FOCUSED QUESTION
Is early mobilization safe and more effective than usual care in promoting recovery and functional independence in clients in the intensive care unit (ICU) who have been on mechanical ventilation?


CLINICAL BOTTOM LINE:
Critically ill patients in the ICU setting are at a higher risk for long-term complications, including ICU-acquired weakness and neuropsychiatric disease. Immobilization secondary to sedation could exacerbate these problems. The results of the current study suggest that, when working in the ICU with clients who have been on mechanical ventilation, early exercise and mobilization (administered by an interprofessional team of physical therapists [PTs] and occupational therapists [OTs]) can lead to recovery and returning to independent functioning upon hospital discharge. Early mobilization includes range of motion exercise for all limbs, bed mobility activities, supine to sit, activities of daily living (ADLs) to encourage increased independence, transfer training, and pre-gait exercises/walking. The authors defined independent functional status as the ability to perform six ADLs (bathing, dressing, eating, grooming, transferring from bed to chair, using the toilet) and walk independently.

The interventions illustrated in this study were provided by an interprofessional team of PTs and OTs, suggesting evidence for interprofessional collaboration in the ICU. OTs can work with other professionals, including PTs, respiratory therapists, nurses, and other ICU staff to promote functional gains in patients.

The results of this study suggest clinical implications for occupational therapy practice. Specifically, the study supports reimbursement for occupational therapy services in the critical care setting. Also, in designing new and maintaining current educational curriculum, occupational therapy programs can utilize the results of this study to integrate the most recent intervention practices.

Occupational therapy in critical care is a specialized practice. As interprofessional practice in critical care becomes more relevant, it will become more important for OT educators to address this method of treatment in their curriculums and fieldwork placements. It is crucial that further research be conducted to determine what constitutes entry-level practice.
RESEARCH OBJECTIVE(S)
List study objectives.

- Evaluate whether implementation of sedation combined with physical and occupational therapy in the earliest days of critical illness prevents sedative-related immobility
- Evaluate whether implementing this intervention would affect both functional outcomes and neuropsychiatric outcomes, such as ICU-associated delirium

DESIGN TYPE AND LEVEL OF EVIDENCE:

<table>
<thead>
<tr>
<th>Randomized controlled trial (RCT)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Level I</td>
</tr>
<tr>
<td>2 groups (intervention vs. control)</td>
</tr>
</tbody>
</table>

Limitations (appropriateness of study design):  
Was the study design type appropriate for the knowledge level about this topic? *Circle yes or no, and if no, explain.*

YES/NO | As an RCT, this study was appropriate for assessing the effectiveness of early intervention versus controlled standardized care. In addition, the study ensured the safety of the participants by implementing strict guidelines for intervention.

SAMPLE SELECTION
How were subjects selected to participate? Please describe.

Participants were recruited from two medical centers: University of Chicago Medical Center (Chicago) and University of Iowa Hospitals (Iowa City). The institutional review boards at both centers approved the study, and written informed consent was obtained from participants or their authorized representatives. Of the 1,161 medical ICU patients who were screened, 818 were determined to be eligible for enrollment, and a final 104 patients were enrolled and randomized.

Inclusion Criteria

- Sedated adults
- Patients in the medical ICU
- Ages 18 years or older
- Have been on mechanical ventilation for less than 72 hours
- Expected to continue mechanical ventilation for at least 24 hours
- Met the criteria for baseline functional independence. The authors defined baseline functional independence as a Barthel Index score of $\geq 70$.

Exclusion Criteria

- Rapidly developing neuromuscular disease
- Cardiopulmonary arrest
- Irreversible disorders with 6-month mortality estimated at more than 50% raised intracranial pressure
- Absent limbs
- Enrollment in another trial
SAMPLE CHARACTERISTICS

N = 104 enrolled and randomized

<table>
<thead>
<tr>
<th>% Dropouts</th>
<th>0</th>
</tr>
</thead>
<tbody>
<tr>
<td>#/ (%) Male</td>
<td>52 males(50%)</td>
</tr>
</tbody>
</table>

Ethnicity
Authors included that approximately 59% of the participants were of the “black race” (as reported in article, p. 1876).

Disease/disability diagnosis
Adults who are under sedation in the ICU for less than 72 hours, and who were expected to continue sedation for at least 24 hours. The primary diagnoses of the participants on admission to ICU included acute lung injury (55% intervention/56% control), chronic obstructive pulmonary disorder exacerbation (8%/11%), acute exacerbation of asthma (10%/7%), sepsis (14%/16%), hemorrhage (2%/4%), and malignancy (4%/2%).

Check appropriate group:

<table>
<thead>
<tr>
<th>Group</th>
<th>101–149/study group</th>
<th>150–200/study group</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 20/study group</td>
<td>20–50/study group</td>
<td>51–100/study group</td>
</tr>
</tbody>
</table>

INTERVENTION(S) AND CONTROL GROUPS

Add groups if necessary

Group 1: Intervention Group (n = 49)

<table>
<thead>
<tr>
<th>Brief Description</th>
<th>The participants included in the intervention group underwent physical and occupational therapy beginning on the day of enrolment. The techniques that were used with these patients include early exercise and mobilization during periods of daily interruption of sedation. Specifically OTs and PTs worked with clients on active assistive range of motion /active range of motion exercises, supine to sit, ADLs, transfer training, and/or pre-gait exercises and walking.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Setting</td>
<td>ICUs of two medical centers: University of Chicago Medical Center and University of Iowa Hospitals</td>
</tr>
<tr>
<td>Who Delivered?</td>
<td>The designated OTs and physical therapists treated the clients in the intervention.</td>
</tr>
<tr>
<td>Frequency?</td>
<td>1.5 days from intubation to first OT/PT session</td>
</tr>
<tr>
<td>Duration?</td>
<td>5.9 days (time in ICU)</td>
</tr>
</tbody>
</table>
Group 2: Control Group \((n = 55)\)

<table>
<thead>
<tr>
<th>Brief Description</th>
<th>The patients in the control group of this study received standard care, with physical and occupational therapy delivered as ordered by the primary care team.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Setting</td>
<td>Both the intervention and the control groups were treated in the ICU of two medical centers: University of Chicago Medical Center and University of Iowa Hospitals.</td>
</tr>
<tr>
<td>Who Delivered?</td>
<td>The designated OTs and PTs treated the clients in the intervention.</td>
</tr>
<tr>
<td>Frequency?</td>
<td>7.4 days from intubation to first occupational therapy/physical therapy session</td>
</tr>
<tr>
<td>Duration?</td>
<td>7.9 days (time in ICU)</td>
</tr>
</tbody>
</table>

**Intervention Biases:** *Circle yes or no and explain, if needed.*

- Contamination: YES/NO
- Co-intervention: YES/NO
  - Sedation and analgesia did not differ between groups. The interventions intended to improve independence was solely OT and PT.
- Timing: YES/NO
  - The objective of this study was based around the timing of intervention. The duration of the study was individualized to each patient according to his or her discharge date.
- Site: YES/NO
  - There was no bias found involving the intervention site. Two ICUs of hospitals were utilized in this study; neither site routinely provides physical therapy for patients who are on mechanical ventilation for less than 2 weeks, nor has dedicated physiotherapists for such practice. At both sites, a computer-generated, permuted block randomization scheme was used to allocate patients to study group. Thus, there is variation among the intervention sites.
- Use of different therapists to provide intervention: YES/NO
  - NR

**MEASURES AND OUTCOMES**

Complete for each relevant measure when answering the evidence-based question:

Name of measure, what outcome was measured, whether the measure is reliable and valid (as reported in article—yes/no/NR [not reported]), and how frequently the measure was used.

- Functional Independence Measure (FIM)
Independent functional status, as defined by the authors, is the ability to perform six activities of daily living and ability to walk independently. The FIM was used as a basis for identifying these outcomes. ADL scores that were rated \( \geq 5 \) were deemed as performed independently by the patient (i.e., no need for physical assistance). Patients were assessed by physical and occupational therapists who were unaware of randomization assignment.

Validity/reliability = NR
Frequency = every 48 hours

Name of measure, what outcome was measured, whether the measure is reliable and valid (as reported in article—yes/no/NR [not reported]), and how frequently the measure was used.

**Barthel Index**
The Barthel Index is an ordinal scale that was used to measure performance of ADLs. Patients were assessed by physical and occupational therapists who were unaware of randomization assignment.

Validity/reliability = NR
Frequency = within 24 hours of discharge

Measurement Biases
Were the evaluators blind to treatment status? *Circle yes or no, and if no, explain.*

**YES/NO** Assessors were blind to group allocation. To maintain blinding, the group of assessment therapists was distinct from the therapists who undertook the intervention. Before each assessment, the patients and any visitors were instructed (via a structured introductory statement) not to discuss previous interventions. Furthermore, assessments occurred in the afternoon at a time distant from the morning therapy intervention.

Recall or memory bias. *Circle yes or no, and if yes, explain.*

**YES/NO** Authors did not indicate whether there was a recall or memory bias for the FIM and Barthel Index.

Others (list and explain):

**RESULTS**
List results of outcomes relevant to answering the focused question

Include statistical significance where appropriate \( (p < 0.05) \)
Include effect size if reported

Return to independent functional status at hospital discharge occurred in more patients in the intervention group than in the control group (59% patients vs. 35% patients; \( p = 0.02 \) for return to independent functional status at hospital discharge). Length of stay in ICU was shorter in the intervention group (5.9 days) than the control group (7.9 days). The percentage of participants in the intervention group who were discharged to the home setting was significantly higher (43%) than in the control group (24%).
Was this study adequately powered (large enough to show a difference)? Circle yes or no, and if no, explain.

YES/NO

Were appropriate analytic methods used? Circle yes or no, and if no, explain.

YES/NO

Were statistics appropriately reported (in written or table format)? Circle yes or no, and if no, explain.

YES/NO

CONCLUSIONS
State the authors’ conclusions that are applicable to answering the evidence-based question.

In this RCT, daily interruption of sedation, combined with physical and occupational therapy from the start of critical illness in patients on mechanical ventilation, resulted in an improved return to (premorbid) independent functional status at hospital discharge compared with daily interruption of sedation and standard care. Thus, this trial shows that both functional and psychological outcomes of patients on mechanical ventilation can be improved by the implementation of physical and occupational therapy in the earliest stages of critical illness.

This work is based on the evidence-based literature review was completed by Ashley Chacon-Baker, BSHOT; Danielle Zenda, BSHOT; and Salvador L. Bondoc, OTD, OTR/L, FAOTA, Faculty Advisor, Quinnipiac University.


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