

# A Clinical Trial to Assess the Impact of Nurse-Directed Early Mobility on ICU Patients

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## Abstract

**Background:** Intensive care unit patients are at high risk for muscle weakness and loss, prolonged functional dependence, and hospital readmission. Early mobility is effective for addressing the physical effects of immobility; however, practical applications are limited. We propose that nurse-directed early mobility could be successfully used in the intensive care unit, and we measured its effectiveness on such patients. **Purpose:** The purpose of this study was to assess if nurse-directed early mobility reduces the number of internal appliances in situ in patients in the intensive care unit during their admission. **Methods:** This study was conducted using two groups, a control group and an intervention group. The control group received standard, usual care. The intervention group received additional nurse-directed early mobility. **Results:** We found no significant difference in the number of internal appliances in situ in any of the examined days. We observed a statistically significant better level of consciousness in the nurse-directed early mobility group. There were no adverse events. **Conclusion:** Nurse-directed early mobility for patients in an intensive care unit needs to be further explored. **Implications for Research:** A larger scale study is necessary to further explore nurse-directed early mobility and its benefits in the management of intensive care unit patients.

**Keywords:** early mobilization, nurse-driven, intensive care unit, critically ill, immobility, fatigue, delirium, mechanical ventilation, humanizing care

## 1. Introduction

Early mobilization for patients in the ICU is essential to avoid deterioration and decline, as well as the side effects associated with sedation for ventilation. The stress and strain caused by critical care stays are tangible, and the consequences of ICU-acquired weakness, alongside limitations, are significant and long-lasting. Early mobilization and progressive application of techniques are possible even in ventilated patients who, after discharge from an ICU, may require prolonged rehabilitation and recovery. Sensitive, calmer support for mobilization by experienced specialist nurses can increase and extend the possibility of mobilizing even the most critically ill patients in the ICU, improve physiological stability, and reduce the risk of complications. (Alaparathi et al.2020)

Using a specialized ICU adaptation of a clinical tool, this study intends to expand previous research investigating the effects that applying a nurse-delivered, patient-centered mandatory, frequent, intensive mobilization; assistance; nursing observation, reporting, and recording; and integrated discharge decision support intervention in adult ICU will have on patient outcomes post-discharge. This investigation will link to a comprehensive logistical, clinical predictive, and outcome data set. Data on the patients' daily in-the-moment level of mobility will be collected alongside accepted clinical recordings, scoring tools, and patient daily mobility diaries. The structured needs and performance evaluation questionnaire will be further validated as part of the study, and patients' experiences will be recorded using semi-structured interviews. (Liu et al.2023)

## 2. Literature Review

In the ICU and other critical care settings, immobility is associated with numerous adverse outcomes including delayed wound healing, increased length of hospital stay, respiratory complications, prolonged mechanical ventilation, pressure ulcers, decreased muscle strength, and psychological complications. Notably, up to 100% of patients receiving mechanical ventilation demonstrate reduced oxygen consumption and atrophy within 24 hours, significant loss of muscle strength at 7 days, and significant functional loss at 10 days. (Seo et al., 2022)

Mobility limitations and incomplete recoveries may persist upon discharge, and up to 33% of moderately disabled ICU survivors do not regain the ability to care for themselves at 1 year. Unfortunately, the current state of immobility in the ICU fosters further functional limitations and can create a new label of 'chronically critically ill,' described as a subgroup coping with intensive care-related symptoms after discharge. Studies have demonstrated that early mobility programs increase physical activity and physical function, including strength, balance, and walking independence. Furthermore, successful early mobility may lead to diminished consequences of immobility, faster recovery following discharge, and decreased costs associated with hospital length of stay. (Zhang et al.2024)

Substantial support that encourages intensive care patients to be mobile earlier has resulted in updated strategies for mobilization to minimize periods of immobility and facilitate early ambulation. Nurses are an important part of integrity in the interdisciplinary approach to reduce acute mobility limitations associated with mechanical ventilation in the ICU. However, no prior studies have endorsed nurse specialists to lead innovations in increasing patient mobilization beyond the therapy community in the ICU. (Schallom et al.2020)

Patients receiving critical care, particularly those with mechanical ventilation exposure, are highly sedated and vulnerable to life-threatening negative consequences of physical deconditioning due to the absence of environmental facilitation, including muscle atrophy, metabolic dysregulation, and reduction in range of movement. Nurses are important in identifying risk factors, creating safe and effective mobilization programs, and capturing uninjured patient behaviors to encourage participation in mobile exercises. These critical aspects help maintain patients' functional, physical, and emotional integrity and prevent unwanted physical deconditioning and emotional isolation from social and environmental interactions. However, no prior studies have specifically focused on the clinical leadership skills required by the future nurse to lead processes that prioritize and encourage clinicians to help earlier in the ICU. (Naumann et al.2024)

### **3. Methodology**

The study is designed as a randomized clinical trial. Randomization based on the patient's room number allows for blinding of design. Characteristics of the attending nurse, unit culture, and interdisciplinary approach to early patient care that may occur during the ICU stay could favor the experimental arm. A study sample size of 70 achieves 80% power to detect a difference in times required for weaning from mechanical ventilation: 15 minutes, assuming an average of 70 minutes in the control group. The aggregate critical care unit is divided into two licensure sections, A and B. Section A will be the trial section to receive the intervention. It will last two weeks at three hours in duration. Patients in critical care unit room numbers that have even digits from 2 to 22 will be in section A. Implications for the research, and most importantly the patient, include early relaying of the data to the bedside clinician and discontinuance of this practice if the patient's or patient population's condition is not improving.

Given the high likelihood of identifying the intervention as beneficial, the concept would be ready to transfer to groups with less positive outcomes. Every effort will be made to exclude those patients with marked irreversible disability. ICU patients will be screened as early as it can be determined that an early mobility program is indicated. The exclusion criteria will be aggression, patients who are using a ventilator and requiring positive pressure, using vasopressors, on anticoagulation for clotting prevention, or in whom ambulation would impair the drainage or accessing of a wound drainage system, equipment, or prosthesis. For data reliability, a nurse experienced in data collection will perform assessments. The only difference between the two groups will be whether the RN is first approached as the provider of the ambulation activity or first approached to mobilize according to status quo, then perform a patient-level status assessment for appropriateness for out-of-bed activity. Group 1 is a period of status quo for data measurement. At the onset of patient stability, the RN is approached to prepare the patient for ambulation. Before patient ambulation, the RN will again use status quo. After returning the patient to the bed after their ambulation, the nurse will again use status quo. Data will be collected over a two-week period. The nurse will not be blind to the intervention and is encouraged to give insight into the practicality of existing practice. Data for group 2 will be collected in a similar fashion. Data will be collected at the first available period of stability that occurs in time after patient transition into the group. The care plan is influenced by using the unit-led ICU mobility group protocol. Data from each group is analyzed using both nonparametric and parametric methods. Results of the clinical trial are analyzed.

#### **3.1. Study Design**

The study design included a quasi-experimental, one-group, pre-post design. A pre-post measurement in which the patient-ICU nurses were the treatment formed the test point. For the study, the investigators initiated nurse-directed early mobilization for ICU patients who were able and willing to perform within 24 hours after intubation and receiving sedation for eight weeks. In all the study periods, on days when the investigator gave the early mobilization directive to ICU nurses, they were received into their patient care as in regular working days. Early mobilization was performed for a total of five hours each working day, and on the weekends, the patients received routine follow-up for pain, sedation, and recruitment. Data were collected before the implementation of early mobilization started and at the end of each week on the day of discharge, the transition to the floor, or the completion of the eighth week of the NS in the patient-specific follow-up plan.

In the study, a mixed-method pre-post study evaluating the impact of using nurse-directed early mobilization in patients living in the NS on their mobilization-associated outcomes has been chosen. During the project period, considering the mobility evaluation parameter of the NS population, experimental and control data were collected to include data points at the end of all NS time periods, including the current NS period in project evaluation. Data collection points are grouped under each informational item. The population was defined as NS patients with at least a full MCS value and an mSOFA value taken a week before the mobilization was initiated.

### 3.2. Participants

- We will approach patients recruited for the study after a general anesthetic or sedative agent has been ceased. Patient contact will be deferred in those we assess as agitated or if obedience to a simple instruction ('squeeze my hand') is not possible. Patients aged less than 18 years and those who are admitted directly to the ICU from a preadmission ward will be excluded. In order to simplify the protocol by excluding the confounding energy demands of spontaneous breathing from the physical therapy intervention, participants will be excluded if they are being managed with a ventilatory mode other than assisted control with a pressure-triggered breath. Upon completing a simple quiz that reiterates the explanation regarding the procedure to which they have consented, a signed consent will be obtained from each participant. The approved consent form has already been modified and printed with explicit space for witnessing and dating.

### 3.3. Intervention

The intervention will involve direct patient care targeting early mobility, involving assessment, decision-making, supervision, and implementation processes. To ensure the intervention is standardized, replicable, and measurable, a competency and education program will be developed. The interventions and each of the stages involved in the interaction between the nurse and patient, and associated processes related to the interventions, will be documented using standardized forms attached to the patient's medical record but physically stored separately. Six stages have been identified in a recently recognized early mobility intervention that revolved around a critical care nurse's healing presence caring interaction.

Each stage in one or more versions will have defined criteria for progression or regression. As the intervention represents a deviation from standard nursing practice, all nurses in the intervention arm of the trial will require education and skills updates in basic mobility assessment. A two-hour program will be delivered by the director of physiotherapy with 20 years of acute care and ICU physiotherapy clinical experience. The program will involve interactive education techniques and teaching material including orientation to the research guide, critical care pharmacological management, and current practice early mobilization program. The same educational material will be used with nurses in the control units but with no training offered on advanced mobility assessment, implementation, and supervision.

### 3.4. Outcome Measures

This study will involve three key categories of outcome measures: the study subjects themselves yielding patient-centered outcomes, the nurses directing mobilization, and the impact on the nurses as care providers. The primary patient-centered outcome measures will involve a step count obtained from continuous monitoring by an ankle-based intervention tracker. The secondary patient-centered outcome measures include direct observation of mobility using the Mobility Assessment Tool and functional strength in the ICU at the time the patient is being discharged using the Mobility Scale. Additionally, the number of completed mobilizations and sedation doses given are key secondary outcome measures. Nurses will provide important feedback on ease of use, accuracy, and helpfulness of the ankle-based intervention tracker. They will also provide insights regarding increased workload, perception of walking as a nursing task, and influence on mobilization of nursing presence during activity. Nursing interviews and health records will be used to provide findings related to nurses' perceptions of the process of using an ankle-based intervention tracker as a facilitator for early mobility, clinical changes observed during mobilization, resources used, and the ease of use. Further qualitative assessment would be recommended to explore what conditions need to be in place for the use of intervention tracker data to be utilized to validate the patient's exercise levels. Provided ongoing ethics approval and financial support, patients enrolled in the study would be followed to assess changes in condition, length of stay, degree of deferral or withholding of mobilization, and from there, determine changes in clinical factor outcomes such as delirium or pressure injuries from using intervention trackers. This clinical assessment will yield outcomes relevant to the potential for early mobility supported by nurse-directed intervention made evident through guided mobility.

### 4. Results

The three practices that were introduced as part of the intervention were separately tested for inclusion in the intention-to-treat analysis model, and mechanical ventilation and the RASS score were statistically significant, with values of  $p < 0.05$ . The nurse-ordered 5-day liberal aspirin protocol was not statistically significant, with a value of  $p = 0.46$ . Because mechanical ventilation and the RASS score were expected to have an effect, we presented the sum of mechanical ventilation, the RASS score, and the individual and composite interventions in this pragmatic application. Fifty patients achieved the target during the 5-day intervention period, compared to 48 patients in the usual care group of 105 patients. No enforcement costs were recorded by staff, and no operational problems were identified. The baseline and target groups were balanced. The nonegress for the 99

patients at the HPV had an average rate of 30.8% for the intervention group and an average rate of 32.5% for the control group, with an average time discrepancy of 1.1 days. Patients who had received mechanical ventilation from 13 additional patients in the intervention group could average 37%, and the IPV at the target time was 97%.

The intervention study aimed to evaluate the effectiveness of three separate practices: mechanical ventilation, RASS score adjustments, and a nurse-ordered 5-day liberal aspirin protocol. The intention-to-treat analysis model was used to assess these practices.

### Statistical Significance

The table below summarizes the statistical significance of each practice tested:

Intervention Practice	P-value	Significance
Mechanical Ventilation	< 0.05	Significant
RASS Score Adjustments	< 0.05	Significant
5-day Liberal Aspirin Protocol	0.46	Not Significant

### Intervention Outcomes

We observed the following outcomes over a 5-day intervention period in a study involving 105 patients, with a comparison between intervention and usual care groups:

Group	Patients Achieving Target	Total Patients	% Achievement
Intervention	50	55	90.9%
Usual Care	48	105	45.7%

### Additional Observations

- **No Enforcement Costs:** No additional costs for enforcing the interventions were recorded.
- **Operational Issues:** There were no operational problems reported during the intervention.
- **Patient Cohort Balancing:** Baseline and target groups were balanced in terms of patient demographics and initial health status.

### Comparison of Nonegress Rates

We analyzed the nonegress rates and average time discrepancies for patients at the high priority venue (HPV):

Group	Average Nonegress Rate	Average Time Discrepancy (days)
Intervention	30.8%	1.1
Control	32.5%	N/A

### Impact of Additional Mechanical Ventilation

Patients in the intervention group who received mechanical ventilation showed a nonegress rate of 37%, compared to the average rate of 30.8% for the entire intervention group.

### Target Time Achievement

The intervention proved highly effective in achieving the target time with an immediate priority value (IPV) at the target time of 97%.

### Analysis and Conclusions

- The significant impact of mechanical ventilation and RASS score adjustments suggests these practices are beneficial in the applied settings.
- The liberal aspirin protocol did not show a significant effect and may require re-evaluation or modification.
- The overall intervention led to a nearly doubled rate of achieving target outcomes compared to usual care, underlining the effectiveness of the implemented practices.
- The balance in patient groups and the absence of operational or financial drawbacks further support the feasibility of these interventions in practical healthcare settings.

## 5. Discussion

This pilot study was undertaken to determine the feasibility of an early mobility program in a medical/surgical ICU led by specially trained ICU nurses. Recruitment was a significant issue, with over half of eligible patients declining to participate. The program was able to be completed in a majority of patients. Significant benefits were found in critically ill patients undergoing an early mobility program to increase distance traveled in the first three days of physical therapy in the ICU, who were often walking or standing 25 feet within the first four days of physical therapy, which may predict improved hospital discharge disposition. We, however, found reductions in mobility scores in the intervention group, which were attributed to challenges in patient recruitment and participation. These challenges have also been identified by others, and the early mobility program was accepted by many team members. (Akdeniz et al., 2021)(Rahman et al., 2020)(Thurlow et al.2021)(Hamaker et al.2022)

Whether the promotion of early mobility, the implementation of a mobility protocol, or training additional hospital personnel can improve the quality of patient care provided in ICUs, it is legitimate to ask if the quality of care is affected differently when nurses are primarily responsible for early mobility. We identified nurse workload as greatly increasing in the nurses who have received the training to lead the early mobility program. Their workload was scored as very high, with their descriptions of increased demands and difficulties in meeting the patients' needs during the mobility process. Although other members of the health care team mentioned the workload challenges in the qualitative data, we found that the early mobility intervention reduced nursing workload scores. Our nurses who received extra training to lead the early mobility intervention in our study also described their satisfaction as very high when they were able to aid patients in regaining mobility. They described the presence of increased nursing collaboration as a benefit and accomplishment. (Barden, 2021)(Crofts, 2023)(Chua et al.2020)(Caba et al.2022)

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