Treatment of invasively ventilated adults with Early Activity and Mobilisation (TEAM) trial

Proposed Tables and Figures for the TEAM manuscript

On behalf of the TEAM Investigators

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Table 1. Characteristics of the patients at baseline.

Characteristic	Early Mobilization (n=xxx)	Standard Care Physiotherapy (n=xxx)
Age, yr	xx.x ± xx	xx.x ± xx
Female sex, no. (%)	xxx (xx)	xxx (xx)
BMI, kg/m^2, median (IQR)	xx.x (x.x – x.x)	xx.x (x.x – x.x)
Baseline Frailty and function		
Clinical Frailty Scale†	x.x ± xx	x.x ± xx
Functional comorbidity index ††	xx.x ± xx	xx.x ± xx
WHODAS 2.0 score ‡	xx.x ± xx	xx.x ± xx
Highest score on the ICU mobility scale in the week prior to ICU admission§	xx.x ± xx	xx.x ± xx
Hours from hospital admission to randomization, median (IQR)	xx (xx – xx)	xx (xx – xx)
Hours from ICU admission to randomization, median (IQR)	xx (xx – xx)	xx (xx – xx)
ICU admission type, no. (%)		
Planned ICU admission following elective surgery	xx (xx)	xx (xx)
Unplanned ICU admission	xx (xx)	xx (xx)
RASS at randomization, median (IQR)	xx (xx - xx)	xx (xx - xx)
ICU interventions at randomization		
PEEP cmH_20, median (IQR)	xx (xx – xx)	xx (xx – xx)
PaO_2/FiO_2,	x.xx ± x.xx	x.xx ± x.xx
Receiving vasopressors via infusion, no. (%)	xx (xx)	xx (xx)
Receiving renal replacement therapy, no. (%)	xx (xx)	xx (xx)
APACHE II score ‖	xx.x ± xx	xx.x ± xx
Diagnosis subgroup, no. (%)		
Sepsis ¶	xxx (xx)	xxx (xx)
Trauma	xxx (xx)	xxx (xx)
COVID-19 infection	xxx (xx)	xxx (xx)

Plus-minus values will be expressed as mean ± SD

* Statistically significant differences in baseline characteristics between groups will be indicated by * for P value <0.05, ** for P value <0.01, and *** for P value <0.001. Additional data describing the characteristics of trial participants at baseline will be provided in the online supplement.

† The Clinical Frailty Scale (CFS) categorizes patients as CFS 1 (very fit), CFS 2 (well), CFS 3 (managing well), CFS 4 (vulnerable), CFS 5 (mildly frail), CFS 6 (moderately frail), CFS 7 (severely frail), or CFS 8 (very severely frail) based on their pre-illness state.

†† The Functional Comorbidity Index includes 18 diagnoses and scores from 0 to 18 with the score equal to the number of specified comorbidities present. Higher scores are associated with greater levels of physical limitation.

‡The 12-item WHODAS 2.0 covers six domains of functioning with scores from 0 (no difficulty) to 4 (extreme difficulty) and a total score ranging from 0 to 48, with higher scores representing greater disability. The total score is divided by 48 and multiplied by 100 to convert it to a percentage of maximum disability.

§ The ICU Mobility Scale categorises patients as IMS 0 (nothing, lying in bed), IMS 1 (sitting in bed, exercises in bed), IMS 2 (passively moved to chair, no standing), IMS 4 (standing), IMS 5(transferring bed to chair), IMS 6 (marching on spot, at bedside), IMS 7 (walking with assistance of 2 or more people), IMS 8 (walking with assistance of 1 person), IMS 9 (walking independently with gait aid), IMS 10 (walking independently without a gait aid).

‖ Scores on the APACHE II range from 0 to 71, with higher scores indicating more severe disease and a higher risk of death.

¶ Sepsis was defined as present when there was suspected or confirmed infection plus (i) A SOFA score of two or greater (if there was no known pre-existing organ dysfunction) OR (ii) more than a two-point increase in SOFA score (if there was pre-existing organ dysfunction)

Abbreviations: APACHE: Acute Physiology And Chronic Health Evaluation; BMI: body mass index; CFS: Clinical Frailty Scale; COVID-19: Coronavirus disease 2019; FiO_2: fraction of inspired oxygen; ICU: Intensive Care Unit; IQR: interquartile range; no.: number; PaO2: arterial partial pressure of oxygen , PEEP: Positive End-Expiratory Pressure; cm H20: centimeters of water, RASS: Richmond Agitation Sedation Scale, SOFA: Sequential Organ Failure Assessment; WHODAS: World Health Organization Disability Assessment Schedule 2.0 (12 Level)

Table 2. Mobilization in the ICU.

Characteristic	Early Mobilization (n=xxx)	Standard Care Physiotherapy (n=xxx)	Between group difference (95% CI)
Days from randomization until first physiotherapy assessment	xx.x ± x.x	xx.x ± x.x	x.x (x.x-x.x)
Proportion of days per patient on which a physiotherapy assessment occurred in ICU, mean (SD)**	xx.x ± x.x	xx.x ± x.x	x.x (x.x-x.x)
Active mobilization time per day in ICU, minutes, mean (SD) **	xx.x ± x.x	xx.x ± x.x	x.x (x.x-x.x)
Time mobilizing at specific IMS levels per day in ICU, minutes†			
Sitting over the edge of the bed (IMS 3)	xx.x ± xx	xx.x ± xx	x.x (x.x-x.x)
Standing (IMS 4)	xx.x ± xx	xx.x ± xx	x.x (x.x-x.x)
Transferring to a chair (IMS 5)	xx.x ± xx	xx.x ± xx	x.x (x.x-x.x)
Marching on the spot (IMS 6)	xx.x ± xx	xx.x ± xx	x.x (x.x-x.x)
Walking with the assistance ≥2 people (IMS 7)	xx.x ± xx	xx.x ± xx	x.x (x.x-x.x)
Walking with the assistance of 1 person (IMS 8)	xx.x ± xx	xx.x ± xx	x.x (x.x-x.x)
Walking independently with a gait aid (IMS 9)	xx.x ± xx	xx.x ± xx	x.x (x.x-x.x)
Walking independently without a gait aid (IMS 10)	xx.x ± xx	xx.x ± xx	x.x (x.x-x.x)
Mobilized to an IMS of 3 or more in the ICU, no. (%)	xx (xx)	xx (xx)	
Days from randomization until first IMS 3 or more achieved, mean SD**	xx.x ± x.x	xx.x ± x.x	x.x (x.x-x.x)
Mobilized to an IMS of 4 or more in the ICU, no. (%)	xx (xx)	xx (xx)	
Days from randomization until first IMS 4 or more achieved (mean**)	xx.x ± x.x	xx.x ± x.x	x.x (x.x-x.x)
Mobilized to an IMS of 7 or more in the ICU, no. (%)	xx (xx)	xx (xx)	
Days from randomization until first IMS 7 or more achieved (mean**)	xx.x ± x.x	xx.x ± x.x	x.x (x.x-x.x)

Plus-minus values will be expressed as mean ±SD

† IMS 0-2 were not timed. IMS 3 (sitting over the edge of the bed) could involve assistance of staff but required that the patient was actively sitting over the side of the bed with some trunk control; IMS 4 (standing) required weight bearing through the feet in a standing position with or without assistance (the use of a standing lifter or tilt table device was allowed); IMS 5 (transferring from bed to chair) required active transferring weight from one leg to another to move to the chair. If the patient had been stood with the assistance of a medical device, they were required step to the chair (an IMS of 5 was not considered achieved if the patient was wheeled in a standing lifter device.); IMS 6 (marching on the spot) required the patient to walk on the spot by lifting alternate feet least 4 times (twice on each foot) with or without assistance; IMS 7 (walking with assistance of ≥ 2 people) required walking away from the bed/chair by at least 5 metres assisted by ≥2 people; IMS 8 (walking with the assistance of 1 person) required walking away from the bed/chair by at least 5 metres assisted by 1 person; IMS 9 (walking independently with a gait aid) required walking away from the bed/chair by at least 5 metres with a gait aid, but no assistance from another person. In a wheelchair bound person, this activity level included wheeling the chair independently 5 metres away from the bed/chair; IMS 10 (walking independently without a gait aid was defined as walking away from the bed/chair by at least 5 metres without a gait aid or assistance from another person.

Abbreviations: ICU: intensive care unit; IMS: ICU mobility scale; IQR: interquartile range**;** no.: number.

** prefer mean over median unless data substantially ~~s~~kewed

Note: IMS categories may be collapsed if the numbers in particular categories are small.

Table 3. Primary Outcome, Key Secondary Outcomes, and Adverse Events.

	Early Mobilization (n=xxx)	Standard Care Physiotherapy (n=xxx)	Between-Group Difference†	Unadjusted odds ratio
Primary outcome				
Days alive and out of hospital to day 180				
Median (IQR)	xxx (xxx – xxx)	xxx (xxx – xxx)	xx (95% CI)‡	
Key secondary outcomes				
Day 180 mortality, no. (%)	xx (xx)	xx (xx)		xx (xx to xx)
Days from randomization until death, censored at day 180	xx (xx – xx)	xx (xx – xx)	xx (xx to xx)	
Median no. of ventilator-free days to day 28 (IQR)	xx (xx – xx)	xx (xx – xx)	xx (xx to xx)	
Median no. of ICU-free days to day 28 (IQR)	xx (xx – xx)	xx (xx – xx)	xx (xx to xx)	
Day 180 functional outcomes				
EQ5D5L utility score§	xx.x ± xx	xx.x ± xx	xx (xx to xx)	
EQ Visual Analogue Scale‖	xx.x ± xx	xx.x ± xx	xx (xx to xx)	
Median Barthel Index of ADL score (IQR) ¶	xx (xx – xx)	xx (xx – xx)	xx (xx to xx)	
Median IADL score (IQR) **	xx (xx – xx)	xx (xx – xx)	xx (xx to xx)	
12-item WHODAS 2.0 score††	xx (xx – xx)	xx (xx – xx)	xx (xx to xx)	
Adverse events, no. (%)‡				
Any adverse event§§	xx (xx)	xx (xx)		xx (xx to xx)‡

† All differences in medians will be calculated using quantile regression after adjustment for trial site.
‡ A P value will be presented for the principal analysis of the primary end point and for the comparison of adverse events only.
§ The EQ-5D-5L is a generic preference-based health status instrument which is comprised of five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression. Utility score ranges from -0.6 to +1 where the maximum score of +1 indicates the best health state.
‖ The EQ Visual Analogue Scale provides a single global rating of self-perceived health and is scored on a 0 to 100 mm scale representing "the worst…" and "the best health you can imagine", respectively
¶ The Barthel Index of Activities of Daily Living measures functional disability in 10 ADLs by quantifying patient performance. 5-point increments are used in scoring, with a maximal score of 100 indicating full independence in physical functioning whilst a lowest score of 0 indicating a patient with a complete bed-bound state.
** The Lawton IADL Scale is a valid and reliable functional assessment instrument which assesses independent living skills across 8 domains of function. A summary score ranges between from 0 and 8 with higher scores indicating greater levels of independence.
†† The 12-item WHODAS 2.0 score scores from 0 (no difficulty) to 4 (extreme difficulty) for each item and a total WHODAS score ranges from 0 to 48, with higher scores representing greater disability. The total score is divided by 48 and multiplied by 100 to convert it to a percentage of maximum disability.
§§ Specific adverse events by treatment group are shown Table S7 in Supplementary Appendix.
Abbreviations: ADL: Activities of Daily Living; CI: Confidence Interval; EQ5D5L: European quality of life 5 dimensions 5 levels; EQVAS: European Quality of Life Visual Analogue Scale; IADL: Lawton Instrumental Activities of Daily Living; ICU: Intensive Care Unit; IQR: Interquartile range; WHODAS: World Health Organisation Disability Assessment Schedule.

Figure 1: Consort diagram of patient flow through the trial
Figure 2: Mobilization in the Intensive Care Unit by treatment group

Proposed Tables and Figures for the Supplement

Table S1. Additional characteristics of the patients at baseline: demographics.

Characteristic	Early Mobilization (n=xxx)	Standard Care Physiotherapy (n=xxx)
Weight, kg	xx.x ± xx	xx.x ± xx
Country of enrolment, no. (%)		
Australia	xx (xx)	xx (xx)
Brazil	xx (xx)	xx (xx)
Ireland	xx (xx)	xx (xx)
Germany	xx (xx)	xx (xx)
New Zealand	xx (xx)	xx (xx)
United Kingdom	xx (xx)	xx (xx)
Ethnicity, no. (%) †		
Asian	xx (xx)	xx (xx)
European	xx (xx)	xx (xx)
Māori	xx (xx)	xx (xx)
Pacific Island Peoples	xx (xx)	xx (xx)
Middle Eastern / Latin / African	xx (xx)	xx (xx)
Other	xx (xx)	xx (xx)
Employment and living situation		
Married or de facto relationship, no. (%)		
Yes	xx (xx)	xx (xx)
No	xx (xx)	xx (xx)
Unknown	xx (xx)	xx (xx)
Type of home living, no. (%)		
Home alone	xx (xx)	xx (xx)
Home with partner (spouse, de facto)	xx (xx)	xx (xx)
Home— living with other people (e.g. daughter/son, friend)	xx (xx)	xx (xx)
Other	xx (xx)	xx (xx)
Current employment status, no. (%)		
Employed, full or part-time	xx (xx)	xx (xx)
Self-employed, full or part-time	xx (xx)	xx (xx)
Student, full or part-time	xx (xx)	xx (xx)
Non-paid work (e.g. voluntary work)	xx (xx)	xx (xx)
Retired or full-time home duties	xx (xx)	xx (xx)
Unemployed (due to health reasons)	xx (xx)	xx (xx)
Unemployed (due to other reasons)	xx (xx)	xx (xx)
Other	xx (xx)	xx (xx)

Plus-minus values will be expressed as mean ±SD
† Ethnicity data were only collected for participants enrolled in New Zealand
Abbreviations: kg: kilogram; SD: standard deviation.

Table S2. Additional characteristics of the patients at baseline: frailty and function.

Characteristic	Early Mobilization (n=xxx)	Standard Care Physiotherapy (n=xxx)
Clinical frailty scale category, no. (%) †		
Very fit	xx (xx)	xx (xx)
Well	xx (xx)	xx (xx)
Managing well	xx (xx)	xx (xx)
Vulnerable	xx (xx)	xx (xx)
Mildly frail	xx (xx)	xx (xx)
Moderately frail	xx (xx)	xx (xx)
Severely frail	xx (xx)	xx (xx)
Very severely frail	xx (xx)	xx (xx)
Frail, CFS 5 and above, no. (%)	xx (xx)	xx (xx)
WHODAS 2.0 score category, no. (%) ‡		
No disability	xx (xx)	xx (xx)
Mild disability	xx (xx)	xx (xx)
Moderate disability	xx (xx)	xx (xx)
Severe disability	xx (xx)	xx (xx)
Complete disability	xx (xx)	xx (xx)

Plus-minus values will be expressed as mean ±SD
† The Clinical Frailty Scale (CFS) categorizes patients as CFS 1 (very fit), CFS 2 (well), CFS 3 (managing well), CFS 4 (vulnerable), CFS 5 (mildly frail), CFS 6 (moderately frail), CFS 7 (severely frail), or CFS 8 (very severely frail) based on their pre-illness state.
‡ The 12-item WHODAS 2.0 covers six domains of functioning with scores from 0 (no difficulty) to 4 (extreme difficulty) and a total score ranging from 0 to 48, with higher scores representing greater disability. The total score is divided by 48 and multiplied by 100 to convert it to a percentage of maximum disability. Participants were categorized as follows based on their percentage score: no disability (0–4%); mild disability (5–24%); moderate disability (25–49%); severe disability (50–95%); and complete disability (96–100%).
Abbreviations: CFS: clinical frailty scale; WHODAS: World Health Organisation Disability Assessment Score

Table S3. Additional characteristics of the patients at baseline: comorbidities.

Functional Comorbidity Index Conditions, no. (%)	Early Mobilization (n=xxx)	Standard Care Physiotherapy (n=xxx)
No comorbid conditions	xx (xx)	xx (xx)
Arthritis (rheumatoid and osteoarthritis)	xx (xx)	xx (xx)
Osteoporosis	xx (xx)	xx (xx)
Asthma	xx (xx)	xx (xx)
Chronic obstructive pulmonary disease (COPD), acute respiratory distress syndrome (ARDS), or emphysema	xx (xx)	xx (xx)
Angina	xx (xx)	xx (xx)
Congestive heart failure (or heart disease)	xx (xx)	xx (xx)
Heart attack (myocardial infarction)	xx (xx)	xx (xx)
Neurological disease (e.g., multiple sclerosis or Parkinson's disease)	xx (xx)	xx (xx)
Stroke or transient ischemic attack (TIA)	xx (xx)	xx (xx)
Peripheral vascular disease	xx (xx)	xx (xx)
Diabetes types I and/or type II	xx (xx)	xx (xx)
Upper gastrointestinal disease (e.g., ulcer, hernia, reflux)	xx (xx)	xx (xx)
Depression	xx (xx)	xx (xx)
Anxiety or panic disorders	xx (xx)	xx (xx)
Visual impairment (e.g. cataracts, glaucoma, macular degeneration)	xx (xx)	xx (xx)
Hearing impairment (i.e. very hard of hearing, even with hearing aids)	xx (xx)	xx (xx)
Degenerative disc disease (e.g. back disease, spinal stenosis, or severe chronic back pain)	xx (xx)	xx (xx)
Obesity and/or body mass index (BMI) ≥30	xx (xx)	xx (xx)

Plus-minus values will be expressed as mean ±SD
Abbreviations: ARDS: acute respiratory distress syndrome; BMI: body mass index COPD: chronic obstructive pulmonary disease; TIA: transient ischemic attack.

Table S4. Additional characteristics of the patients at baseline: ICU admission source and diagnosis.

Characteristic	Early Mobilization (n=xxx)	Standard Care Physiotherapy (n=xxx)
ICU admission source, no. (%)		
Emergency Department	xx (xx)	xx (xx)
Hospital Ward	xx (xx)	xx (xx)
Transfer from another ICU	xx (xx)	xx (xx)
Transfer from another hospital (except from another ICU)	xx (xx)	xx (xx)
Admitted from Operating Theatre following emergency surgery	xx (xx)	xx (xx)
Admitted from Operating Theatre following elective surgery	xx (xx)	xx (xx)
Operative admission diagnosis, no. (%)		
Cardiovascular	xxx (xx)	xxx (xx)
Gastrointestinal	xxx (xx)	xxx (xx)
Gynecological	xxx (xx)	xxx (xx)
Musculoskeletal / skin	xxx (xx)	xxx (xx)
Neurological	xxx (xx)	xxx (xx)
Renal	xxx (xx)	xxx (xx)
Respiratory	xxx (xx)	xxx (xx)
Trauma	xxx (xx)	xxx (xx)
Non-operative admission diagnosis, no. (%)		
Cardiovascular	xxx (xx)	xxx (xx)
Gastrointestinal	xxx (xx)	xxx (xx)
Hematological	xxx (xx)	xxx (xx)
Metabolic	xxx (xx)	xxx (xx)
Musculoskeletal / skin	xxx (xx)	xxx (xx)
Neurological	xxx (xx)	xxx (xx)
Renal	xxx (xx)	xxx (xx)
Respiratory	xxx (xx)	xxx (xx)
Sepsis	xxx (xx)	xxx (xx)
Trauma	xxx (xx)	xxx (xx)

Plus-minus values will be expressed as mean ±SD
Abbreviations: ICU: intensive care unit.

Table S5. Additional characteristics of the patients at baseline: physiology and ICU treatment.

Characteristic	Early Mobilization (n=xxx)	Standard Care Physiotherapy (n=xxx)
GCS, median (IQR)	x (x – x)	x (x – x)
Serum creatinine, µmol/liter	xxx ± xx	xxx ± xx
PaO_2 – mmHg, median(IQR)	xx.x (xx.x-xx.x)	xx.x (xx.x-xx.x)
Agitation and delirium		
RASS score, median (IQR)	x.x (x.x – x.x)	x.x (x.x – x.x)
CAM-ICU positive, no. (%)	xx (xx)	xx (xx)
ICU supports and therapies, no. (%)		
Sedatives via continuous infusion	xx (xx)	xx (xx)
Vasopressors via continuous infusion	xx (xx)	xx (xx)
Renal replacement therapy	xx (xx)	xx (xx)
Corticosteroids	xx (xx)	xx (xx)

Plus-minus values will be expressed as mean ±SD
Abbreviations: CAM-ICU: Confusion Assessment Method for the ICU; GCS: Glasgow Coma Score; ICU: intensive care unit; IQR: interquartile range; PaO_2: arterial partial pressure of oxygen; RASS: Richmond Agitation Sedation Scale; SD: standard deviation; µmol: A micromole is a unit of measure defined as 10-6 (one-millionth) of a mole.

Table S6. Representativeness of the study population.

Category	Comment
Disease, problem, or condition under investigation	…
Special considerations rated to	
Sex and gender	…
Race or ethnic group	…
Geography	…
Other considerations	…
Overall representativeness of this trial	…

Table S7. Serious Adverse Events.

	Early Mobilization (n=xxx)	Standard Care Physiotherapy (n=xxx)	P value
Fall to the floor	xx (xx)	xx (xx)	x.xx
Cardiac arrest	xx (xx)	xx (xx)	x.xx
Arrhythmia, no. (%) †	xx (xx)	xx (xx)	x.xx
Desaturation, no. (%) ‡	xx (xx)	xx (xx)	x.xx
Unplanned extubation	xx (xx)	xx (xx)	x.xx
Line removal requiring urgent replacement, no. (%)	xx (xx)	xx (xx)	x.xx
Other, no. (%)	xx (xx)	xx (xx)	x.xx

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
‡ Desaturation is defined as SpO_2 less than 80% for greater than 3 minutes
Abbreviations: SpO_2: oxygen saturation as measured by pulse oximetry

Table S8. Adverse Events.

	Early Mobilization (n=xxx)	Standard Care Physiotherapy (n=xxx)
Total number of Adverse Events per patient, no. (%)		
0	xx (xx)	xx (xx)
1	xx (xx)	xx (xx)
2	xx (xx)	xx (xx)
3 or more	xx (xx)	xx (xx)
Total number of patients with one or more adverse event, no. (%)	xx (xx)	xx (xx)

Adverse events (AE) include events that were reported as probably, possibly or definitely related to the study.

Table S9. Additional Secondary Outcome measures.

	Early Mobilization (n=xxx)	Standard Care Physiotherapy (n=xxx)	Between-Group Difference	Hazard Ratio
Day 28 mortality, no. (%)	xx (xx)	xx (xx)	xx (xx to xx)	
Median no. of coma and delirium-free days to day 28 (IQR)	xx (xx – xx)	xx (xx – xx)	xx (xx to xx)	
Day 180 functional outcomes				
Median MOCA Blind Score (IQR) ‡	xx (xx – xx)	xx (xx – xx)	xx (xx to xx)	
Median HADS Score (IQR) *	xx (xx – xx)	xx (xx – xx)	xx (xx to xx)	
Anxiety symptoms score	xx (xx – xx)	xx (xx – xx)	xx (xx to xx)	
Depression symptoms score	xx (xx – xx)	xx (xx – xx)	xx (xx to xx)	
Median IES-R Score (IQR) †	xx (xx – xx)	xx (xx – xx)	xx (xx to xx)	
Days alive and out of hospital to day 180				
Patients who survived	xx (xx – xx)	xx (xx – xx)	xx (xx to xx)	
Patients who died	xx (xx – xx)	xx (xx – xx)	xx (xx to xx)	
Days in hospital, rehabilitation, or a nursing home to day 180				
Patients who survived	xx (xx – xx)	xx (xx – xx)	xx (xx to xx)	
Patients who died	xx (xx – xx)	xx (xx – xx)	xx (xx to xx)	
Time from randomization to ICU discharge §	xx (xx – xx)	xx (xx – xx)		xx (xx to xx)
Patients who survived	xx (xx – xx)	xx (xx – xx)		xx (xx to xx)
Patients who died	xx (xx – xx)	xx (xx – xx)		xx (xx to xx)
Time from randomization to hospital discharge §	xx (xx – xx)	xx (xx – xx)		xx (xx to xx)
Patients who survived	xx (xx – xx)	xx (xx – xx)		xx (xx to xx)
Patients who died	xx (xx – xx)	xx (xx – xx)		xx (xx to xx)
No. of days of hospitalization among survivors, geometric mean (95% CI)	xxx (xxx – xxx)	xxx (xxx – xxx)	xx (xx to xx)	

‡ The MOCA-Blind assesses different cognitive domains: attention and concentration, memory, language, conceptual thinking, calculations, and orientation to provide an overall assessment of Cognition on a scale from 0 to 22. A score of 18 or higher is considered normal.
* The Hospital Anxiety and Depression Scale measures symptoms of anxiety and depression on a scale from 0 to 21 with a higher number indicating a higher number of symptoms.
† The Impact of Events Scale - Revised measures the impact of stressful life events on a scale ranging from 0 (no symptoms) to 88 (the most severe symptoms)
§Time from randomisation events will be calculated across the index admission only.
Abbreviations: HADS: Hospital Anxiety and Depression Scale; ICU: Intensive Care Unit; IES-R: The Impact of Events Scale; IQR: interquartile range; MOCA: Montreal Cognitive Assessment

Table S10. Process of Care Measures and Cointerventions.

	Early Mobilization (n=xxx)	Standard Care Physiotherapy (n=xxx)	Effect estimate
			Odds ratio (95% CI)
Tracheostomy, no. (%)	xx (xx)	xx (xx)	x.xx (x.xx to x.xx)
Neuromuscular blockers, no. (%)	xx (xx)	xx (xx)	x.xx (x.xx – x.xx)
Reintubation, no. (%)	xx (xx)	xx (xx)	x.xx (x.xx – x.xx)
New kidney replacement therapy, no. (%)	xx (xx)	xx (xx)	x.xx (x.xx – x.xx)
Corticosteroids in ICU, no. (%)	xx (xx)	xx (xx)	x.xx (x.xx – x.xx)
			Difference in medians (95% CI)
Vasopressor free days to day 28*, median (IQR)	xx.x (xx.x-xx.x)	xx.x (xx.x-xx.x)	xx.x (xx.x to xx.x)

Plus-minus values will be expressed as mean ±SD
* Patients who died at any time were assigned zero vasopressor-free days.
Abbreviations: ICU: intensive care unit; IQR: interquartile range

Table S11. Sensitivity Analyses for the Primary Outcome.

Purpose of analysis	Analysis	Category or subgroup	Between-Group Difference
Primary analysis	Linear quantile regression analysis adjusted for site		xx (xx to xx)
Adjustment for baseline imbalance*	Linear quantile regression adjusted for covariate imbalance*		xx (xx to xx)
Adjustment for missingness†			
	Best-worst case analysis†		xx (xx to xx)
	Worst-best case analysis†		xx (xx to xx)
	Multiple imputation analysis†		xx (xx to xx)
Primary outcome treatment effect estimates by country (site) of enrolment	Linear quantile regression		
		Australia	xx (xx to xx)
		Brazil	xx (xx to xx)
		Ireland	xx (xx to xx)
		Germany	xx (xx to xx)
		New Zealand	xx (xx to xx)
		United Kingdom	xx (xx to xx)

* This analysis will be conducted in the event that there is baseline variable imbalance (P value <0.05) despite randomization. Unbalanced variables will be included as fixed terms in the linear quantile regression analysis.
† In the event that more than 5% of primary outcome data are missing, we will conduct a best-worst case analysis, a best-worst case analysis, and, if necessary, multiple imputation under the assumption that data are missing at random.

Table S12. Primary Outcome assessed as ordered categories of days alive and out of hospital to day 180.

	Early Mobilization (n=xxx)	Standard Care Physiotherapy (n=xxx)	Odds ratio (95% CI)
Days alive and out of hospital to day 180			x.xx (x.xx – x.xx)
1st quartile, no. (%)**	xx (xx)	xx (xx)	
2nd quartile, no. (%)**	xx (xx)	xx (xx)	
3rd quartile, no. (%)**	xx (xx)	xx (xx)	
4th quartile, no. (%)**	xx (xx)	xx (xx)	

Proportional odds cumulative logistic model treating DAOH180 as an ordinal categorical random variable. The wide range of DAOH180 categories has been collapsed to a convenient and clinically meaningful smaller number of ordered categories.
**Four quantiles for illustration only, number of ordered categories of DAOH180 will be decided based on the data.

Table S13. EuroQoL-5D-5L quality of life at 180 days.

	Early Mobilization (n=xxx)	Standard Care Physiotherapy (n=xxx)
Mobility, no. (%)		
No problems with walking around	xx (xx)	xx (xx)
Slight problems with walking around	xx (xx)	xx (xx)
Moderate problems with walking around	xx (xx)	xx (xx)
Severe problems with walking around	xx (xx)	xx (xx)
Unable to walk around	xx (xx)	xx (xx)
Personal care, no. (%)		
No problems with washing or dressing	xx (xx)	xx (xx)
Slight problems with washing or dressing	xx (xx)	xx (xx)
Moderate problems washing or dressing	xx (xx)	xx (xx)
Severe problems with washing or dressing	xx (xx)	xx (xx)
Unable to wash or dress	xx (xx)	xx (xx)
Usual activities (e.g. work, study, housework, family or leisure activities), no. (%)		
No problems with usual activities	xx (xx)	xx (xx)
Slight problems with usual activities	xx (xx)	xx (xx)
Moderate problems with usual activities	xx (xx)	xx (xx)
Severe problems with usual activities	xx (xx)	xx (xx)
Unable to do usual activities	xx (xx)	xx (xx)
Pain / discomfort, no. (%)		
No pain / discomfort	xx (xx)	xx (xx)
Slight pain / discomfort	xx (xx)	xx (xx)
Moderate pain / discomfort	xx (xx)	xx (xx)
Severe pain / discomfort	xx (xx)	xx (xx)
Extreme pain / discomfort	xx (xx)	xx (xx)
Anxiety / depression, no. (%)		
No anxiety / depression	xx (xx)	xx (xx)
Slight anxiety / depression	xx (xx)	xx (xx)
Moderate anxiety / depression	xx (xx)	xx (xx)
Severe anxiety / depression	xx (xx)	xx (xx)
Extreme anxiety / depression	xx (xx)	xx (xx)

* The EQ-5D-5L is a generic preference-based health status instrument which is comprised of five dimensions: mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.
Abbreviations: EQ5D5L: European quality of life 5 dimensions 5 levels

Table S14. WHODAS 2.0 score categories at 180 days.

	Early Mobilization (n=xxx)	Standard Care Physiotherapy (n=xxx)
No disability, no. (%)	xx (xx)	xx (xx)
Mild disability, no. (%)	xx (xx)	xx (xx)
Moderate disability, no. (%)	xx (xx)	xx (xx)
Severe disability, no. (%)	xx (xx)	xx (xx)
Complete disability, no. (%)	xx (xx)	xx (xx)

Abbreviations: WHODAS: World Health Organisation Disability Assessment Score

Table S15. Subgroup Analyses for Days Alive and Out of Hospital to Day 180.				
	Standard Care Physiotherapy (n=xxx)	**Purpose of Early Mobilization (n=xxx)**	**Between-group difference**	**Interaction P value**
Days alive and out of hospital				
WHODAS 2.0 disability category				
No or mild disability	xxx (xxx – xxx)	xxx (xxx – xxx)	xx (xx to xx)	x.xx
Moderate, severe or complete disability	xxx (xxx – xxx)	xxx (xxx – xxx)	xx (xx to xx)	
Age				
Median age or below	xxx (xxx – xxx)	xxx (xxx – xxx)	xx (xx to xx)	x.xx
Above median age	xxx (xxx – xxx)	xxx (xxx – xxx)	xx (xx to xx)	
Admission Diagnosis				
Sepsis	xxx (xxx – xxx)	xxx (xxx – xxx)	xx (xx to xx)	x.xx
All other diagnoses	xxx (xxx – xxx)	xxx (xxx – xxx)	xx (xx to xx)	
Admission Diagnosis				
Trauma	xxx (xxx – xxx)	xxx (xxx – xxx)	xx (xx to xx)	x.xx
All other diagnoses	xxx (xxx – xxx)	xxx (xxx – xxx)	xx (xx to xx)	
Illness severity				
Median APACHE-II* score or below	xxx (xxx – xxx)	xxx (xxx – xxx)	xx (xx to xx)	x.xx
Above median APACHE-II* score	xxx (xxx – xxx)	xxx (xxx – xxx)	xx (xx to xx)	
Frailty				
Well and vulnerable	xxx (xxx – xxx)	xxx (xxx – xxx)	xx (xx to xx)	x.xx
Frail	xxx (xxx – xxx)	xxx (xxx – xxx)	xx (xx to xx)	
SARS-CoV 2 status				
Positive	xxx (xxx – xxx)	xxx (xxx – xxx)	xx (xx to xx)	x.xx
Negative or unknown	xxx (xxx – xxx)	xxx (xxx – xxx)	xx (xx to xx)	

* Scores on the APACHE II range from 0 to 71, with higher scores indicating more severe disease and a higher risk of death.
Abbreviations: WHODAS: World Health Organisation Disability Assessment Score; SARS-CoV 2: Severe acute respiratory syndrome coronavirus 2

Figure S1: Kaplan-Meier Survival Plot of survival time by treatment group through to day 180
Figure S2: Differential effect of TEAM intervention on Days Alive and Out of Hospital to day 180 across quantiles of DAOH180
Figure S3: Subgroup Analyses for Days Alive and Out of Hospital to day 180.
Figure S4: Daily Richmond Agitation Sedation Scale until day 28
Figure S5: Daily Intensive Care Unit Mobility Scale
Figure S6: Daily proportion of patients assessed by a physiotherapist
Figure S7: Daily active mobilization time per day in Intensive Care Unit
Figure S8: Proportion of patients with a positive CAM-ICU per day in Intensive Care Unit
Figure S9: Daily reasons for why higher degree of physical activity was not possible
Figure S10: Daily ventilatory support