

Mapping Randomized Controlled Trials of Early Mobilization Interventions for ICU Delirium: A Scoping Review

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ABSTRACT

Background. Intensive Care Unit (ICU) delirium is a frequent manifestation of acute brain dysfunction among critically ill adults and is associated with prolonged hospitalization, increased mortality, institutionalization, long-term cognitive impairment, and functional decline. Early mobilization is included in contemporary ICU care bundles; however, the randomized trial literature remains heterogeneous in how mobilization is defined, implemented, and reported, and in how delirium outcomes are measured.

Objective. The study aimed to map and characterize randomized controlled trials (RCTs) evaluating early mobilization interventions for ICU delirium, focusing on intervention components, implementation and progression features, eligibility criteria, safety parameters, and delirium outcome reporting.

Methods. This scoping review was conducted in accordance with the Joanna Briggs Institute (JBI) Manual for Evidence Synthesis (Chapter on scoping reviews) and is reported following PRISMA-ScR. PubMed and CINAHL were searched from January 2009 to April 2024. We included RCTs enrolling adults in ICUs who received an early mobilization intervention during ICU stay and reported delirium incidence and/or duration measured using validated tools. Two reviewers independently screened records and charted data using a structured extraction form. Findings were synthesized descriptively.

Results. Six (6) RCTs (n = 859) met the inclusion criteria, enrolling predominantly middle-aged to older adult ICU populations (mean/median ages approximately 55–75 years), reflecting the higher delirium risk profile in this demographic. Interventions ranged from passive range-of-motion and bed mobility to sitting, standing, pre-ambulation, ambulation, cycling, progressive resistance exercise, and basic activities of daily living. Across trials, patient selection, physiological stability thresholds, session frequency/duration, progression rules, and termination criteria varied.

Delirium was commonly assessed using the Confusion Assessment Method for the ICU (CAM-ICU), but outcomes were reported using non-uniform metrics (e.g., delirium incidence, delirium days, percentage time delirious, delirium-free days).

Conclusion. The RCT literature on early mobilization for ICU delirium demonstrates substantial heterogeneity in intervention design, eligibility and safety criteria, and outcome reporting. This mapping clarifies the structure of randomized evidence and highlights priorities for standardizing intervention descriptions, safety reporting, and delirium outcome metrics to support future synthesis and implementation research.

Keywords: ICU delirium, delirium, intensive care unit, early mobilization



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INTRODUCTION

The Intensive Care Unit (ICU) is a highly specialized clinical environment for the management of patients with life-threatening conditions requiring continuous monitoring and advanced organ support.¹ A defining feature of intensive care medicine is its capacity to temporarily support or replace failing organ systems, requiring complex decision-making and rapid response from a multidisciplinary team delivering round-the-clock care.^{1,2} While advances in critical care have improved survival, complications associated with critical illness remain common and continue to drive morbidity, mortality, and resource utilization.¹ ICU delirium—an acute, fluctuating disturbance of attention and cognition—is a particularly important complication because it signals acute brain dysfunction and is associated with both short-term clinical deterioration and long-term neurocognitive sequelae.^{3,4}

Delirium in the ICU is clinically heterogeneous. Patients may present with hyperactive features (agitation, restlessness, and emotional lability), hypoactive features (lethargy, decreased responsiveness, and reduced motor activity), or mixed phenotypes that fluctuate across the day.^{5,6} Hypoactive delirium is frequently underrecognized because behavioral disruption may be minimal, yet its prognostic implications are substantial.⁵ Multiple factors contribute to delirium risk, including underlying illness severity, mechanical ventilation, sedation practices, sleep disruption, immobility, infection, metabolic derangements, and pre-existing vulnerabilities such as older age and cognitive impairment.^{4,7}

Epidemiologic estimates of ICU delirium vary by case mix and measurement strategy, but delirium is consistently common among critically ill adults.⁸ Reported incidence ranges from 20% to 70% in older ICU patients and reaches up to 80% among those receiving mechanical ventilation.^{4,9,10} A prospective cohort study identified an overall incidence of 31.5%, with illness severity as an independent predictor.¹¹ Delirium is associated with prolonged mechanical ventilation, increased ICU and hospital length of stay, higher health-care costs, increased mortality, and persistent cognitive and physical decline after critical illness.¹⁰⁻¹³ Psychomotor disturbances and impaired functional engagement frequently accompany cognitive dysfunction, potentially disrupting rehabilitation and recovery.^{5,6,12} In the Philippine setting, delirium has been reported in approximately 29% of ICU patients, typically emerging around the third day of admission, persisting for about five days, and associated with a 35% mortality rate.⁸

The pathophysiology of ICU delirium is multifactorial and incompletely understood. Proposed mechanisms include neuroinflammation triggered by systemic inflammatory cascades, neurotransmitter dysregulation (including cholinergic deficiency and dopaminergic excess), oxidative stress, altered cerebral perfusion, blood-brain barrier disruption, and circadian rhythm disturbances.¹⁴ These inter-

acting pathways provide a biological rationale for multifaceted prevention and management approaches that extend beyond pharmacologic strategies.

Non-pharmacologic interventions constitute the foundation of most delirium prevention and management efforts, often implemented as multicomponent bundles. Contemporary ICU guidance—operationalized in many settings through bundle approaches such as the ABCDEF framework—emphasizes regular delirium monitoring, minimization of sedative exposure, optimization of analgesia, early mobilization, and family engagement.¹⁵ Among these elements, early mobilization is both clinically appealing and operationally challenging. It is appealing because immobility is a modifiable risk factor and because physical activity may contribute to improved functional outcomes and physiologic resilience.¹⁶ It is challenging because patient stability, sedation, staffing, equipment, and safety considerations vary across ICUs and across patient populations.¹⁷

“Early mobilization” is not a single intervention; it is a broad category that may include passive range-of-motion exercises, in-bed mobility, transfers, sitting at the edge of the bed, standing, pre-ambulation activities, hallway ambulation, cycling, progressive resistance training, and activities of daily living.¹⁸⁻²⁰ Trials vary in when mobilization begins, what “early” means (e.g., within a certain number of hours of ICU admission, within a defined window after mechanical ventilation initiation, or after meeting stability criteria), and how progression is structured.¹⁸⁻²¹ Mobilization programs also vary in the professional roles involved (e.g., physical therapists, occupational therapists, nurses, respiratory therapists), frequency and duration of sessions, sedation coordination, and criteria for holding or terminating sessions.^{18,19,22,23}

Because of this complexity, the randomized controlled trial (RCT) literature on early mobilization and delirium can be difficult to interpret using a single effectiveness-focused lens. Even when trials include similar populations, differences in intervention content and intensity, monitoring strategies, and delirium outcome definitions can hinder comparability and synthesis. While systematic reviews can estimate pooled effects when heterogeneity is manageable, a scoping review is particularly useful when the first need is to map what has been studied, how interventions have been operationalized, what outcomes have been measured, and where key methodological and reporting gaps exist.²⁴

Accordingly, the present work is designed as a scoping review to map the landscape of RCTs evaluating early mobilization interventions in adult ICU patients with delirium outcomes. The focus is descriptive: to characterize intervention components and delivery features, eligibility and stability criteria, safety parameters and termination rules, and delirium outcome measurement and reporting patterns. This mapping is intended to inform future trial design, support standardization of reporting, and lay groundwork for future synthesis where appropriate.

METHODS

Design and Reporting Standards

The review methodology was developed a priori and registered with the Research Grants Administration Office of the University of the Philippines Manila (Registration No. RGAO-2024-0677). The protocol outlined the review objectives, eligibility criteria structured using the Population–Concept–Context (PCC) framework, search strategy, screening procedures, and data charting approach. The review was conducted in accordance with this prespecified protocol and aligned with the Joanna Briggs Institute (JBI) methodological guidance for scoping reviews.²⁴ Reporting was guided by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR).²⁵ A scoping review approach was selected because the objective was to map and characterize the randomized evidence base rather than to compute pooled estimates of effect or to issue practice guidelines.

Review Questions

This scoping review was conducted to map and characterize randomized evidence on early mobilization interventions for adult ICU patients with delirium outcomes.

The review addressed the following questions:

1. What early mobilization intervention components and delivery features have been evaluated in RCTs of adult ICU patients with delirium outcomes?
2. What patient eligibility criteria and physiological stability thresholds were used to determine readiness for mobilization?
3. What safety parameters, contraindications, and termination criteria were reported for mobilization sessions?
4. How were delirium outcomes assessed and reported across trials (e.g., incidence, duration, delirium-free days), and what variability exists in outcome definitions and reporting units?

These questions were designed to capture heterogeneity in trial design, operationalization of interventions, and outcome reporting.

Eligibility Criteria (PCC Framework)

Eligibility criteria were framed using the Population–Concept–Context (PCC) approach. The population comprised of adults (≥ 18 years) admitted to any ICU setting, including medical, surgical, or mixed units. The concept was early mobilization interventions delivered during ICU stay, broadly defined as structured physical activity ranging from passive or in-bed exercises to progressive out-of-bed mobility and functional tasks.²⁰ The context included all intensive care settings where early mobilization was implemented. We limited inclusion to RCTs to map how early mobilization has been operationalized and tested under randomized conditions and to characterize delirium outcome reporting

in trials. Pediatric populations, non-ICU settings, non-randomized designs, conference abstracts without full text, grey literature, and non-English publications were excluded to maintain feasibility and ensure adequate methodological detail for charting.

Information Sources and Search Strategy

Electronic searches were conducted in PubMed and CINAHL from January 2009 to April 2024 using search strategies that combined concepts related to early mobilization (e.g., early mobilization, early mobility, physiotherapy, rehabilitation) with delirium-related terms (e.g., ICU delirium, delirium, acute brain dysfunction). Boolean operators and database-specific syntax optimized sensitivity. Reference lists of included studies were examined (ancestral searching) to identify additional eligible trials. The complete search terms and search combinations used to identify eligible studies are provided in Appendices A and B, respectively.

Selection of Evidence Sources

All records were imported into a reference management workflow, and duplicates were removed. Two reviewers independently screened titles and abstracts for potential eligibility. Full texts of potentially relevant records were retrieved and assessed independently by two reviewers against the eligibility criteria. Disagreements were resolved through discussion; when consensus was not achieved, a third reviewer adjudicated.

Data Charting Process and Data Items

Data were extracted using a structured charting form piloted prior to use. Two reviewers independently extracted and cross-checked data, including publication details, ICU setting, sample size, patient characteristics, inclusion/exclusion criteria, sedation and ventilation status, early mobilization intervention components, staffing model, timing of initiation, frequency, duration, and intensity descriptors, progression criteria, safety parameters, contraindications and termination criteria, delirium assessment tools and frequency, and delirium outcome reporting formats. Adverse events related to mobilization were also charted when reported.

Operational Definition and Coding of Mobilization Components

For the purposes of this scoping review, early mobilization components were categorized using a structured coding framework developed a priori. Interventions were grouped into the following domains: (1) Range-of-Motion (ROM) exercises, defined as passive, active-assisted, or active joint movements performed in-bed; (2) Bed mobility, including repositioning, rolling, and transitions within the bed; (3) Transfers, such as bed-to-chair or sit-to-stand transitions; (4) Sitting activities, including supported or unsupported sitting at the edge of the bed or in a chair; (5) Standing and pre-

ambulation activities, including weight-shifting and balance tasks; (6) Ambulation, defined as walking with or without assistance; (7) Cycling, including in-bed or bedside cycle ergometry; (8) Progressive resistance exercises (PREs) using resistance bands or external loads; and (9) Basic activities of daily living (BADLs) integrated into mobilization sessions.

Each included trial was reviewed and coded according to the presence or absence of these components, as well as reported progression criteria, session frequency, and duration. When detailed descriptions were unavailable, categorization was based on the intervention narrative provided in the published manuscript. This structured coding approach was used to enhance consistency in mapping heterogeneous mobilization strategies across trials.

Critical Appraisal

Consistent with JBI scoping review guidance, formal critical appraisal was not used to exclude studies or derive hierarchical judgments of evidence certainty. The intent was to map trial characteristics and reporting patterns rather than to rate effectiveness certainty. Where relevant to understanding trial variability (e.g., feasibility of blinding, reporting of allocation concealment), methodological features were described narratively as part of trial characterization.

Synthesis of Results

Data were synthesized descriptively and organized into four domains: (1) intervention components and delivery/progression features; (2) eligibility and readiness criteria; (3) safety parameters and termination criteria; (4) delirium assessment and outcome reporting. Study-level narrative summaries contextualized heterogeneity and highlighted gaps in reporting. Pooled effect estimates were not calculated because this review was not designed as an effectiveness systematic review and because the mapped heterogeneity in interventions and reporting metrics limited comparability.

RESULTS

Search and Study Selection

The study selection process is presented in the PRISMA flow diagram adapted for scoping reviews (PRISMA-ScR) (Figure 1). Database searches identified 1,015 records (PubMed: 246; CINAHL: 769). After deduplication, 513 records remained and were screened by title and abstract, resulting in the exclusion of 450 records. Sixty-three reports were sought for full-text retrieval; 26 reports could not be retrieved. The remaining 37 full-text reports were assessed for eligibility, of which 33 were excluded because they were not RCTs, were conducted outside ICU settings, or did not

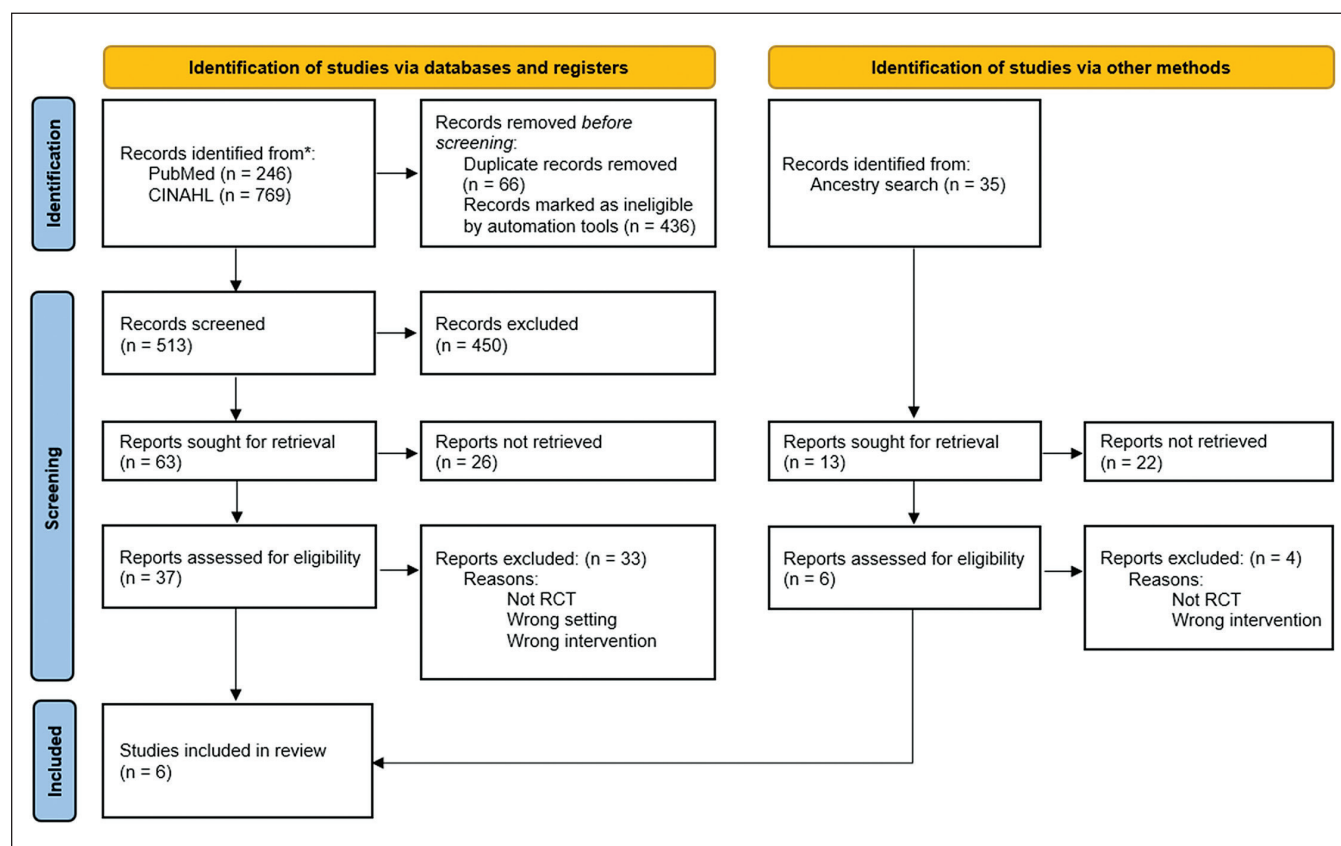


Figure 1. PRISMA flow diagram.

Table 1. Summary of Included Randomized Controlled Trials

Study #	Title	Author/s	Year of Publication	Number of Participants
1	Early physical and occupational therapy in mechanically ventilated, critically ill patients: a randomised controlled trial ²⁶	Schweickert WD, Pohlman MC, Pohlman AS, Nigos C, Pawlik AJ, Esbrook CL, Spears L, Miller M, Franczyk M, Deprizio D, Schmidt GA, Bowman A, Barr R, McCallister KE, Hall JB, Kress JP	2009	104
2	Mobilization in the evening to prevent delirium: A pilot randomized trial ²⁷	Nydahl P, McWilliams D, Weiler N, Borzikowsky C, Howroyd F, Brobeil A, Lindner M, von Haken R	2022	46
3	Impact of Pain, Agitation, and Delirium Bundle on Delirium and Cognitive Function ²⁸	Wang XP, Lv D, Chen YF, Chen N, Li XD, Xu CF, Li Y, Tian L	2022	243
4	The effect of range of motion exercises on delirium prevention among patients aged 65 and over in intensive care units ²⁹	Karadas C, Ozdemir L	2016	94
5	Standardized rehabilitation and hospital length of stay among patients with acute respiratory failure ³⁰	Morris PE, Berry MJ, Files DC, Thompson J, Hauser JI, Flores L, Dhar S, Chmelo E, Lovato J, Case LD, Bakhru RN, Sarwal A, Parry SM, Campbell P, Mote A, Winkelman C, Hite RD, Nicklas BJ, Chatterjee A, Young M	2016	300
6	Effect of in-bed cycling on acute muscle wasting in critically ill adults: A randomised clinical trial ³¹	Nickels M, Aitken LM, Barnett A, Walsham J, King S, Gale NE, Bowen AC, Peel BM, Donaldson SL, Mealing ST, McPhail S	2020	72

involve eligible early mobilization interventions. Additional records were identified through reference list (ancestral) searching (n = 35). Thirteen reports were retrieved and screened, with six assessed at full text. Four of these were excluded for failing to meet eligibility criteria. In total, six RCTs were included in the scoping review and were subjected to data extraction and narrative synthesis.

Overview of Included Studies

Table 1 summarizes included trials, including study titles, authorship, year of publication, design, and sample size. The six included RCTs comprised a total of 859 participants, with individual trial sample sizes ranging from 46 to 300 participants (Table 1). All included studies were RCTs. Delirium assessment was commonly performed using CAM-ICU, although the frequency and reporting metrics varied.

Study-by-study Narrative Synthesis

Study 1: Early physical and occupational therapy in mechanically ventilated, critically ill patients²⁶

This multicenter RCT evaluated early mobilization initiated within 1.5 days of ICU admission in mechanically ventilated patients. The intervention combined passive and active range-of-motion exercises, sitting at the edge of the bed, standing, and functional mobility with assistance from physical and occupational therapists. Progression was guided by patient tolerance, hemodynamic stability, and sedation levels, with clear criteria for holding sessions. Delirium was assessed daily using the Confusion Assessment Method for the ICU (CAM-ICU). The study reported a reduction in delirium duration and improvements in functional outcomes at hospital discharge. Key distinctions included

structured progression, interdisciplinary delivery, and explicit safety and termination rules, which serve as a reference for operationalizing early mobilization in critical care.

Study 2: Mobilization in the evening to prevent delirium²⁷

This pilot RCT examined whether an evening mobilization session could reduce delirium incidence in ICU patients. Interventions consisted of in-bed cycling, sitting upright, and assisted standing, delivered once daily by trained nurses and physiotherapists. Although the intervention focused on mobility progression rather than formal functional retraining, patients were encouraged to perform simple evening self-care activities—such as washing or brushing their teeth—reflecting basic activities of daily living (BADLs) that may support reorientation and restoration of normal routines. Safety criteria included heart rate, blood pressure, oxygen saturation, and mechanical ventilation parameters. Delirium was assessed using CAM-ICU, and outcomes included delirium incidence, delirium-free days, and patient tolerance of mobility sessions. Findings suggested feasibility and potential benefit in reducing delirium, while highlighting challenges in session timing, staffing, and integration with routine care. The study provides insight into flexible mobilization schedules and underscores the impact of circadian factors on delirium management.

Study 3: Impact of Pain, Agitation, and Delirium (PAD) Bundle on delirium and cognitive function²⁸

This RCT investigated early mobilization within the context of a comprehensive PAD bundle, which included sedation management, analgesia optimization, delirium monitoring, and early mobilization. The early mobilization component involved passive and active exercises, transfer

training, and ambulation, coordinated with nurses, physiotherapists, and respiratory therapists. Safety thresholds were clearly defined, including hemodynamic and respiratory parameters. Delirium outcomes were assessed using CAM-ICU and delirium-free days as primary endpoints. The study emphasized the synergistic effect of multicomponent interventions and suggested that early mobilization alone may be insufficient without complementary strategies addressing pain, sedation, and sleep.

Study 4: Effect of range-of-motion exercises on delirium prevention in patients aged ≥ 65 years²⁹

This RCT targeted older adults, a population at high risk for ICU delirium. The intervention consisted of structured passive and active range-of-motion exercises performed twice daily, focusing on all major joints. Nurses delivered the intervention, following strict safety protocols for vital signs and patient responsiveness. Delirium assessment was conducted using CAM-ICU, with delirium incidence as the primary outcome. The study found that the intervention group had lower delirium incidence, although differences were not statistically significant. This underscores the potential of utilizing low-intensity mobility interventions for vulnerable populations. This study highlights the importance of age-specific considerations and feasible, nurse-led interventions in delirium prevention.

Study 5: Standardized rehabilitation and hospital length of stay among patients with acute respiratory failure³⁰

This RCT evaluated a structured early rehabilitation program in mechanically ventilated patients, integrating passive and active exercises, sitting, standing, and ambulation into daily care. Sessions were delivered by a multidisciplinary team including physical therapists, nurses, and respiratory therapists, guided by explicit progression and safety criteria. Delirium was assessed using CAM-ICU, with additional outcomes including hospital length of stay, functional independence, and ventilator-free days. The study reported

improvements in functional outcomes and examined delirium outcomes descriptively. Key insights include the role of a structured, team-based approach and the necessity of clear protocols for timing, intensity, and safety.

Study 6: Effect of in-bed cycling on acute muscle wasting in critically ill adults³¹

This RCT explored device-assisted early mobilization using in-bed cycling in critically ill adults. Sessions were performed daily and adjusted based on hemodynamic stability and patient tolerance. The intervention aimed to prevent muscle wasting and included secondary outcomes related to delirium incidence, assessed using CAM-ICU. While primarily targeting muscle preservation, the study showed trends toward improved delirium-free days, demonstrating that device-assisted mobilization can be safely integrated into ICU care. It highlights an alternative mobilization modality that allows consistent exercise delivery even in patients unable to participate in conventional out-of-bed activities.

The distribution of early mobilization components and intervention characteristics across the six included trials is summarized in Table 2. Across all included trials, early mobilization interventions exhibited considerable variability in content, intensity, and delivery. Core components such as passive or active range-of-motion exercises, bed mobility, and sitting at the edge of the bed were consistently implemented, as seen in Schweickert et al. and Karadas & Ozdemir.^{26,29} Interventions progressed to standing and pre-ambulation activities, as reported in Morris et al. and Nydahl et al.^{27,30} Ambulation was incorporated in some trials, including Schweickert et al. and Morris et al., but was not universal, reflecting differences in patient stability, sedation practices, staffing, and available equipment.^{26,30} A smaller subset of trials integrated adjunct modalities such as in-bed cycling or progressive resistance exercises.^{26,31} Reporting of session frequency, duration, timing of initiation, and progression criteria varied widely across studies, limiting the ability to directly compare intervention “dose” and standardize operational definitions of early mobilization.

Table 2. Early Mobilization Components and Intervention Descriptors across Trials

Study	ROM	Bed Mobility	Transfers	Sitting	Stand; Pre-ambulation	Ambulation	Cycling	PREs	BADLs
Schweickert et al. ²⁶	Yes	Yes	Yes	Yes	Yes	Yes			
Nydahl et al. ²⁷				Yes	Yes	Yes			Yes
Wang et al. ²⁸	Yes	Yes	Yes	Yes	Yes				
Karadas & Ozdemir ²⁹	Yes								
Morris et al. ³⁰	Yes		Yes	Yes	Yes	Yes		Yes	
Nickels et al. ³¹				Yes	Yes		Yes		
Total	4	2	3	5	5	3	1	1	1

ROM – Range of Motion; PREs – Progressive Resistive Exercises; BADL – Basic Activities of Daily Living

Eligibility and Readiness Criteria

Eligibility criteria across trials reflected careful attempts to balance the potential benefits of early mobilization with patient safety (Table 3). Common themes included requirements for hemodynamic stability (e.g., stable blood pressure and heart rate), adequate respiratory function, sedation targets such as Richmond Agitation-Sedation Scale (RASS) scores permitting safe participation, and considerations related to mechanical ventilation. The RASS is a tool used to assess the level of alertness and agitation in critically ill patients.³² One of the primary characteristics is mechanical ventilation, cited in six studies, encompassing both invasive and noninvasive methods. Some trials incorporated illness severity indices, such as Acute Physiology and Chronic Health Evaluation (APACHE) scores, or baseline functional assessments such as the Barthel Index to further characterize the population or guide inclusion.³³ The Barthel Index is a measure of ability to perform activities of daily living (ADLs) on a ten-item scale, examining functions such as feeding, bathing, continence, mobility, and dressing.³⁴ Considerable variability in these criteria across studies likely influenced both the generalizability of findings and the heterogeneity of enrolled patients, underscoring the importance of clearly defined readiness thresholds when implementing early mobilization protocols.

Safety Parameters, Contraindications, and Termination Criteria

Safety reporting across trials commonly included physiological thresholds for blood pressure, heart rate, respiratory rate, oxygen saturation, and other clinical indicators.^{26,28,29} Several studies specified mean arterial pressure ranges and excluded patients with conditions such as active myocardial ischemia, unstable arrhythmias, or escalating vasopressor requirements.^{26-28,29} Termination criteria typically encompassed hemodynamic instability, oxygen desaturation, respiratory distress, agitation, or patient-reported intolerance.²⁶⁻²⁸ While Table 4 consolidates the reported safety parameters, the completeness of safety reporting varied considerably across trials, and threshold values were not standardized, highlighting a critical source of heterogeneity in early mobilization protocols and underscoring the need for consensus guidelines to guide safe implementation.

Delirium Assessment and Outcome Reporting

Table 5 summarizes delirium assessment tools, assessment frequency and timing, and the outcome metrics reported across the six included trials. All included trials assessed delirium using validated instruments, most frequently the Confusion Assessment Method for the ICU (CAM-ICU).³⁵ Despite this consistency in measurement tools, the frequency of assessment and the operationalization of delirium outcomes varied widely. Trials reported delirium as incidence (proportion of patients experiencing delirium), duration (total days or hours in a delirious state), percentage of ICU time spent delirious, or delirium-free days. Some studies focused on delirium occurrence within a defined observation window, whereas others reported cumulative delirium days over the entire ICU stay. This variability in outcome definitions, assessment timing, and reporting units limits comparability across trials and poses challenges for secondary synthesis, highlighting the need for standardized delirium outcome measures in future research.

In addition to variability in outcome metrics, the frequency and timing of delirium assessments differed across trials. Most studies conducted daily CAM-ICU assessments during ICU admission; however, follow-up duration, assessment intervals, and reporting windows (e.g., cumulative ICU stay versus fixed 28-day periods) were not uniform. This variability in assessment frequency may influence reported incidence and duration estimates and further limits direct cross-trial comparability.

DISCUSSION

Principal Findings

This scoping review mapped six RCTs evaluating early mobilization interventions in adult ICU patients with delirium outcomes. The mapped evidence demonstrates substantial heterogeneity in what constitutes “early mobilization,” how readiness is defined, the safety thresholds used, and the ways in which delirium outcomes are measured and reported. Foundational mobility tasks (range-of-motion, bed mobility, sitting) are common, while higher-intensity activities (ambulation, cycling, progressive resistance) are less consistently represented and appear context-dependent.

Table 3. Patient Eligibility Characteristics and Baseline Clinical Features

Study	Mechanical ventilation (MV)	Barthel Index	RASS	APACHE score
Schweickert et al. ²⁶	MV <72 hours	≥70		APACHE II score: 20 (15.8-24)
Nydahl et al. ²⁷	MV		≥-3	
Wang et al. ²⁸	MV at least 72 hours		≥-3	APACHE II score: 23.65 (3.96)
Karadas & Ozdemir ²⁹	Noninvasive MV		≥-3	
Morris et al. ³⁰	MV via endotracheal tube or noninvasive MV via mask			APACHE III score: 76 (26)
Nickels et al. ³¹	MV >48 hours			APACHE III score: 67 (48-82)

RASS – Richmond Agitation-Sedation Scale; APACHE – Acute Physiology and Chronic Health Evaluation

Table 4. Safety Parameters, Contraindications, and Termination Criteria Reported across Trials

Study	MAP	SBP	HR	RR	O ₂ Sat	Arrhythmia	Other factors
<i>Schweickert et al.</i> ²⁶	Less than 65 mm Hg or more than 110 mm Hg	More than 200 mm Hg	Less than 40 beats per minute or more than 130 beats per minute	Less than 5 breaths per min or more than 40 breaths per minute	Less than 88%	Arrhythmia	Raised intracranial pressure; active gastrointestinal blood loss; active myocardial ischemia; continuing procedures including intermittent hemodialysis (but not including continuous ultrafiltration or hemodialysis); patient agitation that needed increased sedative administration in the past 30 min; and unsecure airway. Further criteria that prevented continuation of therapy were marked ventilator asynchrony; patient distress (evidenced by non-verbal cues, gestures); the patient being physically combative; concern for myocardial ischemia; and concern for airway device integrity
<i>Nydahl et al.</i> ²⁷							The intervention was not delivered in cases where patients were (a) already sleeping and unresponsive to verbal questions, (b) refused the mobilization, (c) in pain, and (d) not available because of procedures.
<i>Wang et al.</i> ²⁸	Decrease in mean arterial pressure	More than 180 mm Hg	Less than 50 beats per minute or more than 130 beats per minute	Less than 5 breaths per min or more than 40 breaths per minute	Less than 88%	Arrhythmia	Changes in the patient's condition were closely monitored during exercise, and the exercise was stopped when signs of fatigue were observed. The safety screening criteria for early exercise were as follows: respiratory system, FiO ₂ >60%; circulatory system, increasing doses of vasopressor infusions in the past 2 hours; myocardial infarction; and injuries in which mobility is contraindicated (e.g., unstable fractures). The failure screening criteria included obvious man-machine confrontation, patient restlessness
<i>Karadas & Ozdemir</i> ²⁹	Less than or equal to 65 mm Hg	Greater than or equal to 200 mm Hg and above	Less than or equal to 40 or greater than or equal to 130 per minute	Less than or equal to 5 or greater than or equal to 40 per minute	Less than or equal to 88%	Arrhythmia	not reported
<i>Morris et al.</i> ³⁰	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported
<i>Nickels et al.</i> ³¹	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported	Not reported

MAP – Mean Arterial Pressure; SBP – Systolic Blood Pressure; HR – Heart Rate; RR – Respiratory Rate; O₂ Sat – Oxygen Saturation; FiO₂ – Fraction of Inspired Oxygen

The age range of included participants (approximately 55–75 years in most trials) reflects a population at increased baseline risk for delirium and functional decline. Age-related vulnerability may influence both delirium prognosis and responsiveness to early mobilization interventions.^{3,7}

Mechanistic Pathways Linking Mobilization and Delirium

Although this scoping review does not evaluate effectiveness quantitatively, mapping the literature benefits from considering plausible pathways through which mobilization might relate to delirium outcomes. First, early mobilization may reduce systemic inflammation and mitigate neuroinflammatory signaling by promoting physiologic

homeostasis and reducing complications of immobility (e.g., atelectasis, infections).^{4,7,12,14} Second, mobilization can improve cardiopulmonary function and potentially enhance cerebral oxygenation and perfusion, which may influence delirium risk in vulnerable patients.^{4,10} Third, physical activity may support restoration of circadian rhythms and sleep–wake cycling, particularly when mobilization is coordinated with daytime routines and sedation minimization.^{4,15} Fourth, mobilization often requires decreased sedative exposure and greater patient engagement, which may reduce exposure to delirium-promoting medications and increase orientation and interaction with the environment.^{4,15} Finally, maintaining functional capacity may reduce the burden of critical illness weakness, facilitate communication,

Table 5. Delirium Outcome Reporting across Trials

Study	Delirium Tool	Outcome Metric	Assessment Frequency/Timing	Incidence of ICU Delirium	Duration of ICU Delirium
<i>Schweickert et al.</i> ²⁶	CAM-ICU	Delirium days	Assessed daily during ICU stay	ICU delirium days: Intervention: 2.0 (0.0–6.0) Control: 4.0 (2.0–7.0) p = 0.03	Time (%): Intervention: 33% (0–58) Control: 57% (33–69) p = 0.02
<i>Nydahl et al.</i> ²⁷	CAM-ICU	Incidence; delirium-free days	Assessed once daily for 28 days	17 (36.9) Intervention: 7 (26.9) Control: 10 (50)	28-day free of delirium (median, IQR): 28 (26.7–28) Intervention: 28 (27–28) Control: 27.5 (26–28)
<i>Wang et al.</i> ²⁸	CAM-ICU	Incidence; duration (days)	Assessed daily during ICU admission	Intervention: 29 (23.58) Control: 48 (40.00) p = 0.004	Intervention: 2.83 (1.20) Control: 4.02 (1.99) p = 0.005
<i>Karadas & Ozdemir</i> ²⁹	CAM-ICU	Incidence; duration (hours)	Assessed daily	Intervention: 4 patients (8.5%) Control: 10 (21.3%) p >0.05	Intervention: 15 hours (range: 3–144 h) Control: 38 hours (range: 9–120 h) p >0.05
<i>Morris et al.</i> ³⁰	CAM-ICU	Incidence	Assessed daily	0 (0 to 1) p = 0.77	Not presented
<i>Nickels et al.</i> ³¹	CAM-ICU	Incidence; duration (%)	Assessed daily	Intervention: 9 (25%) Control: 13 (36%)	Intervention: 14 (3.7%) Control: 26 (7.0%)

and support participation in reorientation and cognitive engagement strategies.^{12,13,26} These outcomes align with the perspective of the International Classification of Functioning, Disability and Health, which conceptualizes recovery in terms of interactions among body functions, activity performance, and participation in meaningful tasks.³⁶

International Guideline Context and Bundle-based Care

International critical care guidance emphasizes non-pharmacologic delirium prevention and management, often operationalized through multicomponent bundles.^{4,37,38} The Society of Critical Care Medicine (SCCM) and related international bodies have supported early mobility as part of bundled care approaches such as ABCDEF.¹⁵ However, implementation guidance is frequently stated at the level of principle (“mobilize early as feasible”) rather than with universally standardized protocols.^{18,19} The mapped RCT literature reflects this reality: trials differ in timing (hours vs days; post-stability vs fixed windows), intensity (passive vs active), progression models, and staffing/equipment requirements.^{26,27,30,31} The absence of standardized intervention reporting—including clear “dose” descriptors and fidelity measures—limits comparisons and may partially explain variability in reported delirium outcomes across studies.

Implications for Research Design and Reporting

The mapping identifies several priorities for future RCT design and reporting. First, clearer operational definitions of early mobilization are needed, including explicit reporting of components, timing, session frequency, duration, intensity, and progression rules. Second, readiness and safety thresholds should be reported consistently and, where feasible, aligned

with common physiological parameters. Third, delirium outcomes should be operationalized using standardized metrics to enhance comparability, including consistent reporting of incidence, duration, and assessment frequency. Fourth, reporting of co-interventions (sedation protocols, spontaneous awakening/breathing trials, family engagement) is important because bundled care elements may interact with mobilization and delirium outcomes. Finally, feasibility, staffing, and resource considerations should be explicitly reported, particularly in resource-constrained settings, to support implementation research and contextual adaptation.

Implications for Practice and Implementation

While scoping reviews do not issue practice recommendations based on effect estimates, mapping the RCT landscape can still inform implementation planning. The predominance of foundational mobility activities suggests a potential minimum “core” set of mobilization elements that may be feasible across diverse ICUs, whereas advanced components may require additional staffing or equipment. Reporting variability in safety thresholds highlights the importance of local protocol development that incorporates patient stability assessment, interdisciplinary coordination, and clear termination criteria. Importantly, implementation should be embedded within broader ICU best practices for sedation minimization and delirium monitoring.

Limitations

This review has several limitations. The search strategy was restricted to PubMed and CINAHL, which were selected for their broad indexing of biomedical and rehabilitation research relevant to ICU populations. Although additional databases (e.g., Embase or CENTRAL) may index related studies, ancestral searching of included articles was performed

to enhance retrieval of eligible randomized controlled trials. As this review aimed to map the methodological characteristics and reporting patterns of randomized trials rather than to conduct exhaustive effect estimation, the database restriction may have influenced the number of included trials but is unlikely to substantially change the mapped domains identified. Nevertheless, this limitation is acknowledged. Restriction to RCTs was intentional and aligned with the objective of mapping randomized evidence, but it does not represent the full breadth of early mobilization literature (including observational studies and implementation studies). In addition, scoping review methodology does not prioritize pooled effect estimation; thus, findings should be interpreted as descriptive mapping rather than quantitative evidence of benefit or harm.

CONCLUSION

The randomized evidence base evaluating early mobilization interventions for ICU delirium comprises heterogeneous interventions and heterogeneous outcome reporting. Mapping these trials clarifies key domains of variability—intervention components and dose descriptors, readiness and safety thresholds, and delirium outcome definitions. Standardization in intervention reporting, safety parameter reporting, and delirium outcome metrics is warranted to enhance future comparability and to support both rigorous effectiveness synthesis and pragmatic implementation research.

Statement of Authorship

Both authors certified fulfillment of ICMJE authorship criteria.

Author Disclosure

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APPENDICES

Appendix A. Complete search terms

((early mobilization) OR (early mobility) OR (physical activity)) AND ((ICU delirium) OR (delirium) OR (encephalopathy) OR (acute brain failure) OR (metabolic encephalopathy) OR (toxic encephalopathy))
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Appendix B. Search combinations

early mobilization	ICU delirium
early mobility	delirium
physical activity	encephalopathy
exercise	metabolic encephalopathy
	toxic encephalopathy
	acute brain failure