1181-1184.

#### **Challenges:**

- 1. Variable definition and reporting of serious adverse events
- 2. Interpretation of serious adverse events in light of natural history of critical illness
- 3. Attribution of serious adverse events to the drug being tested
- 4. Attribution of death to serious adverse events
- 5. Interpretation of serious adverse events by REBs

## Serious Adverse Events (Table S15)

Table S15. Serious Adverse Events*								
	Early Mobilization (n=371)	Usual Care (n=370)	P value					
Fall to the floor	0 (0)	0 (0)	1.0					
Cardiac arrest	0 (0)	0 (0)	1.0					
Arrhythmia, no. (%) †	5 (1.3)	0 (0)	0.06					
Desaturation, no. (%) ‡	1 (0.3)	1 (0.3)	1.0					
Unplanned extubation	0 (0)	0 (0)	1.0					
Line removal requiring urgent replacement, no. (%)	0 (0)	0 (0)	1.0					
Other. no. (%)§	1 (0.3)	0 (0)	1.0					

\*Serious Adverse Events (SAE) include events that, in the investigator's opinion, were reported as probably, possibly or definitely related to the study. The SAE categories were prespecified at the outset of the trial.

† Arrhythmia includes rapid atrial fibrillation (defined as ventricular rate >150bpm), ventricular tachycardia or other dangerous arrhythmia

1 Desaturation is defined as SpO2 less than 80% for greater than 3 minutes

§ The event in the "other" category was a cerebrovascular accident resulting in unilateral weakness.

Abbreviations: no.: number; SpO2: oxygen saturation as measured by pulse oximetry

#### 8 serious adverse events: 7 patients in early mobilization group; 1 patient in usual care

# Adverse events (Table 3; not pre-specified)

-	N=371	N=370		
Adverse events — no. (%) ¶¶				
Patients with ≥1 adverse event potentially due to mobilization — no. (%)	34 (9.2)	15 (4.1)	2.55 (1.33–4.89)§	0.005
Adverse events per patient — no. (%)				0.02
0	337 (90.8)	355 (95.9)		
(1)	19 (5.1)	11 (3.0)		
2	4 (1.1)	2 (0.5)		
≥3	11 (3.0)	2 (0.5)		
Type of adverse events — no. (%)				
Altered blood pressure	13 (3.5)	8 (2.2)		0.27
Cardiac arrhythmia	13 (3.5)	4 (1.1)		0.03
Oxygen desaturation	8 (2.2)	1 (0.3)		0.02
Pain or agitation	4 (1.1)	1 (0.3)		0.37
Removal of invasive line	2 (0.5)	2 (0.5)		1.00
Gastrointestinal	2 (0.5)	1 (0.3)		1.00
Tachypnea	3 (0.8)	0		0.25
Altered neurologic state	1 (0.3)	1 (0.3)		1.00
Other	4 (1.1)	0		0.12

49 adverse events: 34 patients in early mobilization group; 15 in usual care

# Safety of Patient Mobilization and Rehabilitation in the Intensive Care Unit

#### Systematic Review with Meta-Analysis

Peter Nydahl<sup>1</sup>\*, Thiti Sricharoenchai<sup>2</sup>\*, Saurabh Chandra<sup>3</sup>, Firuzan Sari Kundt<sup>4</sup>, Minxuan Huang<sup>5</sup>, Magdalena Fischill<sup>6</sup>, and Dale M. Needham<sup>7</sup> Nydahl et al., Ann Am Thorac Soc Vol 14, No 5, pp 766–777, May 2017



## Increased mortality?



#### <u>Consider</u>:

- Totality of evidence
- Baseline mortality rate
- Need for an updated systematic review

### Physical Rehabilitation in the ICU: A Systematic Review and Meta-Analysis

Wang et al., Crit Care Med. 2022 Mar 1;50(3):375-388

Time point	Study	N	Intervention n (%)	Control n (%)	
ICU Discharge	Wang et al. 2022	2,752	215/1,379 (15.6)	207/1,373 (15.1)	30 studies
28-day mortality	TEAM	741	58/371 (15.6)	41/370 (11.4)	
Hospital discharge	Wang et al. 2022	3,143	244/1,567 (15.5)	250/1,576 (15.9%)	26 studies
	TEAM	?	?	?	
6 months	Wang et al. 2022	1,373	193/684 (28.2)	187/689 (27.1)	9 studies
180 days	TEAM	741	83/371 (22.5)	71/370 (19.5)	

# How does this study fit in the literature?

### When should we measure the primary outcome?



#### <u>Consider</u>:

- Primary outcome measured at 6-months post-ICU
- Proximity of primary outcome to treatment intervention
- Time to muscle weakness
- Confounding post-ICU

# ICU Rehabilitation study heterogeneity

Intervention	Author	Enrolled	Population				
	Hodgson et al., 2016	50	Sepsis/not reported				
	Schaller et al., 2016	200	Mixed				
Progressive Mobility	Dong et al., 2014	60	Medical				
	Dong et al., 2016	106	Cardiovascular		?	-?	
	Roberts et al., 2014	71	Not reported		?	?	
			ICU Admit	<7 days	>7 days	ICU d/c	Hospital d/c
Intervention	Author	Enrolled	Diagnostic				
	Morris et al., 2016	300	Medical -				
	Brummel et al., 2014	87	Medical/surgical -				
	Schweickert et al., 2009	104	Medical				
	Kayambu et al., 2015	50	Medical				
	Nava et al., 1998	80	Medical		?		
Multi-	Denehy et al., 2013	150	Medical				
component	Moss et al., 2016	120	Medical/surgical		-		>
	Yosef-Brauner et al., 2015	18	Medical/surgical		?		
	Chen et al., 2012	36	Medical		?	10 sessions	
	Dantas et al., 2012	59	Not reported		?		
	Chen et al., 2011	49	Medical/surgical		?		6 weeks
_	Patman et al., 2001	236	Cardiovascular		?	;	28 days
			ICU Admit	<7 days	>7 days	ICU d/c	Hospital d/c



Reid et al. Journal of Intensive Care (2018) 6:80

Author	Docign						
(Year)	(n)	Intervention	Primary Outcome	ICU D/C	Hospital D/C	Post- hospital	Result
Schweickert (2009)	RCT (104)	Order for early exercise and mobilization during sedation interruption	Return to independent functional status		$\checkmark$		$\checkmark$
Morris (2008)	Quazi- random (n=330)	Automatic order for ICU mobility team	% ICU survivors receiving physical therapy		$\checkmark$		$\checkmark$
Burtin (2009)	RCT (n=90)	In-bed cycling, respiratory physiotherapy, upper/ lower limb activity	6-minute walk distance		$\checkmark$		$\checkmark$
Denehy (2013)	RCT (150)	Intensive exercises in ICU, ward, outpatient	6-minute walk distance			6 months	X
Moss (2015)	RCT (120)	Intensive physiotherapy up to 28 days	Continuous scale physical functional performance test short form		1 month		X
Morris (2016)	RCT (300)	Standard rehab from ICU to hospital d/c 7d/wk	Hospital length of stay		$\checkmark$		X
Schaller (2016)	RCT (200)	Early goal-directed mobilization w/ closed loop communication (104)	SICU optimal mobilization score	$\checkmark$			$\checkmark$



# 1 What is your rehab profession?



Occupational therapy



Speechlanguage pathology







# 2 Where do you work?

st joseph's health centre student placement post op surgery hospital royal victoria hospital care guelph general hospital joseph brant hospital icu nosptia brampton civic guelph general st joseph's healthcare







# 4 Are you familiar with the TEAM trial?





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# 5 What other topics are of interest to you for future sessions?

Anything that the audience wants to know about :)

Suctioning





# What would you like to discuss more? Please rank your choice.







Intervention

Where does this study fit in the literature?



# In the TEAM study, the primary outcome was measured at 180 days









# Early mobilization is unsafe







# Based on the TEAM study, we should stop rehabilitation in the ICU









# **Post-lecture feedback**

Strongly disagree

I found the interactive format helpful

I'd like more teaching sessions like this





