BMJ Open

Early mobilisation using a mobile patient lift in the intensive care unit: protocol for a randomised controlled trial

Ginga Suzuki , Hiromi Kanayama, Ryo Ichibayashi, Yoshiaki Arai, Yuji Iwanami, Yuka Masuyama, Saki Yamamoto, Hibiki Serizawa, Yoshimi Nakamichi, Masayuki Watanabe, Mitsuru Honda, Satoru Ebihara

To cite: Suzuki G, Kanayama H, Ichibayashi R, *et al*. Early mobilisation using a mobile patient lift in the intensive care unit: protocol for a randomised controlled trial. *BMJ Open* 2022;**12**:e057942. doi:10.1136/bmjopen-2021-057942

► Prepublication history for this paper is available online. To view these files, please visit the journal online (http://dx.doi.org/10.1136/bmjopen-2021-057942).

Received 03 October 2021
Accepted 08 February 2022

Toho University Omori Medical Center, Tokyo, Japan

Correspondence to
Dr Ginga Suzuki;
ginga.suzuki@med.toho-u.ac.jp

ABSTRACT

Introduction It is important to prevent the deterioration of activities of daily living to improve the long-term prognoses of patients in the intensive care unit (ICU). The patients' conditions, along with the lack of human and technical resources, often become barriers to achieving early mobilisation after the introduction of mechanical ventilation. We plan to verify the usefulness of a mobile patient lift for early mobilisation.

Methods and analysis We will conduct a single-centre, open-label, randomised controlled trial. The inclusion criteria are as follows: age ≥18 years, independent walking before admission and expected mechanical ventilation for at least 48 hours. The participants will be randomly divided into groups with (intervention group) or without (control group) a mobile lift protocol. A mobile lift will be used in the intervention group. The primary endpoint will be the number of days required to achieve an ICU mobility scale of ≥4 (standing position). The results of the two groups will be analysed using the Student's t-test.

Ethics and dissemination This study will be conducted in accordance with the Declaration of Helsinki and with the approval of the Toho University Omori Medical Center Ethics Committee (approval number M20259). The results of this study will be presented internationally at academic conferences and published in the literature.

Trial registration number UMIN000044965.

Strengths and limitations of this study

- This will be a randomised controlled trial to evaluate the effectiveness of using a mobile patient lift during early mobilisation in intensive care unit patients.
- It is not possible to blind this study owing to the nature of the intervention.
- The relationship between early mobilisation using a patient lift and muscle strength requires future prospective studies.

INTRODUCTION

In recent years, the concepts of intensive care unit-acquired weakness (ICU-AW) and post-intensive care syndrome (PICS) have been proposed in ICU patients.[1 2] Weakness during ICU stay and physical and cognitive weakness after ICU discharge have become common problems among ICU patients.[3 4] Since a decline in activities of daily living (ADL) is associated with worsened long-term prognoses,[3] attempts have been made during the ICU stay to prevent ICU-AW or PICS. Early mobilisation during the ICU stay is recommended for this purpose.[5] Early mobilisation has been reported to be effective in preventing ICU-AW and improving physical function and ADL after ICU discharge.[6–12] On the other hand, the patients' condition and resources such as staff and equipment can be barriers to early mobilisation.[13–15]

The Golvo 9000 lowBase (Hillrom BV, Amsterdam, The Netherlands) is a mobile patient lift. Medical staff carry the device to the patient's bed, attach a dedicated sling to the patient, and lift the patient with a motor. The device can also be used for conversion to a sitting position, standing assistance and walking training. We aim to introduce this lift and use it for rehabilitation in the ICU. In the USA, there are facilities with ceiling lifts permanently installed, and it is reported that the lifts can reduce the burden on medical staff.[16 17] However, it has not been verified whether the use of lifts promotes early mobilisation.

Therefore, we will investigate the hypothesis that early mobilisation could be promoted using a mobile patient lift. This study will be the first randomised controlled trial to evaluate the effectiveness of a mobile patient lift during early mobilisation in ICU patients.

METHODS AND ANALYSIS

A single-centre, open-label, randomised controlled trial will be conducted at the Toho University Omori Medical Center in accordance with the Declaration of Helsinki with the approval of the Toho University Omori

Medical Center Ethics Committee (approval number M20259). All participants will provide written informed consent. If a patient cannot provide consent, a consent form will be obtained from the patient's family (an adult family member living with the patient or a relative within the third degree of kinship). This study will be reported following the Standard Protocol Items: Recommendations for Interventional Trials statement.[18]

Participants

We began enrolling patients on 1 August 2021. The study period is planned to be 3 years. The inclusion criteria are as follows: age ≥18 years, ability to walk independently (clinical frailty scale ≤4[19]) before ICU admission, and expected to be ventilated for at least 48 hours. In detail,patients receiving extracorporeal membrane oxygenation will also be included. We will complete the screening within 24 hours of the start of mechanical ventilation. The exclusion criteria are contraindications for load exercise, neuromuscular disease, weight >200 kg, postcardiac arrest, intracranial disease, status epilepticus, transfer after mechanical ventilation for >48 hours and COVID-19 diagnosis. In our ICU, when medical instruments are used for COVID-19 patients, they are cleaned with alcohol and UV (ultraviolet) radiation; therefore, we excluded COVID-19 patients because we thought it was impossible to disinfect deep into the boa of the sling due to the boa fabric attached to the load surface of the sling.

Rehabilitation protocol

The rehabilitation protocol is shown in figure 1. Rehabilitation and mobilisation will be performed according to the criteria proposed by the Japanese Society of Intensive Care Medicine.[20] This criterion was proposed with reference to past literature.[5 21] In addition, rehabilitation will not be performed without the permission of the attending physician. The mobilisation will be done by the usual care team. In this ICU, early mobilisation is part of the usual care. Mobilisation is performed daily according to the patient's condition. The nurses are also trained to support the patient in standing position as they work closely with the physiotherapists.

The mobilisation programme is illustrated in figure 2. This programme is based on a previous report.[22] The level at which rehabilitation should be initiated will be decided on consultation with the attending physician, nurse, and physiotherapist. If the patient does not meet the discontinuation criteria and the initial rehabilitation level is achieved, the patient will step up to the next level. If the patient meets the discontinuation criteria, the rehabilitation level will be lowered by one level and resumed. Physiotherapists work only on weekdays. On Saturdays and Sundays, the nurses will rehabilitate as much as possible. Mobilisation will be performed twice a day and, if possible, thrice a day. The physicians and nurses discuss the number of mobilisations and add more as needed. If refusal to rehabilitation is due to pain or fever, we will

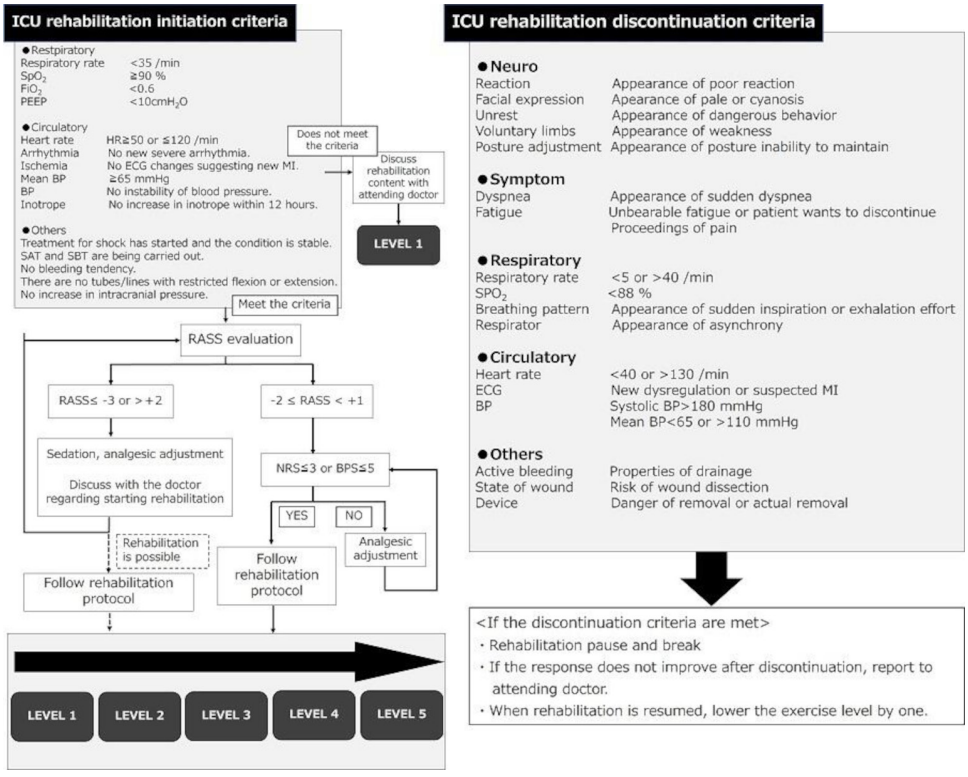

Figure 1 Rehabilitation initiation and discontinuation criteria. BP, blood pressure; BPS, Behavioural Pain Scale; MI, myocardial infarction; NRS, Numerical Rating Scale; PEEP, positive end-expiratory pressure; RASS, Richmond Agitation-Sedation Scale; SAT, spontaneous awaking trial; SBT, spontaneous breathing trial.

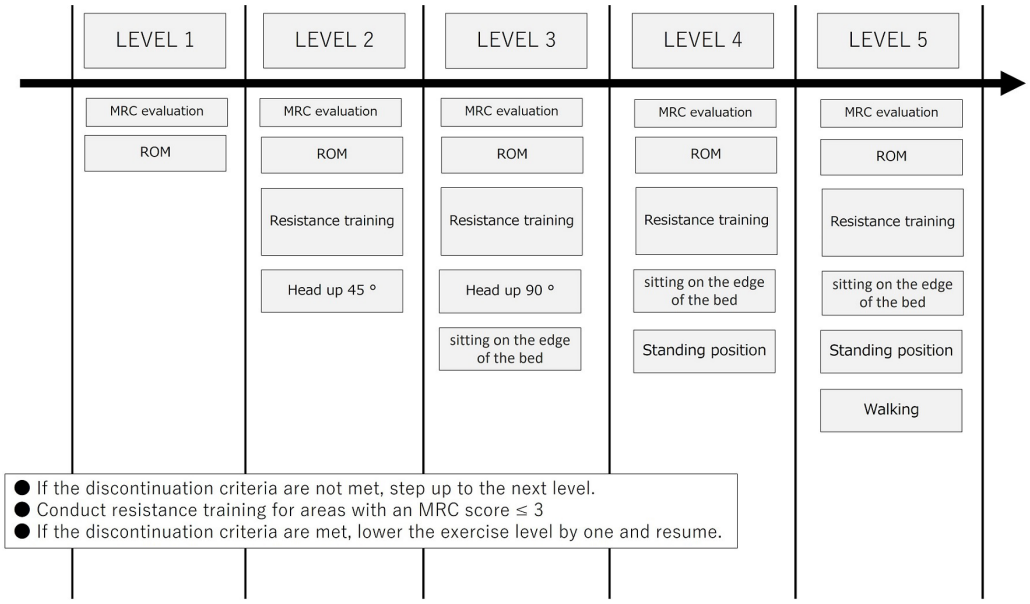

Figure 2 Rehabilitation programme The level at which rehabilitation should be initiated will be decided on consultation with the attending physician, nurse and physiotherapist. MRC, Medical Research Council; ROM, range of motion.

provide symptomatic treatment with medication; if refusal is due to fatigue, we will delay the timing of mobilisation. If refusal is due to depression, we will listen to the patient and not force mobilisation. However, after a while, we will try to speak to the patient again; if the patient agrees, we will perform the mobilisation.

Other protocols

Daily sedation control and spontaneous breathing management will be performed according to the ABCDE bundle. When the respiratory and circulatory status become calm, continuous sedation will be discontinued and delirium and sleep will be controlled to maintain wakefulness during the day. Discontinuation of continuous sedation will be reviewed during daily morning rounds. Whenever possible, delirium will be treated by relieving pain and establishing a diurnal rhythm rather than by medication. If the patient still becomes agitated, we will consider medication. If the patient complains of insomnia, we will administer suvorexant. If the patient is awake during the day, we will try to perform a spontaneous breathing trial. If extubation is not possible due to fluid balance or other problems, we will try weaning.

Interventions

In the control group, patients will be treated according to the above-mentioned protocol. In the intervention group, a mobile patient lift, Golvo 9000 lowBase (Hillrom BV, Amsterdam, The Netherlands) will be used to assist during the standing position. In addition, it will also be used for posture change and sitting position. Although our ICU has 15 beds and only one lift, rehabilitation is fully feasible. The physiotherapist was originally familiar with handling the lift, but the nurses received training from the physiotherapist to use the lift in a month's period. Often, the nurse alone would perform the standing position, although the physiotherapist was more likely to perform the higher stages of mobilisation. Both physiotherapists and nurses will routinely follow the protocol shown in figures 1 and 2, and the endotracheal tube and ventilator will not interfere with the standing position. Even in such a situation, if the patient's condition permits, mobilisation to the standing position and sometimes beyond will be performed. If the patient's mobility is high and a lift is not necessary, the patient can be placed in a standing position without using a lift. After ICU discharge, nurses will not actively participate in the rehabilitation of patients; therefore, the lift will not be used in the general ward.

Randomisation

Among patients admitted to the ICU with mechanical ventilation, a consent form will be obtained when mechanical ventilation is predicted to continue for at least 48 hours. We will randomise the patients after obtaining consent. The block method will be used for randomisation. In addition, because physiotherapists work only on weekdays, admission on Thursday or Friday may cause a difference in the timing of physiotherapist intervention. Therefore, stratified randomisation will be performed between admission on Thursdays or Fridays and other days. That is, patients admitted on Thursday or Friday and those admitted on other days of the week will be divided and randomised in each group.

Sample size estimation

There is no suitable pilot data, but a similar study using tilt beds[23] had a recruitment sample size of 80. Although this study is an observational study and the method is different, we calculated the sample size using G*Power (V.3.1, Kiel, Germany) based on that study's data. The effect size was 0.56, and the required sample size was 80

in total, calculated with an α error of 0.05, and a power of 80%. Considering the possibility that the severity of illness is high and the number of dropouts will increase due to death, the sample size of this proposed study was set to 92.

Outcome

The primary endpoint will be the number of days from meeting the rehabilitation initiation criteria to achieving an ICU mobility scale (IMS) ≥4 (standing position).[24] As indicated in the rehabilitation protocols section, IMS is an assessment method that has not been incorporated into our protocol. We adopted IMS as a measure of mobilisation to evaluate the effect of adding a lift to an existing protocol, and since the standing section of IMS clearly states that it includes the use of a lift, we adopted IMS as the measure of mobilisation in this study. The secondary endpoints will be time of preparation and postprocessing of mobilisation, mobilisation time, the Sequential Organ Failure Assessment score at first achieving IMS≥4, Functional Status Score (FSS)-ICU and Medical Research Council (MRC) score at the start of mobilisation, IMS/FSS-ICU/MRC at ICU discharge, Barthel index/MRC at hospital discharge, presence and duration of delirium (confusion assessment method (CAM)-ICU), length of ICU stay, 28 ventilator-free days, ICU mortality and hospital mortality. Other unexpected adverse events will be recorded in the data set as appropriate.

Statistical analyses

Data on baseline factors related to demographics, condition severity and prognosis will be collected. We will perform χ^2 tests for categorical variables. If the variables are continuous or ordinal, the Student's t-test (for normal distribution) or the Man-Whitney U test (for non-normal distribution) will be used.

The results will be analysed by intention-to-treat analysis. In other words, even if an intervention different from the protocol is performed for grouping, the outcomes will be accumulated and analysed according to the grouping. However, if the patient is transferred to another hospital, leaves the ICU, or dies before meeting the rehabilitation initiation criteria, they will be excluded from the analysis. We will not perform interim analysis.

Statistical analyses will be performed using StatFlex V.7 (Artec, Osaka, Japan). Differences will be considered statistically significant when the $p<0.05$. Statistical analyses will be performed by a different individual and not the clinicians involved in the study to eliminate bias.

Ethics and dissemination

All participants will provide written informed consent. However, the consent withdrawal form will also be simultaneously given to participants so that consent can be withdrawn at any time. The data set will be pseudonymised on a desktop computer in the ICU and stored in a password-protected file. The correspondence table will be managed using a password. The results of the study will be presented internationally in academic conferences and literature and will be presented in a form that does not include personally identifiable information.

Trial status

This protocol was finalised on 30 June 2021. Patient inclusion will begin on 1 August 2021, with a 3-year implementation period.

Contributors GS performed the statistical analyses and drafted the manuscript. GS, HK, RI, YA, YI, YM, SY, HS, YN, MW, MH and SE contributed to the acquisition of data. HK participated in the design of the study design and study coordination. MH conceived the study, participated in the study design and coordination, and contributed to manuscript writing. All authors read and approved the final manuscript.

Funding The authors have not declared a specific grant for this research from any funding agency in the public, commercial or not-for-profit sectors.

Competing interests None declared.

Patient and public involvement Patients and/or the public were not involved in the design, or conduct, or reporting, or dissemination plans of this research.

Patient consent for publication Not applicable.

Provenance and peer review Not commissioned; externally peer reviewed.

ORCID iD

Ginga Suzuki http://orcid.org/0000-0002-9854-3411

REFERENCES

1 Latronico N, Bolton CF. Critical illness polyneuropathy and myopathy: a major cause of muscle weakness and paralysis. *Lancet Neurol* 2011;10:931–41.
2 Needham DM, Davidson J, Cohen H, *et al*. Improving long-term outcomes after discharge from intensive care unit: report from a stakeholders' conference. *Crit Care Med* 2012;40:502–9.
3 Yende S, Austin S, Rhodes A, *et al*. Long-term quality of life among survivors of severe sepsis: analyses of two international trials. *Crit Care Med* 2016;44:1461–7.
4 Harvey MA, Davidson JE. Postintensive care syndrome: right care, right Now…and later. *Crit Care Med* 2016;44:381–5.
5 Hodgson CL, Stiller K, Needham DM, *et al*. Expert consensus and recommendations on safety criteria for active mobilization of mechanically ventilated critically ill adults. *Crit Care* 2014;18:658.
6 Ding N, Zhang Z, Zhang C, *et al*. What is the optimum time for initiation of early mobilization in mechanically ventilated patients? A network meta-analysis. *PLoS One* 2019;14:e0223151.
7 Schweickert WD, Pohlman MC, Pohlman AS, *et al*. Early physical and occupational therapy in mechanically ventilated, critically ill patients: a randomised controlled trial. *Lancet* 2009;373:1874–82.
8 Zhang L, Hu W, Cai Z, *et al*. Early mobilization of critically ill patients in the intensive care unit: a systematic review and meta-analysis. *PLoS One* 2019;14:e0223185.
9 Tipping CJ, Harrold M, Holland A, *et al*. The effects of active mobilisation and rehabilitation in ICU on mortality and function: a systematic review. *Intensive Care Med* 2017;43:171–83.
10 Needham DM, Korupolu R, Zanni JM, *et al*. Early physical medicine and rehabilitation for patients with acute respiratory failure: a quality improvement project. *Arch Phys Med Rehabil* 2010;91:536–42.
11 Zang K, Chen B, Wang M, *et al*. The effect of early mobilization in critically ill patients: a meta-analysis. *Nurs Crit Care* 2020;25:360–7.
12 Hashem MD, Parker AM, Needham DM. Early mobilization and rehabilitation of patients who are critically ill. *Chest* 2016;150:722–31.
13 TEAM Study Investigators, Hodgson C, Bellomo R, *et al*. Early mobilization and recovery in mechanically ventilated patients in the ICU: a bi-national, multi-centre, prospective cohort study. *Crit Care* 2015;19:81.
14 Harrold ME, Salisbury LG, Webb SA, *et al*. Early mobilisation in intensive care units in Australia and Scotland: a prospective,

observational cohort study examining mobilisation practises and barriers. *Crit Care* 2015;19:336.
15 Bakhru RN, Wiebe DJ, McWilliams DJ, *et al*. An environmental scan for early mobilization practices in U.S. ICUs. *Crit Care Med* 2015;43:2360–9.
16 Kucera KL, Schoenfisch AL, McIlvaine J, *et al*. Factors associated with lift equipment use during patient lifts and transfers by hospital nurses and nursing care assistants: a prospective observational cohort study. *Int J Nurs Stud* 2019;91:35–46.
17 Lee S-J, Rempel D. Comparison of lift use, perceptions, and musculoskeletal symptoms between ceiling lifts and floor-based lifts in patient handling. *Appl Ergon* 2020;82:102954.
18 Chan AW, Tetzlaff JM, Altman DG. Spirit 2013 statement: defining standard protocol items for clinical trials. *Ann Intern Med* 2010;152:726–32.
19 Rockwood K, Song X, MacKnight C, *et al*. A global clinical measure of fitness and frailty in elderly people. *CMAJ* 2005;173:489–95.
20 Ad Hoc Committee for Early Rehabilitation, The Japanese Society of Intensive Care Medicine. Evidence based expert consensus for early rehabilitation in the intensive care unit. *Nihon Shuchu Chiryo Igakukai zasshi J Jpn Soc Intensive Care Med* 2017;24:255–303.
21 Perme C, Nalty T, Winkelman C, *et al*. Safety and efficacy of mobility interventions in patients with femoral catheters in the ICU: a prospective observational study. *Cardiopulm Phys Ther J* 2013;24:12–17.
22 Morris PE, Goad A, Thompson C, *et al*. Early intensive care unit mobility therapy in the treatment of acute respiratory failure. *Crit Care Med* 2008;36:2238–43.
23 McWilliams D, Atkins G, Hodson J, *et al*. The Sara Combilizer® as an early mobilisation aid for critically ill patients: A prospective before and after study. *Aust Crit Care* 2017;30:189–95.
24 Hodgson C, Needham D, Haines K, *et al*. Feasibility and inter-rater reliability of the ICU mobility scale. *Heart Lung* 2014;43:19–24.