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

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**Effects of vibration therapy on the physical function of critically ill adults (VTICIA trial): A randomized controlled trial**

Short running title: A randomized controlled trial of vibration therapy in critically ill adults

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**Brief summary:**

In the VTICIA trial, vibration therapy in the sitting position partially improved physical functions of critically ill patients upon ICU discharge without any adverse event. Vibration therapy is a noninvasive promising rehabilitation device in the ICU.

**KEYWORDS:** vibration therapy, intensive care unit, critically ill patients, rehabilitation, mobilization

**ABSTRACT**

**OBJECTIVE:** Vibration therapy uses vibration to rehabilitate physical functions. Recently, it has been demonstrated to be safe for critically ill patients. However, its effects on physical functions are unclear.

**DESIGN:** Randomized controlled trial.

**SETTING:** A single-center, intensive care unit (ICU).

**PATIENTS:** Patients were randomly assigned to either vibration therapy coupled with protocolized mobilization or protocolized mobilization alone. We included patients who could sit at the edge of the bed or in a wheelchair during their ICU stay. The exclusion criteria were based on the early mobilization inhibition criteria.

**INTERVENTIONS:** The primary outcome was the Functional Status Score for the ICU (FSS-ICU) at ICU discharge. Secondary outcomes were the Medical Research Council score, ICU-acquired weakness, delirium, ICU Mobility Scale (IMS), and ventilator- and ICU-free days. For safety assessment, vital signs were monitored during the intervention.

**RESULTS:** Among 180 patients, 86 and 90 patients remained in the vibration therapy and control groups, respectively. The mean age was 69 ± 13 *vs.* 67 ± 16 years in the vibration therapy and control groups, and the APACHE II score was 19 (14–25) *vs.* 18 (13–23). The total FSS-ICU at ICU discharge was 24 (18–27) and 21 (17–26) in the intervention and control groups, respectively

($p = 0.09$), and the supine-to-sit ability significantly improved in the intervention group ($p < 0.01$). The secondary outcomes were not significantly different. Vital signs remained stable during vibration therapy. In the predefined subgroup analysis, FSS-ICU improved in the population with a higher body mass index (≥23 kg/m$^2$), lower APACHE II scores (<19), and higher IMS scores (≥6).

**CONCLUSION:** Vibration therapy did not improve the total FSS-ICU. However, the supine-to-sit ability in the FSS-ICU improved without any adverse event.

**KEY POINTS**

**Question:** Does vibration therapy in the sitting position improve the physical functions of critically ill patients upon ICU discharge?

**Findings:** This randomized controlled trial revealed that vibration therapy did not significantly improve the total FSS-ICU but improved the supine-to-sit ability of the FSS-ICU. The effect was prominent in people with higher BMIs, lower APACHE II scores, and higher ICU Mobility Scale scores.

**Meaning:** Vibration therapy in critically ill patients is a promising tool that can improve some physical functions in critically ill patients. It was more effective in patients with high BMIs, patients in less critical conditions, and more mobilized patients.

## INTRODUCTION

One-third of intensive care unit (ICU) survivors experience prolonged physical, cognitive, and mental impairments even after hospital discharge (1). These conditions are referred to as "postintensive care syndrome" (2). One of the causes of prolonged physical impairments is newly acquired physical impairments during ICU stay. Physical impairments are caused by acute muscle loss and weakness, referred to as "ICU-acquired weakness" (ICU-AW) (3, 4). These physical impairments at ICU discharge are associated with return-to-home and long-term outcomes (5, 6). To prevent physical impairments during ICU stays, early rehabilitation and mobilization are important (7, 8).

Because of the increasing awareness of early physical therapy, patients are urged to sit at the edge of the bed or be transferred to a wheelchair. Even among mechanically ventilated patients, one-third can sit in the ICU (9). However, more active mobilization is limited. It has been reported that only 2% of patients can ambulate (9). This limitation in ambulation has two reasons. First, very active mobilization, such as ambulation, imposes a heavy workload on the staff. Insufficient staffing and a heavy workload are common barriers to mobilization (10). Second, patients with very active mobilization often meet the criteria for ICU discharge. Therefore, we believe that maximizing passive mobilization under sitting conditions is one of the best strategies to improve the physical functions of critically ill patients.

In settings where human resources are limited, a strategy for rehabilitation involves using equipment and devices to support physical therapy. Various devices can be used in the ICU. Electrical muscle stimulation helps prevent physical impairments in the ICU; however, the pricking sensation hampers its use in conscious patients (11). Cycling has been reported as a strenuous activity for critically ill patients, necessitating careful application (12, 13). Vibration therapy is another possible strategy to support physical rehabilitation in the ICU. Vibration, transmitted by vibration therapy, stimulates muscle spindles and produces muscle contractions. This device can be used passively in the sitting position without imposing a heavy workload. The safety of vibration therapy has been reported in critically ill patients (14).

Although the safety of vibration therapy has been proven in a previous study, its effects have not been tested in critically ill patients. We hypothesized that vibration therapy can maximize passive mobilization under sitting conditions and improve the physical functions of critically ill patients. Therefore, we conducted a single-center randomized controlled trial (RCT) on the use of Vibration Therapy in Critically Ill Adults (VTICIA trial). Before the study, we precisely planned the protocol for the VTICIA trial and published a protocol paper (15). The present study aimed to investigate the effects of vibration therapy on the physical functions of critically ill patients at ICU discharge and various other outcomes.

## MATERIALS AND METHODS

### Study design and settings

From December 2020 to September 2023, we conducted a single-blinded RCT at the mixed medical/surgical ICU of Tokushima University Hospital in Japan. This study was suspended from June 2022 to January 2023 due to the absence of the chief staff. This study was approved by the Clinical Research Ethics Committee of Tokushima University Hospital (Approval number: 3763, Approval date: October 26, 2020, Title: The effect of vibration therapy in patients admitted in the ICU). The Clinical Research Committee supervised and monitored the study. Any adverse effect or complication was immediately reported. All procedures were followed in accordance with the ethical standards of the responsible committee on human experimentation and with the Helsinki Declaration of 1975. This study was registered on April 1, 2020, in the UMIN-Clinical Trials Registry (Registry Number 000039616). This study was based on the prospective, randomized, open-label, blinded endpoint study model and the standard protocol items: recommendations for interventional trials (SPIRIT) statement (16, 17). All datasets were stored using identification codes to anonymize the information of the study participants.

### Inclusion and exclusion criteria

During study enrollment, written informed consent was obtained from the patients or their

authorized surrogate decision-makers. We included consecutive critically ill patients aged ≥18 years who could sit at the edge of the bed or wheelchair with or without mechanical ventilation. We excluded patients based on the consensus for early mobilization in the Japanese Society of Intensive Care Medicine (JSICM) (18), as follows (Table S1): (I) no permission from the primary physician; (II) excessive agitation; (III) impaired consciousness; (IV) unstable vital signs; (V) sustained low blood pressure; (VI) dynamic blood pressure changes; (VII) risk of rupture of untreated aneurysms; (VIII) uncontrolled pain; (IX) uncontrolled intracranial pressure; (X) unstable phase in the head or cervical spine injury; (XI) metal implants or unstable bone fractures; (XII) active bleeding; (XIII) insufficient stabilization or length of catheters; (XIV) insufficient staffing; and (XV) no consent from patients or surrogates.

**Withdrawal criteria**

Withdrawal criteria from the research were based on the JSICM criteria (18), as follows (Table S2): (I) Generalized unstable symptoms; (II) Subjective unstable symptoms; (III) Unstable respiration parameters; (IV) Unstable hemodynamics; (V) Device removal; and (VI) Other conditions such as the desire to withdraw from the study.

**Randomization**

The patients were randomized using computer-generated randomization lists (19). Randomization was stratified by age (<70 years or ≥70 years) and sex (female or male), and the randomization lists were generated with a block size of four before recruitment (20). The lists were created by an independent person unrelated to the research team. During allocation, the independent person checked the lists and allocated the patients to receive vibration therapy coupled with protocolized mobilization or protocolized mobilization alone.

**Interventions**

For the intervention group, a vibration device (BW-750, BodyGreen, Taiwan) was used by bedside nurses once daily (Fig. 1). This intervention continued from randomization to ICU discharge. The feet were placed on the device in the sitting position for 15 min. The setting of the device was a continuous automatic course of 5.6, 7, and 8 Hz for 30 s each. The amplitude was 2 mm in the vertical direction. All interventions were performed by nurses. The staff involved in outcome assessments, treatments, and usual rehabilitation were blinded to the interventions.

**Protocolized mobilization**

Protocolized mobilization was performed in all patients with or without intervention. Protocolized mobilization was based on a progressive mobilization protocol (21), in which the

intensity was increased under withdrawal criteria (Fig. S1). The withdrawal criteria were consistent with the withdrawal criteria of vibration therapy (Table S2). Following the progressive mobilization criteria, the mobilization level was gradually increased to sitting on the edge of the bed and ambulation. The mobilization level was restricted for patients meeting the withdrawal criteria.

**Primary outcome**

The primary outcome was physical function assessed using the Functional Status Score for the ICU (FSS-ICU) at discharge from the ICU, which was measured by a masked nurse. The FSS-ICU is a physical function score that includes the following five functional tasks: (I) rolling, (II) transitioning from resting on the spine to sitting, (III) sitting at the edge of the bed, (IV) transitioning from sitting to standing, and (V) ambulation (22). Each task is scored from 0 to 7, with a maximum total score of 35. The masked nurse underwent a 2-month training period for FSS-ICU use before the start of this study to ensure scoring accuracy.

**Secondary outcomes**

**Medical Research Council score and ICU-AW**

Upon ICU discharge, masked nurses assessed the Medical Research Council (MRC) score

and the incidence of ICU-AW among patients with an intact level of consciousness (23). ICU-AW was defined as an MRC score of <48 on two separate occasions (24).

**ICU Mobility Scale (IMS)**

Masked nurses conducted daily assessments using the IMS, a measure of mobilization capabilities scored from 0 (lying in bed) to 10 (walking independently) (25). The maximum IMS score during the ICU stay was used for comparison.

**Delirium**

Masked nurses in the ICU evaluated delirium using the Confusion Assessment Method for the ICU (CAM-ICU), which includes acute changes or fluctuations in mental status, altered level of consciousness, disorganized thinking, and inattention (26). The masked nurses assessed the state of delirium at ICU discharge.

**Defecation**

To determine the effect on bowel movement, the defecation status was monitored. Patients were classified based on whether or not defecation occurred during their ICU stay after vibration therapy.

**ICU- and ventilator-free days**

*ICU-free days* were defined as the number of days after discharge from the ICU within the 28 days after ICU admission, while *ventilator-free days* were defined as the number of days without mechanical ventilation during the 28 days after ICU admission.

**Safety**

Vital signs were monitored, with baseline measurements taken before the initiation of vibration therapy and at 5 or 15 min after therapy. Vital signs included heart rate, blood pressure (systolic and diastolic blood pressure), respiratory rate, and oxygen saturation. In patients with pulmonary artery catheter insertion, cardiac output, cardiac index, and mixed venous oxygen saturation were monitored. Any adverse event within 15 min after the intervention was recorded, which included headache, nausea and vomiting, dizziness, fatigue, and exacerbated pain. Comfortability was also assessed. Finally, patients who experienced any harmful events were followed up on.

**Statistical analysis**

Continuous data are presented as means ± standard deviations or medians (interquartile

ranges [IQR]), whereas categorical data are presented as numbers (%). The *t*-test or Mann–Whitney *U*-test was used for comparisons between the two groups. The sample size calculation was based on previous studies (22, 27). The FSS-ICU at ICU discharge was reported to be 20 (IQR, 10–30), with a minimal clinically important difference of 2.0–5.0. A 3.0 difference was expected for the improvement because vibration therapy was considered to improve standing or ambulating by 2–4. The standard deviation was reported to be 5.9 (27). In this study, the sample size calculation required 171 patients to observe the difference with an alpha value of 0.05 and a power of 90%. The dropout rate from the study was recalculated to one-third of the original 10% during the study progress (February 2022), considering the infrequent dropout rate. In total, 177 patients were required. Subgroup analysis was performed, including pre-specified factors such as Acute Physiology And Chronic Health Evaluation (APACHE) II, maximum IMS score, and days from ICU admission to interventions (15), as well as backgrounds such as ICU admission reason, age, sex, and body mass index (BMI). These factors were divided by their median or average values. Data analyses were performed using JMP (version 13.1.0; SAS Institute). All statistical tests were two-tailed, and *p*-values < 0.05 were used to denote statistical significance.

## RESULTS

In this study, 180 patients were assessed for eligibility and 3 were excluded because of

low blood pressure and insufficient catheter stabilization. The remaining 177 patients were randomized, and 1 patient was not followed up at ICU discharge. Finally, we assessed 86 patients in the vibration therapy group and 90 in the control group (Fig. 2). The mean ages of the vibration therapy and control groups were 69 ± 13 and 67 ± 16 years, respectively ($p$ = 0.38). According to the Japanese Bedriddenness Ranks (28), 65 (76%) and 72 (80%) patients in the intervention and control groups, respectively, had independent or almost independent activities of daily living. The median APACHE II score was 19 (14–25) in the intervention group and 18 (13–23) in the control group ($p$ = 0.37) (Table 1). In the intervention group, vibration therapy started at 2 (2–4) days after the ICU admission, and continued for 2 (1–3) days. No intervention days during the intervention period was 0 (0–0) days. The median IMS level was 0 (0–1) in the intervention group and 0 (0–1) in the control group on day 1 of ICU admission (p = 0.78), 3 (1–4) and 3 (1–5) on day 2 (p = 0.90), 3 (1–6) and 4 (1–6) on day 3 (p = 0.19), 3 (3–6) and 3 (1–6) on day 4 (p = 0.15), 3 (3–6) and 3 (1–6) on day 5 (p = 0.14).

**Primary outcome**

The total FSS-ICU at ICU discharge was 24 (18–27) and 21 (17–26) in the intervention and control groups, respectively ($p$ = 0.09) (Table 2). Rolling, sitting, sit to stand, and ambulation were not statistically different between the intervention and control; however, the supine-to-sit

ability was significantly improved in the intervention group (median score: 6 [3–6] *vs.* 4 [2–6], $p < 0.01$). The average and between-group difference were presented in Table S4.

**Secondary outcomes**

The MRC score slightly improved in the intervention group; however, the difference between the intervention and control groups was not statistically significant (60 [53–60] *vs.* 60 [48–60]; $p = 0.06$). ICU-AW, the maximum IMS score during the ICU stay, delirium occurrence, defecation, and hospital discharge disposition were not significantly different between the intervention and control groups.

**Safety**

No significant differences in heart rate, systolic blood pressure, diastolic blood pressure, respiratory rate, or oxygen saturation were observed between the intervention and control groups (Figure S2). The vibration intervention had no effect on these vital sighs. Furthermore, in patients with a pulmonary artery catheter, no significant differences in cardiac output, cardiac index, or mixed venous oxygen saturation were observed between the intervention and control groups. No significant difference in the incidence of adverse events was observed between the vibration therapy and control groups: headache (0 [0%] *vs.* 2 [2%]; $p = 0.50$), nausea and vomiting (4 [5%]

*vs.* 5 [6%]; $p = 1.00$), dizziness (6 [7%] *vs.* 11 [12%]; $p = 0.24$), fatigue (7 [8%] *vs.* 23 [26%]; $p < 0.01$), and exacerbated pain (4 [5%] *vs.* 11 [12%]; $p = 0.10$). In the intervention group, 52 patients (60%) felt comfortable and five patients (6%) felt uncomfortable.

**Subgroup analysis**

In the subgroup analysis, significant differences in BMI, APACHE II score, and maximum IMS score were observed between the two groups (Table 3). Vibration therapy significantly improved the FSS-ICUs of patients with a BMI of ≥23 kg/m$^2$ (p = 0.04), APACHE II scores of <19 (p = 0.02), and maximum IMS scores of ≥6 (p = 0.03).

**DISCUSSION**

In this VTICIA trial, we investigated the effects of vibration therapy on critically ill patients. For the primary outcome, the vibration therapy did not significantly improve the total FSS-ICU upon ICU discharge. However, we found that vibration therapy improved the supine-to-sit ability assessed using the FSS-ICU upon ICU discharge. The safety of vibration therapy was also noted because it did not affect hemodynamic or respiratory parameters, and no adverse events were observed. Furthermore, subgroup analysis suggested vibration therapy may be effective in patients with a higher BMI, less critical patients, and more mobilized patients.

Although further studies are needed for its validation, vibration therapy may contribute to the supine-to-sit ability in a component of the FSS-ICU. Despite applying vibration therapy to the feet, its effect was observed in the supine-to-sit ability. We considered two possible explanations for this finding. First, vibration therapy influences not only the lower limbs but also the entire body (29). Therefore, it improved the supine-to-sit ability. Second, a ceiling or flooring effect was observed in the sitting, sit-to-stand, and ambulation categories in the FSS-ICU. Even in the control group, the sitting and standing abilities had almost maximum scores (sitting 7/7 and standing 6/7), whereas ambulation had the lowest score (1/7). Ambulation was difficult for critically ill patients, even after vibration therapy. This study will contribute to the design of future studies on vibration therapy in the ICU.

The intervention protocol may be the cause of no-effect result. The intervention duration might have been insufficient to detect differences in the total FSS-ICU. We determined an intervention duration of 15 minutes because a previous study reported that the 15-minute use of vibration therapy is safe in the ICU (14). Furthermore, previous studies demonstrated that vibration therapy for 6–18 min/day was beneficial in patients with cystic fibrosis or stroke (30, 31). Although these studies used vibration therapy for 1–3 months, our intervention was confined to a short duration during the patient's ICU stay. The prolonged use of vibration therapy during hospital stays may have been needed to improve the patient's functional outcomes.

In the analysis of the secondary outcomes, vibration therapy did not improve the MRC score at ICU discharge (60 [53–60] *vs.* 60 [48–60]; $p = 0.06$). Because the maximum MRC score was 60, the effect on MRC score was also affected by the ceiling effect. In previous studies, vibration therapy improved the muscle strength of the knee extensor or handgrip strength in noncritically ill patients (32-34). Therefore, the study population may have affected this result. Because vibration improves circulation to vital organs because of increased nitric oxide or decreased endothelial damage (35-38), we expected that vibration therapy would improve delirium and the digestive system. However, no improvements in delirium or defecation were observed in this study. Because we examined the effect of vibration therapy on physical function rather than organ functions, the effect of vibration therapy on other organs requires further investigation.

In the subgroup analysis, vibration therapy was effective in patients with a higher BMI, less critical patients, and more mobilized patients. Because obesity is a barrier to mobilization (39), the use of vibration therapy may be helpful for rehabilitation support. In a previous study, Fossat et al. reported that electrical muscle stimulation and in-bed leg cycling did not improve the physical function of patients with active mobilization (40). Therefore, we expected that vibration therapy would be more effective in immobilized patients. In contrast, vibration therapy was more effective for more mobilized and less critical patients. We considered two possible reasons for this difference. First, vibration therapy did not have an adequate effect on very critical patients with limited

mobilization because disease severity significantly affects physical function. Second, less critical patients with greater mobility had more motivation for the intervention. Because blinding the patients was impossible, more healthy patients were possibly more motivated to improve their physical functions using vibration therapy.

In previous studies (14, 41), vibration therapy was safely used in critically ill patients. Consistent with the previous studies, vibration therapy did not affect the hemodynamics or respiration of critically ill patients, including patients who underwent postcardiac surgery. The nonheavy workload during vibration therapy did not change cardiac output or mixed venous oxygen saturation. Furthermore, no adverse events were observed after vibration therapy in the ICU. Interestingly, fatigue was less frequently observed in the vibration therapy group. Because vibration therapy has been reported to affect hormone levels (42), vibration may have increased the level of the hormone responsible for relieving fatigue in critically ill patients.

This study has several limitations. First, this was a single-center study conducted in one country. Second, this study performed vibration therapy combined with protocolized mobilization, not vibration therapy alone. Third, double blinding was infeasible because patients could feel the vibration. However, the outcome assessment was blinded. Fourth, we could not evaluate muscle mass changes as planned because the evaluator had shifted to a different facility. Fifth, the subgroup analysis is not based on the sample size, and subgroup analyses could be subject to bias

due to the exploratory nature of the analyses. Sixth, vibration therapy was safe for patients with burns, but the skin grafting tolerance is unknown because it was used before the procedure.

## CONCLUSION

We conducted an RCT to investigate the effects of vibration therapy on critically ill patients. Vibration therapy did not improve the total FSS-ICU. However, it was safe in critically ill patients and improved their supine-to-sit ability at ICU discharge, as assessed using the FSS-ICU.


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## Authors' contributions

SD was involved in study conceptualization, investigation, and methodology. NN was involved in

study conceptualization, methodology, and writing the original draft. YK, KN, and MS took part in the investigation. MS and JO supervised all aspects of this study. All authors read and approved the final manuscript.

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## FIGURE LEGENDS

Figure 1. Image of vibration therapy.

Figure 2. Patients' flow in this randomized controlled trial.

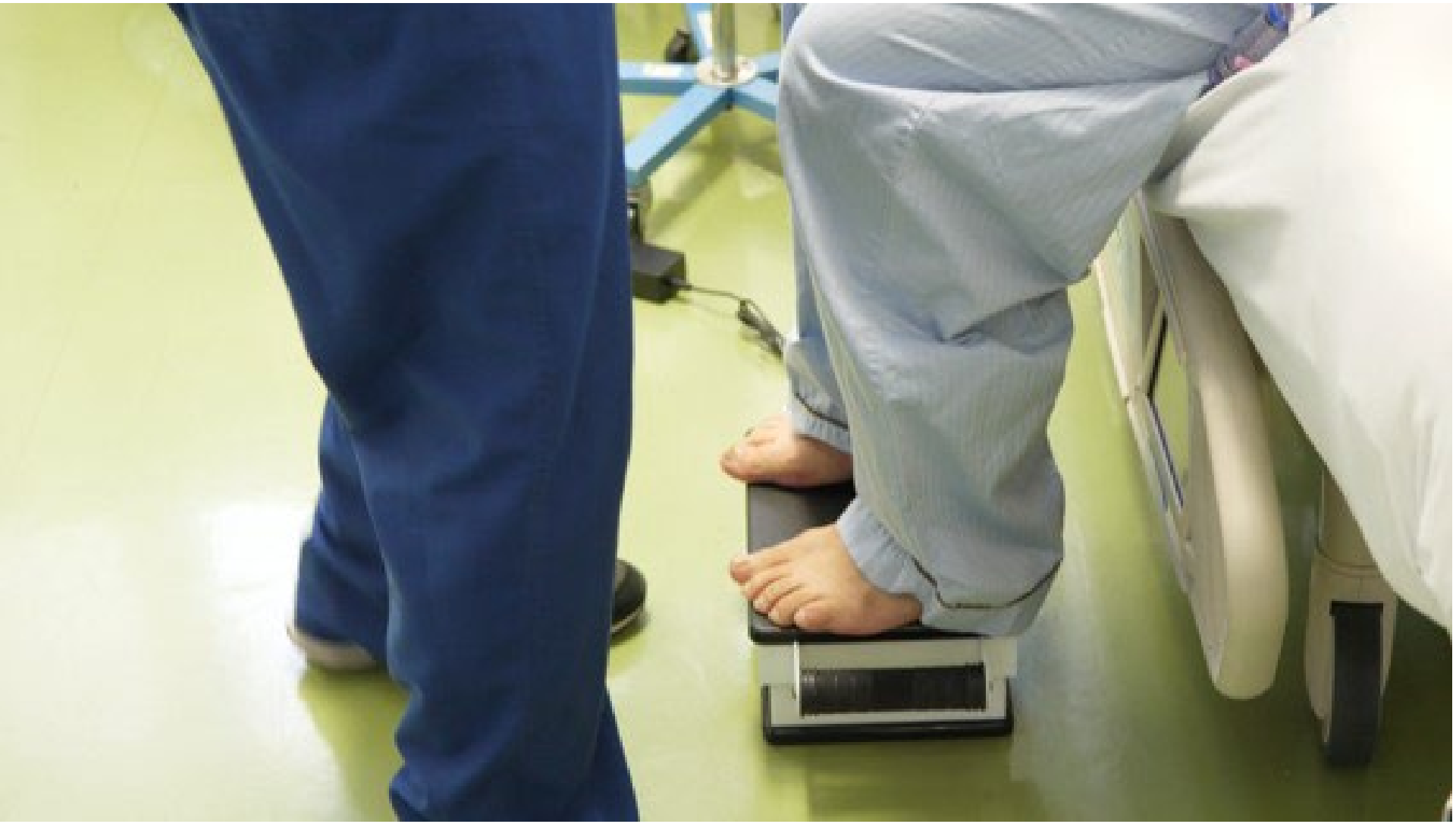
Figure S1. Progressive mobilization protocol

Mobilization protocol used in both the vibration therapy and control groups.

Figure S2. Hemodynamic and respiratory changes after vibration therapy or control intervention.

Dotted lines with blue square markers indicate the control intervention, whereas solid lines with orange circle markers indicate 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 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 (%).



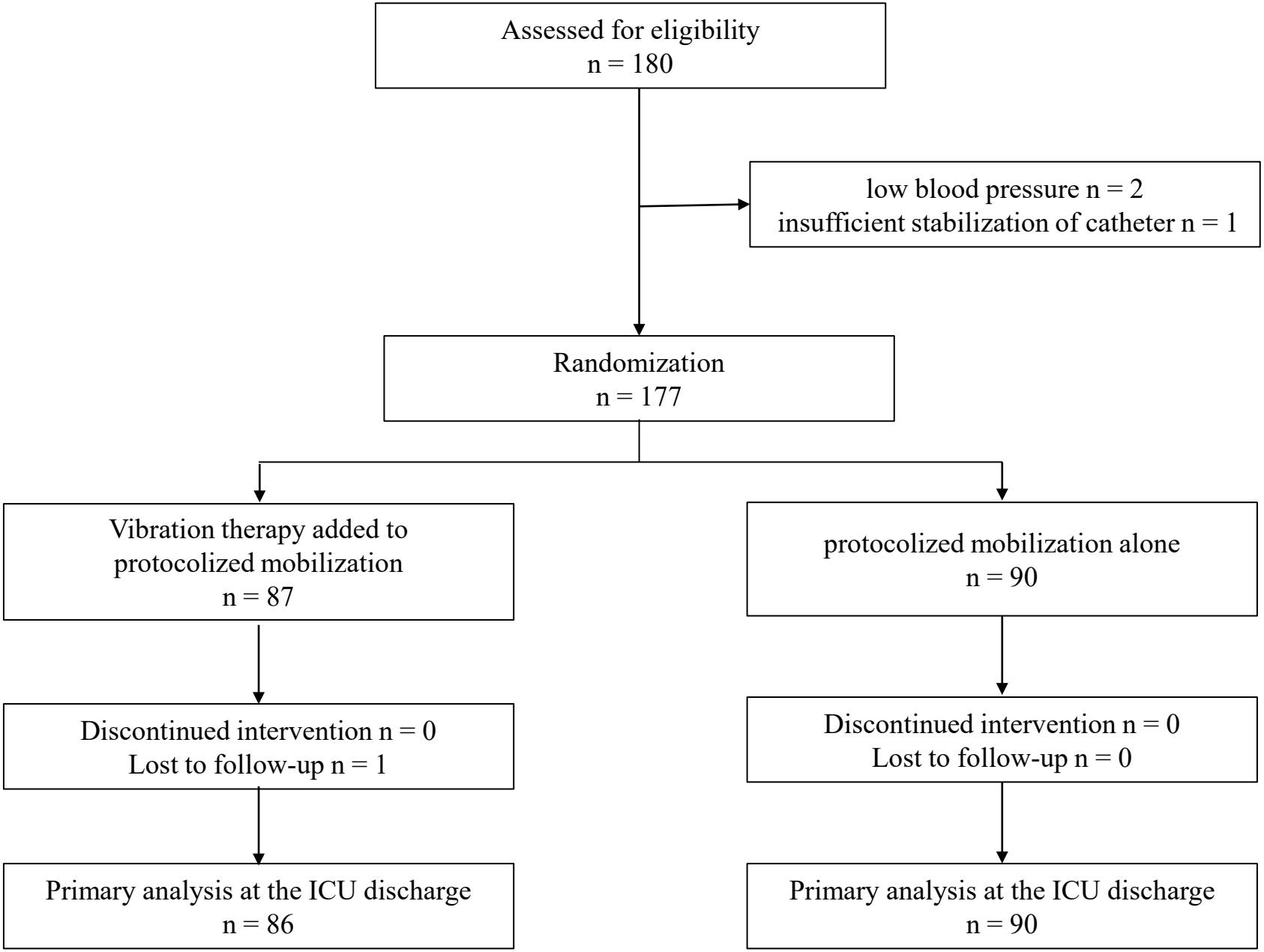

Assessed for eligibility
n = 180
low blood pressure n = 2
insufficient stabilization of catheter n = 1
Randomization
n = 177
Vibration therapy added to protocolized mobilization
n = 87
protocolized mobilization alone
n = 90
Discontinued intervention n = 0
Lost to follow-up n = 1
Discontinued intervention n = 0
Lost to follow-up n = 0
Primary analysis at the ICU discharge
n = 86
Primary analysis at the ICU discharge
n = 90

**TABLE 1. Patient Characteristics**

| Variables | Intervention n = 86 | Control n = 90 |
|---|---|---|
| Age, mean ± SD, y | 69 ± 13 | 67 ± 16 |
| Sex (M/F) | 48/38 | 51/39 |
| Body mass index (kg/m$^2$) | 23 ± 5 | 23 ± 4 |
| ADL before ICU admission* | | |
| Independent | 44 (51) | 58 (64) |
| Almost independent and can go out alone | 10 (12) | 8 (9) |
| Almost independent but cannot go out alone | 11 (13) | 6 (7) |
| Dependent but can sit alone | 7 (8) | 7 (8) |
| Dependent and cannot sit alone | 9 (11) | 3 (3) |
| No information | 5 (6) | 8 (9) |
| APACHE II | 19 (14–25) | 18 (13–23) |
| SOFA | 7 (4–9) | 6 (4–9) |
| ICU admission reasons, n (%) | | |
| Cardiac surgery (valvular heart disease)† | 37 (43) | 34 (38) |
| Cardiac surgery (coronary artery disease) | 13 (15) | 25 (28) |
| Respiratory failure | 16 (19) | 10 (11) |
| Heart failure | 4 (5) | 2 (2) |
| Sepsis, nonrespiratory | 4 (5) | 7 (8) |
| Burn | 2 (2) | 1 (1) |
| Others | 10 (12) | 11 (12) |
| Mechanical ventilation, n (%) | 67 (78) | 62 (69) |
| Noninvasive positive pressure ventilation, n (%) | 18 (21) | 13 (14) |
| Days to sitting at the edge of bed, d | 2 (2–4) | 2 (2–4) |

SD = standard deviation, ADL = activities of daily living, ICU = intensive care unit, APACHE = Acute Physiology and Chronic Health Evaluation, SOFA = Sequential Organ Failure Assessment, IQR = interquartile range

* ADL was based on Japanese Bedriddenness Ranks. † Cardiac surgery (valvular heart disease) includes the surgery related to both of valve and coronary artery.

Data were presented as median (IQR) unless otherwise indicated.

**TABLE 2. Primary and Secondary Outcomes**

| Variables | Intervention n = 86 | Control n = 90 | *p* |
|---|---|---|---|
| Primary outcomes | | | |
| FSS-ICU at the ICU discharge | | | |
| Total | 24 (18–27) | 21 (17–26) | 0.09 |
| Rolling | 6 (6–7) | 6 (6–6) | 0.06 |
| Supine to sit | 6 (3–6) | 4 (2–6) | < 0.01 |
| Sitting | 7 (7–7) | 7 (7–7) | 0.48 |
| Sit to stand | 6 (2–7) | 6 (2–7) | 0.77 |
| Ambulation | 1 (0–1) | 1 (0–1) | 0.61 |
| Secondary outcomes | | | |
| MRC score | 60 (53–60) | 60 (48–60) | 0.06 |
| ICU-AW (%) | 3 (4) | 4 (4) | 1.00 |
| Maximum ICU mobility scale | 6 (5–6) | 6 (5–6) | 0.84 |
| Delirium | 14 (16) | 11 (12) | 0.44 |
| Defecation | 38 (44) | 35 (39) | 0.48 |
| Ventilator-free days, d | 27 (25–28) | 27 (26–28) | 0.29 |
| ICU-free days, d | 24 (22–25) | 24 (22–25) | 0.64 |
| Hospital discharge disposition | | | |
| Home | 53 (62) | 61 (68) | |
| Transfer | 27 (31) | 26 (29) | 0.48 |
| Death | 6 (7) | 3 (3) | |

FSS-ICU = Functional status score for the intensive care unit, ICU = intensive care unit, MRC = medical research council, ICU-AW = intensive care unit-acquired weakness, IQR = interquartile range

Data were presented as median (IQR) unless otherwise indicated.

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

**TABLE 3. Subanalysis in Various Groups**

| Variables | Intervention | Control | *p* |
|---|---|---|---|
| ICU admission reason | | | |
| Cardiac surgery (n=50, n=59) | 26 (21–28) | 23 (19–27) | 0.07 |
| Not cardiac surgery (n=36, n=31) | 19 (16–27) | 17 (13–26) | 0.20 |
| Age | | | |
| < 68 y (n=25, n=30) | 24 (17–28) | 22 (13–26) | 0.14 |
| ≥ 68 y (n=61, n=60) | 24 (18–27) | 21 (18–27) | 0.28 |
| Sex | | | |
| Male (n=48, n=51) | 25 (18–27) | 22 (19–27) | 0.44 |
| Female (n=38, n=39) | 22 (18–27) | 19 (13–26) | 0.08 |
| Body mass index | | | |
| < 23 kg/m$^2$ (n=47, n=46) | 22 (16–27) | 21 (17–26) | 0.73 |
| ≥ 23 kg/m$^2$ (n=39, n=44) | 25 (19–28) | 23 (16–26) | 0.04 |
| APACHE II | | | |
| < 19 (n=40, n=46) | 26 (22–27) | 23 (18–26) | 0.02 |
| ≥ 19 (n=46, n=44) | 20 (16–26) | 20 (14–26) | 0.60 |
| Maximum ICU mobility scale | 6 (2–7) | 6 (2–7) | 0.77 |
| < 6 (n=28, n=27) | 16 (10–22) | 13 (12–19) | 0.30 |
| ≥ 6 (n=58, n=63) | 27 (22–28) | 25 (20–27) | 0.03 |
| Days to intervention after ICU admission | | | |
| < 3 (n=46, n=47) | 26 (21–27) | 23 (19–27) | 0.17 |
| ≥ 3 (n=40, n=43) | 20 (16–27) | 19 (13–26) | 0.27 |

ICU = intensive care unit, APACHE = Acute Physiology and Chronic Health Evaluation, IQR = interquartile range

Data were presented as median (IQR) unless otherwise indicated.

The cutoff value was based on the median or average of each group.