Effects of Vibration Therapy on the Physical Function of Critically Ill Adults Trial: A Randomized Controlled Trial

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TABLE S1. Exclusion Criteria

Category	Contents
(I)	No permission from the primary physician
(II)	Excessive agitation [Richmond Agitation–Sedation Scale (RASS) ≥ 2]
(III)	Impaired consciousness (RASS ≤ −3)
(IV)	Unstable vital signs requiring circulatory support devices, such as intra-aortic balloon pump
(V)	Sustained low blood pressure even with the use of catecholamine
(VI)	Dynamic blood pressure changes after body position changes
(VII)	Risk of rupture of untreated aneurysms
(VIII)	Uncontrolled pain
(IX)	Uncontrolled intracranial pressure ≥ 20 mmHg
(X)	Unstable phase in the head or cervical spine injury
(XI)	Metal implants or unstable bone fractures in the extremities or spine
(XII)	Active bleeding
(XIII)	Insufficient stabilization or length of catheters
(XIV)	Insufficient staffing
(XV)	No consent from patients or surrogates

Exclusion criteria were based on the Japanese Society of Intensive Care Medicine criteria.

TABLE S2. Withdrawal Criteria

Categories	Contents
(I) Generalized symptoms	Unresponsive state; agonized facial expression, pale skin, or cyanosis; newly occurring impaired consciousness; agitation with risk to safety; sudden limb weakness or dependence; inability to sustain posture, and risk of falling
(II) Subjective symptoms	Sudden dyspnea, unbearable fatigue, or suffering and desire to withdraw
(III) Respiration	Respiratory rate < 5/min or > 40/min; oxygen saturation < 88%; increased work of breathing and asynchrony with mechanical ventilation or fighting the ventilator
(IV) Circulation	Heart rate < 40/min or > 130/min; electrocardiogram, newly occurring arrhythmia, sign of cardiac ischemia; systolic blood pressure >180 mmHg, decreased systolic or diastolic blood pressure > 20%, mean arterial pressure < 65 or > 110 mmHg
(V) Devices	Risk of unplanned extubation or removal of tubes, catheters, and drains
(VI) Other conditions	Desire to withdraw from the study; increased drainage of blood; and risk of widening a wound

Withdrawal criteria were based on the Japanese Society of Intensive Care Medicine criteria.

TABLE S3. Progressive Mobilization Criteria

Categories		Contents
(I) Consciousness	Richmond Agitation–Sedation Scale (RASS)	$-2 \leq$ RASS ≤ -1
(II) Pain	Numerical Rating Scale	Numerical Rating Scale ≤ 3
	Behavioral Pain Scale	Behavioral Pain Scale ≤ 5
(III) Respiration	Respiratory rate	< 35/min
	Oxygen saturation	$\geq 90\%$
(IV) Mechanical ventilation	Fraction of inspired oxygen	< 0.6
	Positive end-expiratory pressure	< 10 cmH_2O
(V) Circulation	Heart rate	$50 \leq$ Heart rate ≤ 120/min
	Arrhythmia	Non-newly occurring arrythmia
	Cardiac ischemia	No sign of cardiac ischemia in electrocardiograph
	Mean arterial pressure	$\geq$ 65mmHg
	Catecholamine	Stable vital sign with dopamine $\leq$ 5 μg/kg/min or noradrenaline ≤ 0.2 μg/kg/min
(VI) Other conditions	Sufficient stabilization and length of catheters	
	No active bleeding	
	Intracranial pressure < 20 cmH_2O	
	Consent from patients or surrogates	

Mobilization includes sitting at the edge of bed, standing, or ambulation. It is desirable to meet all categories. When patients cannot meet all these categories, multidisciplinary discussion decides the initiation of mobilization or not.

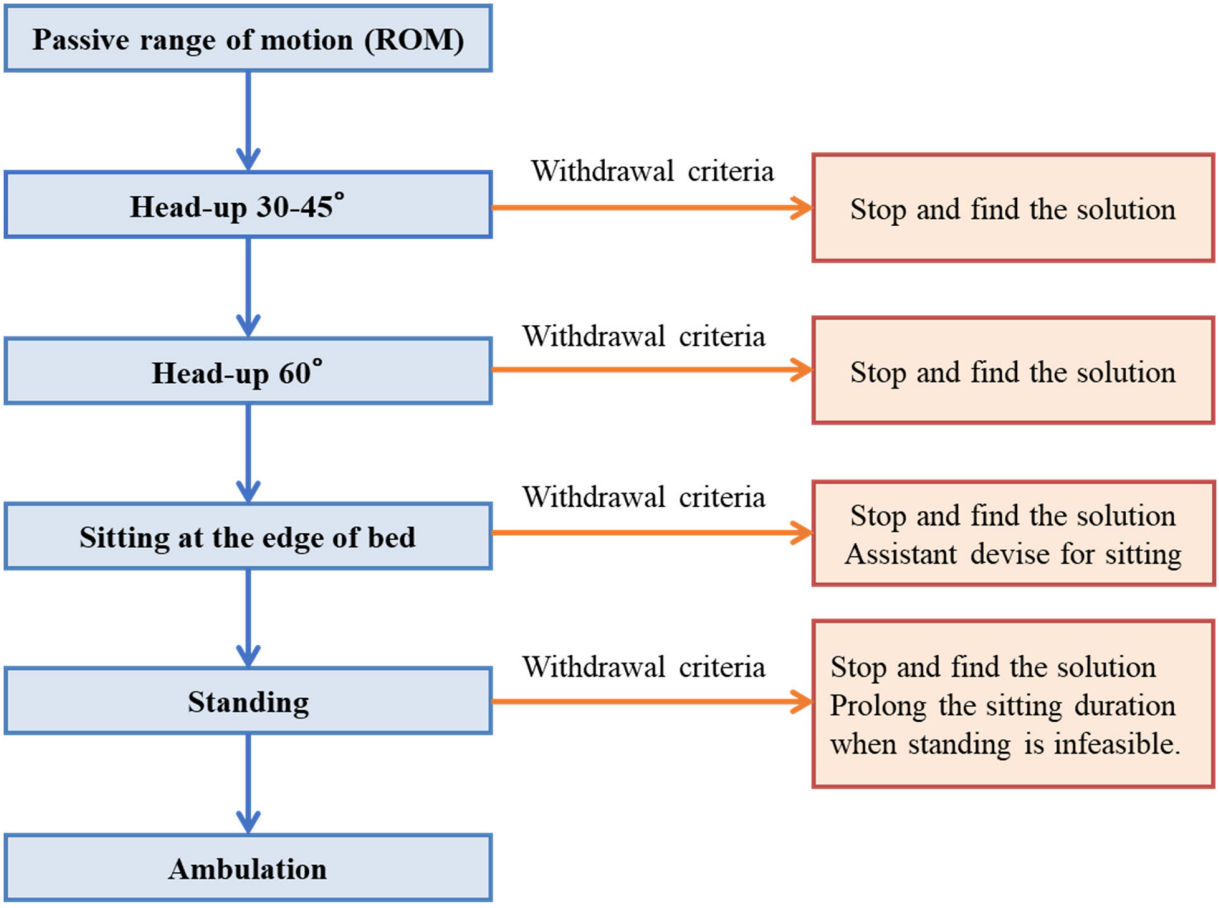


Figure S1. Progressive mobilization protocol

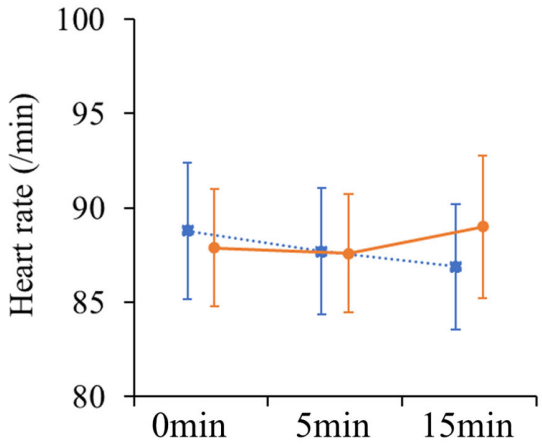
TABLE S4. Average Values and Between-group Difference in Outcomes

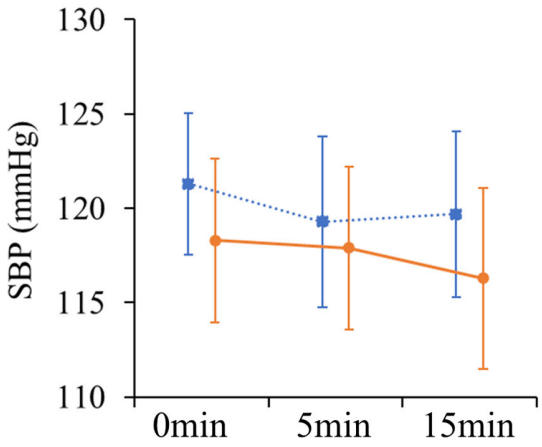
Variables	Intervention n = 86	Control n = 90	Between-Group Difference (95% CI)
Primary outcomes			
FSS-ICU at the ICU discharge			
Total	22.1 ± 6.6	20.7 ± 6.4	1.4 (−0.6 to 3.3)
Rolling	6.0 ± 1.3	5.7 ± 1.4	0.3 (−0.1 to 0.7)
Supine to sit	4.6 ± 2.0	3.7 ± 2.2	0.9 (0.2 to 1.5)
Sitting	6.4 ± 1.3	6.5 ± 1.2	−0.1 (−0.5 to 0.3)
Sit to stand	4.4 ± 2.7	4.4 ± 2.7	−0.1 (−0.9 to 0.8)
Ambulation	1.2 ± 1.5	1.0 ± 1.3	0.2 (−0.3 to 0.6)
Secondary outcomes			
MRC score	55.9 ± 7.6	54.5 ± 9.0	1.4 (−1.1 to 3.9)
Maximum ICU mobility scale	5.7 ± 1.6	5.5 ± 1.4	0.2 (−0.3 to 0.6)
Ventilator-free days, d	25.6 ± 4.0	25.7 ± 5.2	−0.1 (−1.5 to 1.3)
ICU-free days, d	25.6 ± 4.0	25.7 ± 5.2	−0.1 (−1.5 to 1.3)

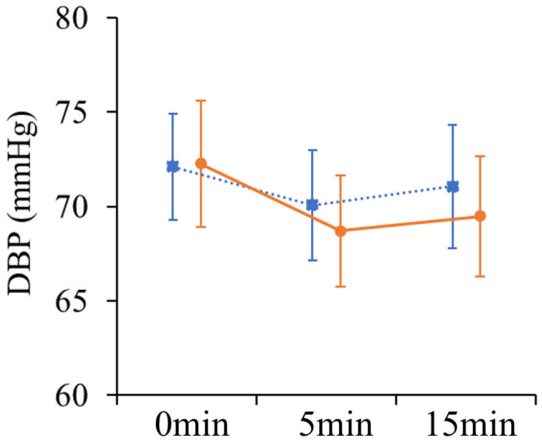
FSS-ICU = Functional status score for the intensive care unit, ICU = intensive care unit, MRC = medical research council

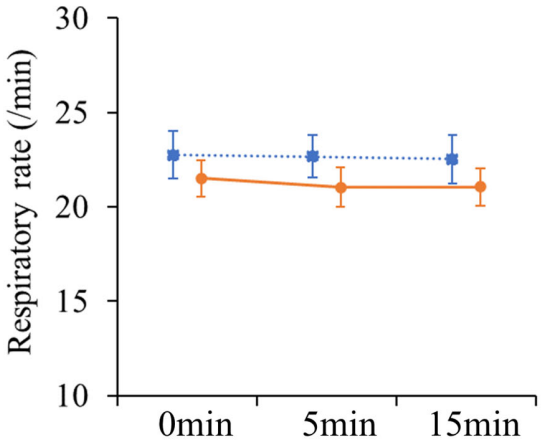
Data were presented as average ± standard deviation.

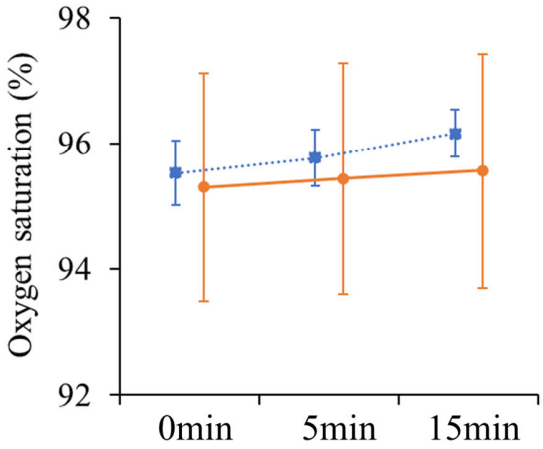
The ventilator and ICU-free days were defined as the number of free days during 28 days after ICU admission.

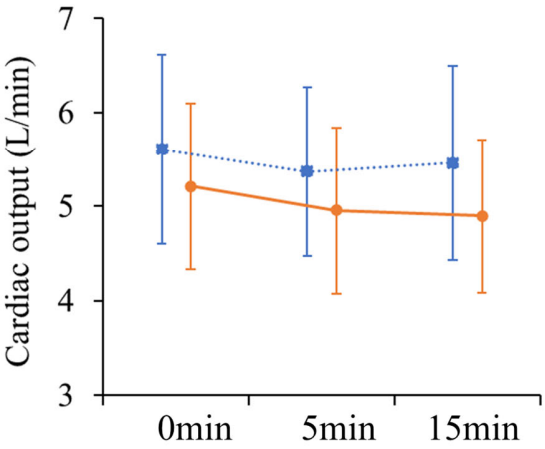

Heart rate (/min)
100
95
90
85
80
0min
5min
15min


SBP (mmHg)
130
125
120
115
110
0min
5min
15min


DBP (mmHg)
80
75
70
65
60
0min
5min
15min


Respiratory rate (/min)
30
25
20
15
10
0min
5min
15min


Oxygen saturation (%)
98
96
94
92
0min
5min
15min


Cardiac output (L/min)
7
6
5
4
3
0min
5min
15min

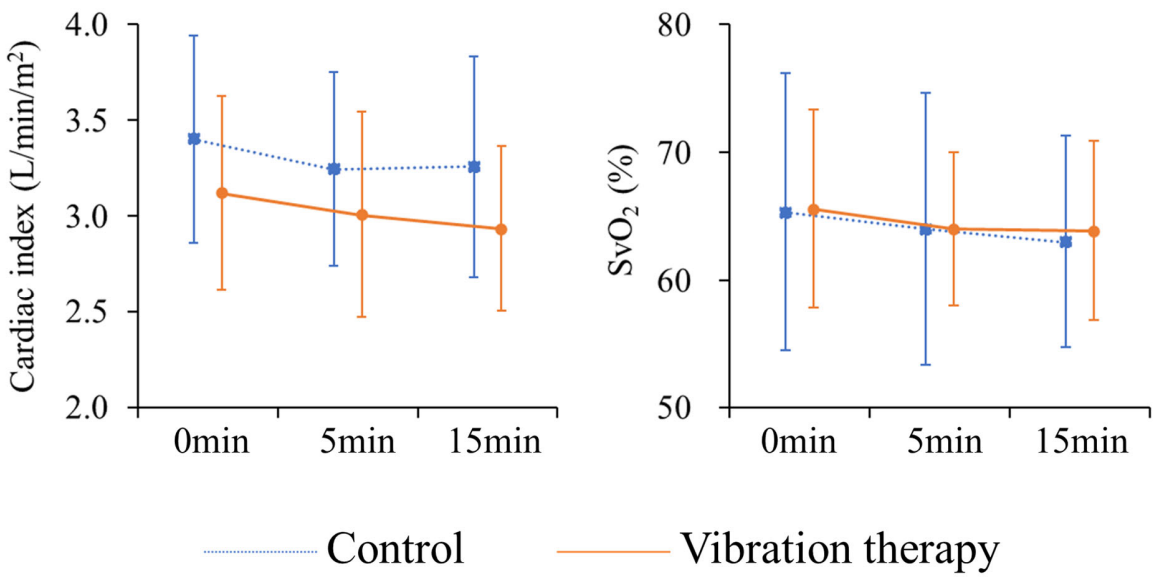


Figure S2. Hemodynamic and respiratory changes after vibration therapy or control intervention. Dot lines with blue square marker shows the control intervention, whereas solid lines with orange circle marker shows vibration therapy. Heart rate, SBP, DBP, respiratory rate, and oxygen saturation were assessed in 86 patients in the intervention group and 90 patients in the control group. Cardiac functions and SvO_2 were evaluated only in patients with a pulmonary artery catheter. Cardiac output and cardiac index were assessed in 14 patients in the intervention group and 15 patients in the control group. SvO2 was assessed in seven patients in the intervention group and six patients in the control group. Data are shown as means ± 95% confidence intervals, and the difference was compared using the t-test at 0, 5, and 15 min after the intervention. No statistically significant differences in all hemodynamic and respiratory parameters were observed.

SBP = systolic blood pressure, DBP = diastolic blood pressure, SvO_2 = mixed venous oxygen saturation (%).