5-1-2023

Comparator Groups in ICU-Based Studies of Physical Rehabilitation: A Scoping Review of 125 Studies

Heather K O'Grady

Julie C Reid

Christopher Farley

Quincy E B Hanna

Janelle Unger
junger6@uwo.ca

See next page for additional authors

REVIEW ARTICLE

OPEN

Comparator Groups in ICU-Based Studies of Physical Rehabilitation: A Scoping Review of 125 Studies

Heather K. O'Grady, BSc[1],
Julie C. Reid, PT, PhD[2],
Christopher Farley, PT, MSc[1],
Quincy E. B. Hanna, BSc[3],
Janelle Unger, PT, PhD[4],
David J. Zorko, MD, MSc[5],
Jackie Bosch, OT Reg (Ont), PhD[1],
Lyn S. Turkstra, Reg-CASLPO, PhD[1],
Michelle E. Kho, PT, PhD[1,3]

OBJECTIVES: To characterize comparator groups (CGs) in ICU-based studies of physical rehabilitation (PR), including the type, content, and reporting.

DATA SOURCES: We followed a five-stage scoping review methodology, searching five databases from inception to June 30, 2022. Study selection and data extraction were completed independently, in duplicate.

STUDY SELECTION: We screened studies by title and abstract, then full-text. We included prospective studies with greater than or equal to two arms enrolling mechanically ventilated adults (≥ 18 yr), with any planned PR intervention initiated in the ICU.

DATA EXTRACTION: We conducted a quantitative content analysis of authors' description of CG type and content. We categorized similar CG types (e.g., usual care), classified content into unique activities (e.g., positioning), and summarized these data using counts (proportions). We assessed reporting using Consensus on Exercise Reporting Template (CERT; proportion of reported items/total applicable).

DATA SYNTHESIS: One hundred twenty-five studies were included, representing 127 CGs. PR was planned in 112 CGs (88.2%; 110 studies), representing four types: usual care ($n = 81$, 63.8%), alternative treatment than usual care (e.g., different from intervention; $n = 18$, 14.2%), alternative treatment plus usual care ($n = 7$, 5.5%), and sham ($n = 6$, 4.7%). Of 112 CGs with planned PR, 90 CGs (88 studies) reported 60 unique activities, most commonly passive range of motion ($n = 47$, 52.2%). The remaining 22 CGs (19.6%; 22 studies) reported vague descriptions. PR was not planned in 12 CGs (9.5%; 12 studies), and three CGs (2.4%; three studies) reported no details. Studies reported a median (Q1–Q3) of 46.6% (25.0–73.3%) CERT items. Overall, 20.0% of studies reported no detail to understand planned CG activities.

CONCLUSIONS: The most common type of CG was usual care. We identified heterogeneity in planned activities and CERT reporting deficiencies. Our results could help guide the selection, design, and reporting of CGs in future ICU-based PR studies.

KEY WORDS: critical care; critical illness; early ambulation; rehabilitation; review

With improved adult ICU mortality, an increasing number of survivors may experience important functional morbidities (1). ICU survivors are at risk of impaired physical function, lasting up to 5 years post-critical illness; these impairments may contribute to decreased participation in daily activities and quality of life (2–6). As a result, it is increasingly important to identify effective treatments to reduce post-ICU morbidities and improve survivorship.

Landmark studies, published over a decade ago, found that physical rehabilitation (PR) delivered in the ICU could improve physical function in ICU

DOI: 10.1097/CCE.0000000000000917

KEY POINTS

Question: What are the characteristics of comparator groups (CGs) in ICU-based studies of physical rehabilitation (PR)?

Findings: 1) In this 125 study scoping review of ICU-based PR, two thirds of CGs were usual care; 2) One in five studies did not report detail to understand CG content; 3) CG content was heterogeneous, with 60 unique planned rehabilitation activities; passive range of motion was most common; and 4) Incomplete reporting and heterogeneity limit understanding of CGs, hindering our ability to assess intervention efficacy and safety.

Meaning: This work could help guide selection, design and reporting of CGs in future ICU-based PR studies.

survivors at hospital discharge (7, 8). Although these initial trials demonstrated promising effects, results of recent randomized controlled trials (RCTs) have been discordant (9, 10). A meta-analysis of 14 RCTs found inconsistent results regarding the impact of PR interventions on physical function at ICU and hospital discharge (10). Interpreting results of these RCTs has been challenging due to the limited and heterogeneous description of planned therapy in comparator groups (CGs) (9, 10). A detailed description of CG PR is necessary to determine separation between groups and contextualize study results. A scoping review of ICU-based PR studies identified reporting gaps in characteristics of intervention and CGs, however, focused on characterizing intervention groups (11). Therefore, we conducted a scoping review to characterize CGs in ICU-based PR studies, including the type, content, and completeness of reporting.

MATERIALS AND METHODS

We followed a five-stage scoping review methodology (12, 13), updating the search, and expanding data collection of a previous scoping review of ICU-based PR interventions (11). We prospectively registered this review in Open Science Framework (https://doi.org/10.17605/OSF.IO/BS342) (14) and followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses Extension for Scoping Reviews (checklist **Supplementary Table S1**, http://links.lww.com/CCX/B193) (15).

Eligibility Criteria

We included: population—critically ill, mechanically ventilated adults greater than or equal to 18 years old; intervention—any planned PR intervention started in the ICU; comparator—any; outcomes—any; and study type—any prospective study with greater than or equal to two arms (i.e., RCTs, nonrandomized trials). We defined CGs as any group of study participants whose outcomes were compared against those of the intervention group (16), including participants who served as their own comparator by receiving two unique treatments (e.g., one limb receiving neuromuscular electrical stimulation [NMES] and the other limb receiving sham). We excluded conference abstracts, studies of chest physiotherapy (airway clearance) only, gray literature, review articles, surveys of practice, studies validating outcome measures, and non-English studies.

Information Sources and Search

We searched five databases from inception to June 30, 2022: Ovid Medline, CINAHL, Allied and Complementary Medicine Database, Embase database, and the Physiotherapy Evidence Database. Our search strategy was developed in consultation with a health research librarian (**Supplementary Table S2**, http://links.lww.com/CCX/B193) (11, 17).

Screening and Data Charting

We imported citations into Covidence (2020, Veritas Health Innovation, Melbourne, VIC, Australia). Two reviewers screened citations independently and in duplicate, first by title and abstract, then full-text. We consulted a third reviewer for conflicts. We completed data charting independently, in duplicate, using a piloted form in Covidence (**Supplementary Table S3**, http://links.lww.com/CCX/B193). By study, we narratively summarized inclusion criteria, admission diagnoses, intervention type, primary outcome, and authors' description of CG. We reviewed each study's methods and supplementary data files (if applicable) and documented authors' description of planned content (i.e., activities) and

characteristics (e.g., frequency, intensity, duration) of CG PR verbatim.

We assessed completeness of reporting using the Consensus on Exercise Reporting Template (CERT) (18). CERT is an extension of the Template for Intervention Description and Replication (TIDieR) and facilitates reporting of additional details necessary for clinical replicability in a rehabilitation context (e.g., dosage) (19–21). CERT items were assessed as "reported," "not reported," or "not applicable" for each CG. For CERT item 13 (dose), we assessed frequency, intensity, timing and duration as discrete items (13A–D), for a total of 22 potentially applicable items. Detailed CERT methods are described in **Supplementary Table S4** (http://links.lww.com/CCX/B193).

Determination of CG Type and Content

We conducted a quantitative content analysis (22) of the authors' verbatim descriptions of CG type and content. To determine CG "type," we reviewed authors' description (e.g., usual care, progressive mobility) and categorized similar types. We then identified the planned PR (i.e., what authors said they would do). We use the term "planned," because we analyzed the reported CG PR methods, and not the results.

To determine CG "content," we reviewed the planned CG PR. For CGs with reported content, we reviewed the authors' description to identify individual PR activities (e.g., passive range of motion, sitting over the edge of the bed). We then grouped similar individual PR activities into unique activities (i.e., synonymous terms; e.g., "passive range of motion" included passive motion, passive joint mobility, etc.) Last, we compared unique PR activities across CGs to identify any common PR programs (i.e., same activity/combination of activities) **Supplementary Table S8** (http://links.lww.com/CCX/B193) summarizes individual and unique activities.

Subgroup Analysis by Type

Previous reviews of PR in stroke rehabilitation and neurorehabilitation identified heterogeneity in "usual care" CGs (23, 24). We conducted a subgroup analysis to explore the content of "usual care," restricting our analysis to usual care PR CGs.

Synthesis and Analysis

Data were analyzed using Stata (v. 15.0, StataCorp LP, College Station, TX). We used descriptive statistics, including counts (percentages) for categorical data and mean (SD) for normal continuous data or median (first–third quartiles) if data were skewed (Shapiro-Wilk test, alpha = 0.05). To quantify completeness of reporting, we calculated reporting scores for each study as a proportion (number reported/total applicable CERT items) (11, 25). We summarized reporting scores by item and across studies, with scores classified as poor (≤ 50%), moderate (51–69%), or adequate (≥ 70%) (11, 26, 27).

Post hoc, we conducted an analysis to understand potential changes in dose of PR over time. We analyzed the reported frequency (CERT item number 13A) and duration (item number 13D) of PR, by CG. To understand changes in PR frequency over time, we grouped studies according to year of publication and compared between years using Pearson chi-square test (alpha = 0.05). To understand changes in duration, we conducted a simple linear regression (time [year of publication] vs duration [min] of PR).

RESULTS

Study Selection

We screened 84,273 unique titles and abstracts, 2,324 full-text articles, and included 125 studies that enrolled 11,894 patients (**Supplementary Fig. S1**, http://links.lww.com/CCX/B193).

Characteristics of Included Studies

Study characteristics are summarized in **Table 1** and detailed in **Supplementary Table S5** (http://links.lww.com/CCX/B193). Of the 125 included studies, 64% were parallel-group, two-arm RCTs (n = 80). Studies occurred in 43 countries, and 85.6% (n = 107) were single-center, conducted in mixed ICUs (n = 55, 44.0%). The first study was published in 1987, while the majority (52.8%) were published between 2016 and 2020 (n = 66). The median (Q1–Q3) number of patients enrolled per study was 60 (36–109).

Patient Characteristics

Patient characteristics are summarized in **Table 2** and detailed in **Supplementary Table S6** (http://links.lww.com/CCX/B193). Of 120 studies (96.0%) that reported

TABLE 1.
Study Characteristics

Characteristics	*n* = 125 Studies
Geographic regions, *n* (%)	
Asia	44 (35.2)
Europe and the United Kingdom	37 (29.6)
South America	17 (13.6)
North America	16 (12.8)
Oceana	9 (7.2)
Africa	2 (1.6)
Year of publication, *n* (%)	
< 2000	2 (1.6)
2001–2005	2 (1.6)
2006–2010	9 (7.2)
2011–2015	26 (20.8)
2016–2020	66 (52.8)
2021 to July 2022	20 (16.0)
Study design	
RCT	93 (74.4)
Two-arm	80 (86.0)
Three-arm	10 (10.8)
Four-arm	3 (3.2)
Non-RCT	19 (15.2)
Other[a]	13 (10.4)
ICU type	
Mixed	55 (44.0)
General	15 (12.0)
Medical	12 (9.6)
Neurosurgery/neurotrauma	10 (8.0)
Other[b]	14 (11.2)
Not specified	19 (15.2)
Number of centers per study	
Median (first–third quartiles)	1 (1–1)
Range (minimum–maximum)	1–7
Patients enrolled per study	
Median (first–third quartiles)	60.0 (36.0–109.0)
Range (minimum–maximum)	8–647

RCT = randomized controlled trial.
[a]Other study designs (*n* = 13): Within-patient RCT 5 (4.0), historical control trial 3 (2.4), cluster RCT 2 (1.6), randomized crossover RCT 2 (1.6), and cluster non-RCT 1 (0.8).
[b]Other ICUs (*n* = 14): Surgical 6 (4.8), respiratory 4 (3.2), cardiac 2 (1.6), trauma 1 (0.8), and thoracic 1 (0.8).
This table summarizes characteristics of included studies. Countries of publication, by geographic region: Asia: China (*n* = 14), Japan (*n* = 6), Taiwan (*n* = 6), Iran (*n* = 4), India (*n* = 3), Turkey (*n* = 3), Israel (*n* = 2), Thailand (*n* = 2), Bangladesh (*n* = 1), ndonesia (*n* = 1), Korea (*n* = 1), and South Korea (*n* = 1). Europe and the United Kingdom: Belgium (*n* = 6), France (*n* = 4), Greece (*n* = 4), Italy (*n* = 4), Switzerland (*n* = 4), United Kingdom (*n* = 4), Germany (*n* = 3), Austria (*n* = 2), Denmark (*n* = 2), Czech Republic (*n* = 1), Iceland (*n* = 1), The Netherlands (*n* = 1), and Sweden (*n* = 1). South America: Brazil (*n* = 15), Argentina (*n* = 1), and Colombia (*n* = 1). North America: United States (*n* = 15) and Canada (*n* = 1). Oceana: Australia (*n* = 9). Africa: Egypt (*n* = 1) and South Africa (*n* = 1).

sex, the median proportion of females enrolled per study was 39.3% (31.9–49.0%). Age was reported in 121 studies (96.8%) with a median of 61.1 years (54.8–65.5 yr). Duration of mechanical ventilation (MV) was reported in 63 studies (50.4%), with a median of 8.3 days (5.3–11.3 d). ICU length of stay was reported in 77 studies (61.6%), with a median of 12.8 days (7.5–20.0 d).

Comparator Group Types

CGs are described in Supplementary Table S6 (http://links.lww.com/CCX/B193). Across 125 studies, there were 127 CGs (two studies each had two CGs) (**Fig. 1**). Three studies (2.4%) did not report any CG details, preventing type classification (**Figs. 1** and **2**). Out of the 127 CGs, PR was planned in 112 (88.2%), representing four types: usual care (*n* = 81, 63.8%; 80 studies), alternative treatment than usual care (*n* = 18, 14.2%; 18 studies), alternative treatment plus usual care (*n* = 7, 5.5%; seven studies) and sham (*n* = 6, 4.7%; five studies) (Figs. 1 and 2). PR was not planned (i.e., CG did not include any planned PR) in 12 CGs (9.5%; 12 studies) (Figs. 1 and 2).

Comparator Group Content

From the 112 CGs (110 studies) with planned PR, we identified instances where authors' descriptions precluded Content classification (e.g., "rehabilitation," "conventional treatment," "physical therapy strategies"). We classified these instances

TABLE 2.
Patient Characteristics

Characteristics	Overall	Intervention	Control
Patients enrolled	11,894	6,112[a]	5,476[a]
n (%) female	4,604 (39.5)[b]	2,058 (34.1)[c]	1,911 (35.3)[c]
% Female per study			
Median (first–third quartiles)	39.3 (31.9–49.0)[b]	38.0 (30.8–47.2)[c]	40.0 (31.3–50.0)[c]
Range	0.0–74.7	0.9–85.7	6.7–87.0
Age			
Median (first–third quartiles)	61.1 (54.8–65.5)[d]	59.9 (54.2–65.0)[e]	60.4 (55.1–66.0)[e]
Mean (SD)	59.3 (9.2)[d]	58.9 (9.2)[e]	59.2 (9.3)[e]
ICU length of stay (d)			
Median (first–third quartiles)	12.8 (7.5–20.0)[f]	12.0 (7.3–18.6)[g]	13.4 (7.9–19.3)[g]
Range (minimum–maximum)	2.6–46.2[f]	2.6–38.8[g]	2.7–56.9[g]
Duration of mechanical ventilation (d)			
Median (first–third quartiles)	8.3 (5.3–11.3)[h]	7.0 (5.1–10.1)[i]	8.0 (5.9–12.7)[i]
Range (minimum–maximum)	0.0–51.2[h]	0.0–32.7[i]	0.0–98[i]

This table summarizes patient characteristics of included studies.
[a]*n* = 113 studies, 12 studies reported overall trial enrollment, not by group.
[b]*n* = 120 studies (11,672 patients), five studies did not report sex.
[c]*n* = 109 studies (intervention—6,029 patients, control *n* = 5,410), 11 studies reported overall sex, not by group.
[d]*n* = 121 studies, four studies did not report age.
[e]*n* = 110 studies, 11 studies reported overall age, not by group.
[f]*n* = 77 studies, 48 studies did not report ICU length of stay (LOS).
[g]*n* = 74 studies, three reported overall LOS, not by group.
[h]*n* = 63 studies, 62 studies did not report duration of mechanical ventilation (MV).
[i]*n* = 60 studies, three studies reported overall duration of MV, not by group.

as ambiguous terms. Twenty-two CGs (17.3%), representing 22 studies (17.6%), only reported ambiguous terms (Figs. 1 and 2). Of the remaining 88 studies (90 CGs), 79 (63.2%) reported PR activities only, and nine (8.0%) reported PR activities and ambiguous terms. Overall, 25 studies (20.0%) did not report any detail to understand planned content.

Out of the 90 CGs (88 studies) that reported PR activities, we identified 100 activities, of which 60 were unique, with a median of 2 (1–5) unique activities per CG (**Supplementary Tables S7** and S8, http://links.lww.com/CCX/B193). The most common activities were passive range of motion (*n* = 47 CGs, 52.2%), positioning (*n* = 28 CGs, 31.1%), and walking (*n* = 28 CGs, 31.1%). Thirty-one CGs reported 19 ambiguous terms, with 71.0% including terms synonymous with "usual care" (*n* = 22) (**Supplementary Table S9**, http://links.lww.com/CCX/B193).

From 88 studies (90 CGs) that reported PR activities, we identified seven common PR programs (i.e., activities or combination of activities) across 26 (20.8%; 28 CGs). Programs were not repeated in 62 studies (49.6%; 62 CGs) (Fig. 2 and **Table 3**). The most common programs were single activities such as passive range of motion (*n* = 8 CGs, 8.9% of all CGs), positioning (*n* = 6, 6.7%), and sham NMES (*n* = 5, 5.6%).

Subgroup Analysis of Usual Care

Out of 125 studies, 80 (64.0%) had a usual care CG (81 CGs). Across 80 studies, we identified 21 terms, most commonly "usual care" (*n* = 20, 25.0%), "standard care" (*n* = 14, 17.5%), and "conventional therapy" (*n* = 10, 12.5%) (**Supplementary Figs. S2** and **S3**, http://links.lww.com/CCX/B193). Fifty-four usual care CGs (66.7%; 53 studies [66.3%]) reported PR activities only,

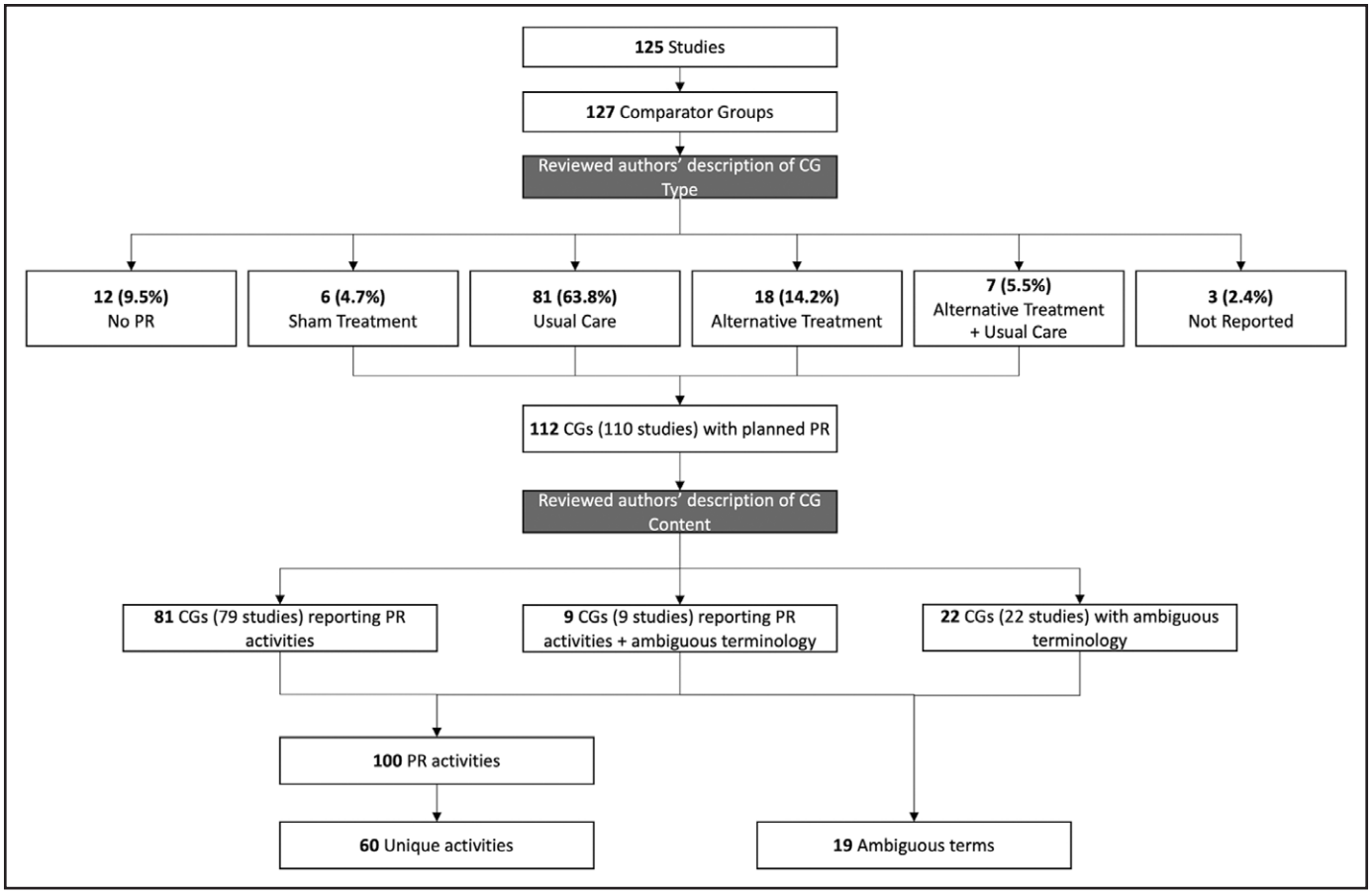

Figure 1. Flowchart of content analysis of reported comparator group (CG) type and content. "Ambiguous terminology" represents terminology for which we could not determine which, if any, physical rehabilitation (PR) activities were planned (e.g., "usual care" with no additional explanation). "PR activities" represents terminology for which we could understand the PR activities that were planned (e.g., passive range of motion). Some studies reported ambiguous content in addition to PR activities.

and five (6.2%; five studies [6.3%]) reported PR activities and ambiguous terms (Supplementary Fig. S3, http://links.lww.com/CCX/B193). Twenty-two studies with usual care CGs (17.6%; 22 CGs) only reported ambiguous terms (Supplementary Fig. S3, http://links.lww.com/CCX/B193).

From the 59 CGs (58 studies) that reported PR activities, we documented 83 activities, of which 55 were unique, with a median of 3 (2–5) per CG (Supplementary Tables S7 and S8, http://links.lww.com/CCX/B193). The most common activities were passive range of motion (n = 32 CGs, 54.2%), positioning (n = 20, 33.9%), and walking (n = 19, 32.2%) (Supplementary Table S7, http://links.lww.com/CCX/B193). Twenty-seven usual care CGs (33.3%) reported 19 ambiguous terms, with the most common terms synonymous with "usual care" (n = 19, 70.4%) (Supplementary Table S9, http://links.lww.com/CCX/B193).

We identified five common PR programs activities across 17 usual care CGs (21.0%; 16 studies [20.0%], while 42 [51.9%; 42 studies (52.5%)]) were not repeated in any other CG (Fig. 2 and Table 3). The most common programs were single activities including passive range of motion (n = 6, 10.2%) and positioning (n = 4, 6.8%).

CG CERT Reporting

The median reporting score was 46.6% (25.0–73.3%) (**Fig. 3**), with a minimum of 0% (n = 2, 1.6%) and maximum of 100% (n = 1, 0.8%) (**Supplementary Table S10**, http://links.lww.com/CCX/B193). The least reported item was "motivation" (CERT item number 6) (n = 8, 9.2%), while the most was "setting" (CERT item number 12) (n = 120, 96.0%) (Fig. 3). Seventy-seven CGs (62.1%) reported PR frequency (CERT item number 13A) which ranged from one

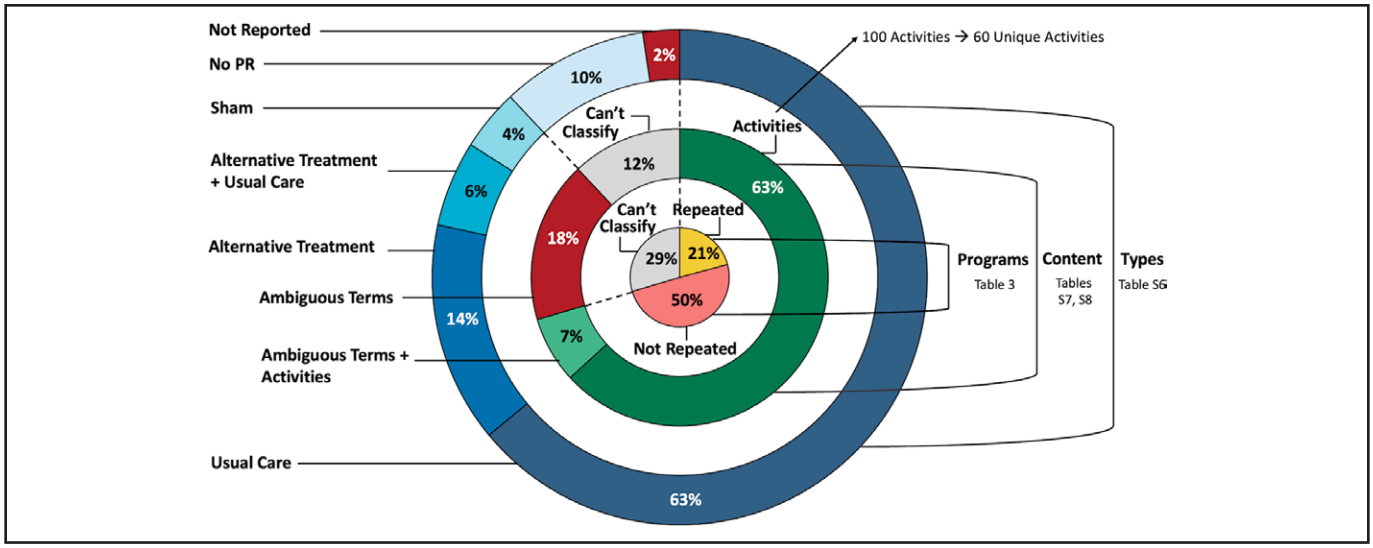

Figure 2. Summary of results ($n = 125$ studies). The *outer circle* summarizes the types of comparator groups (CGs), derived from authors' CG labels (e.g., usual care, progressive mobility). The *middle circle* summarizes CG content (e.g., what authors said they would do). Content is a summary of authors' verbatim descriptions of CG physical rehabilitation (PR), classified into activities. We grouped similar activities together into "unique activities." In some instances, authors' descriptions precluded classification into individual activities, and we labeled these "ambiguous terms." The *innermost* circle summarizes the number of CGs with repeated programs. Programs are activities or combinations of activities. The denominator for all three circles is the total number of studies (125).

session (28–32) to tid (33, 34). Fifty-six CGs (45.2%) reported PR intensity, with most using terminology such as "passive" (n = 50, 89.3%). Fifty-seven CGs (46.0%) reported PR duration (CERT item number 13D) with a range of 5 (35–37) to 60 minutes (38–40) per session.

Seventy-three CGs (57.5%) reported the planned frequency of PR by day, most commonly once per day ($n = 43$, 58.9%) (**Supplementary Table S11**, http://links.lww.com/CCX/B193). We identified a decrease in the proportion of CGs with PR planned less than once a day in studies published between 2011 and 2015 compared

TABLE 3.
Content of Comparator Group Physical Rehabilitation Programs

Physical Rehabilitation Activities	Evaluable Comparator Groups ($n = 90$)	Usual Care ($n = 59$)
Activities	28 (31.1)	17 (28.8)
PROM only	8 (8.9)	6 (10.2)
Positioning only	6 (6.7)	4 (6.8)
Sham neuromuscular electrical stimulation only	5 (5.6)	–
Mobility only	3 (3.3)	3 (5.1)
Airway clearance + manual hyperinflation + PROM + active-assisted range of motion	2 (2.2)	2 (3.4)
PROM + active range of motion	2 (2.2)	–
PROM + kicking stability ball + standing + walking	2 (2.2)	2 (3.4)
Other	62 (68.9)	42 (71.2)

PROM = passive range of motion, - = not applicable.
We examined comparator groups (CGs) to identify those with the same physical rehabilitation (PR) activity/activities. "Other" means that a CG had planned combinations of PR activities that were not repeated in any other study (e.g., Akar 2017 included PROM, active-assisted range of motion, and active range of motion in their CG PR program, which was unique from all other CGs). Further detail in Supplementary Table S6 (http://links.lww.com/CCX/B193).

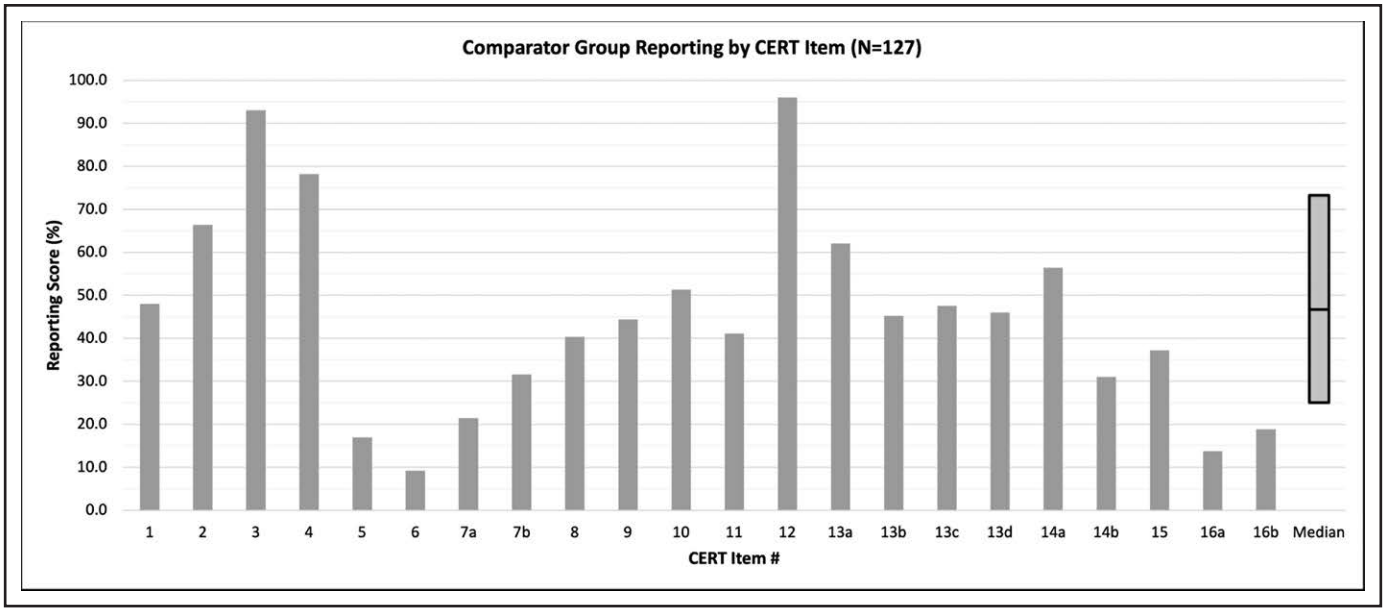

Figure 3. Comparator group (CG) Consensus on Exercise Reporting Template (CERT) reporting, by item. One hundred twenty-seven CGs were included in this analysis. Reporting scores were calculated by dividing the total number of studies that reported each CERT item by the total number of studies for which that CERT item was applicable. An explanation of methods for CERT assessments is included in Supplementary Table S4 (http://links.lww.com/CCX/B193), including reasons for not applicable items. The *last bar* on the right represents the median (first–third quartiles) number of CERT items reported per study. The *middle line* represents the median reporting score (46.7%), while the *bottom* represents the first quartile (25.0%) and the *top* represents the third quartile (73.3%). CERT items: 1) Detailed description of the type of exercise equipment; 2) Detailed description of the qualifications, teaching/supervising expertise, and/or training undertaken by the exercise instructor; 3) Describe whether exercises are performed individually or in a group; 4) Describe whether exercises are supervised or unsupervised and how they are delivered; 5) Detailed description of how adherence to exercise is measured and reported; 6) Detailed description of motivation strategies; 7a) Detailed description of the decision rule(s) for determining exercise progression; 7b) Detailed description of how the exercise program was progressed; 8) Detailed description of each exercise to enable replication; 9) Detailed description of any home program component; 10) Describe whether there are any nonexercise components; 11) Describe the type and number of adverse events that occurred during exercise; 12) Describe the setting in which the exercises are performed; 13a) Frequency; 13b) Intensity; 13c) Timing; 13d) Duration; 14a) Describe whether the exercises are generic (one size fits all) or tailored, whether tailored to the individual; 14b) Detailed description of how exercises are tailored to the individual; 15) Describe the decision rule for determining the starting level at which people commence an exercise program; 16a) Describe how adherence or fidelity to the exercise intervention is assessed/measured; and 16b) Describe the extent to which the intervention was delivered as planned.

with 2016–2020 ($n = 4/13$ [30.8%] vs $n = 3/41$ [7.3%]; $p < 0.05$) (Supplementary Table S11, http://links.lww.com/CCX/B193 and **Supplementary Fig. S4**, http://links.lww.com/CCX/B193). Of the 57 reporting planned daily frequency, 28 (49.2%) did not specify frequency per week. For the remaining 29 that reported weekly frequency, the most common was five times per week (n = 20, 44.4%) (Supplementary Table S11, http://links.lww.com/CCX/B193). Forty-seven CGs (37.0%) reported the planned duration of PR in minutes per day, which was median of 25 minutes (15–30 min). There was no statistically significant change in planned duration of PR over time (**Supplementary Fig. S5** and **Supplementary Table S12**, http://links.lww.com/CCX/B193).

DISCUSSION

Improving outcomes for ICU survivors is a top priority for critical care researchers, clinicians, patients, and families (41, 42). ICU-initiated PR may improve physical function for survivors, and the volume of investigational research has increased rapidly over the past 2 decades (43). However, clinical trials have had discordant results. Previous work focused on understanding PR interventions, however, none have studied CGs in depth. The difference in results between intervention and CGs forms the basis for establishing safety, feasibility, and efficacy of new interventions, informing future research and practice (44, 45). Given our gap in understanding CGs, we conducted a scoping review of

125 studies representing 127 CGs. Usual care was the most common type of CG. The planned content varied considerably, alongside important reporting gaps. One out of every five CGs lacked detail to understand what was planned by investigators.

Heterogeneity in CG Content

Inconsistent labeling of CGs, with sparse content description, may lead to inaccurate interpretation of meta-analyses and subsequent conclusions regarding intervention efficacy. For example, if the same intervention was compared against one usual care PR CG and one CG without PR, there are likely to be different effect estimates (46, 47). We documented 60 unique PR activities, and the majority of CG programs (68.9%) were not repeated in other CGs, suggesting an important source of heterogeneity across studies. Across CGs, we also identified variation in the frequency, intensity, and duration of activities. Variation in CG Content and characteristics limits researchers' ability to appropriately pool results across studies. Differences in the contrast between groups within a study, or in the CG across studies could contribute to an underestimation of treatment effect, leading to inaccurate conclusions regarding an intervention's safety, efficacy, or both (46, 48).

Usual Care

Usual care alone was the most common type of CG, and we identified heterogeneity in terminology and content. These findings are consistent with a systematic review of usual care CGs in stroke rehabilitation (24). Heterogeneity in usual care CGs may be contributing to discordant results in systematic reviews where efficacy is established by comparing an intervention against "usual care." It is evident that "usual care" was not consistent among the 81 PR studies in this review, further emphasizing a need to clearly describe the CG design (49).

CERT Underreporting

One fifth of CGs were not reported with enough detail to understand what was planned, further supporting the "black box" paradigm of rehabilitation interventions, where treatments are not specified with enough detail to allow understanding or replication (50, 51). Of the studies that included CG PR details, CERT assessments identified poorly reported characteristics, particularly measurement of adherence (item 5), motivation (item 6), and treatment fidelity (item 16A). Our analysis of PR dose over time was limited by underreporting; 58% of studies reported daily CG PR frequency, 37% reported duration, and 35% weekly frequency. These findings are consistent with previous reviews of adult and PICU-based PR interventions (11, 52) and with a review of PR for individuals with heart disease (53).

Inconsistent reporting of CG characteristics contributes to avoidable research waste (54). Given the complex nature of PR (55), there is a need for detailed reporting to allow for proper understanding and interpretation of intervention and CGs. Reporting guidelines specific to intervention replication, such as CERT (18) and TIDieR (21), provide a structure for reporting aspects of a treatment on a macro level (e.g., provider or type). However, for complex interventions such as PR, one treatment may have several components with unique targets and rationales. CERT and TIDieR do not adequately capture individual treatment components.

Usual care CGs were also underreported, preventing clinicians from assessing whether what was planned is consistent with their practice (56). Given that usual care is rapidly changing, in some instances the CG PR provided may be outdated or harmful (48). In our review, usual care PR included activities such as cycling (57, 58), which is currently under investigation in clinical trials. Health researchers have an ethical responsibility to compare new interventions to the current best practice. If best practice is not known, researchers are responsible for providing treatment to patients in CGs that will: 1) do no harm, 2) maximize possible benefits, and 3) minimize potential harm (59, 60). In ICU PR, the current best practice is not known, further emphasizing the need to clearly report the planned content of CGs (61). A recent review of 15 active mobilization studies versus usual care in mechanically ventilated patients reported concerns for adverse events in patients receiving active mobilization (62). Gaps in reporting usual care activities could contribute to underestimates of adverse events in these CGs.

Incidentally, we identified that half of studies did not document duration of MV and 40% did not document ICU length of stay. These data are important to

understand patient populations, and contextualize PR dose. While guidelines do not exist for reporting ICU patient characteristics, researchers may consider using resources such as the Critical Care Minimum Data Set from the United Kingdom to improve and standardize reporting (63).

Next Steps

To improve reporting, future studies could employ the Rehabilitation Treatment Specification System (RTSS), a system developed by rehabilitation professionals to improve research and clinical treatment reporting (64). The RTSS describes rehabilitation treatments according to their targets (the aspect of an individual's functioning intended to change), ingredients (what the clinician does or provides), and mechanisms of action (how a clinician hypothesizes the ingredients achieve the target) (65). The RTSS has been applied in other health conditions (e.g., aphasia, dementia) (66, 67) and has been a useful tool for identifying commonalities across treatments. Specification of ICU PR according to the RTSS may allow researchers to clearly articulate PR activities and intended outcomes, aiding clinicians, trialists, and researchers in their understanding and interpretation of ICU PR study results.

Strengths and Limitations

Our study has limitations. We did not assess reviewer agreement in screening. We assessed completeness of reporting using CERT, which was published in 2016. Thus, studies published before the CERT guidelines would not have had access to this tool to guide reporting. We also assigned a reporting score, with each item weighted equally. Some CERT items may be of higher relevance for ICU PR. To aid interpretation, we also presented reporting scores for each CERT item overall and by study. We only included studies published in English for feasibility, potentially introducing a language bias in our results. To maintain feasibility, we did not contact authors for additional CG information that was not readily available in publications or supplemental material. We analyzed the planned CG PR treatment, and aside from CERT, did not evaluate fidelity or analyze what PR was delivered to patients. Last, our search was limited to studies published before July 2022, excluding recent important studies like the Treatment of Mechanically Ventilated Adults with Early Activity and Mobilization trial, which is currently the largest published trial in the field to-date (68).

Our study also has important strengths. To our knowledge, this is the largest review of studies of ICU-based PR and the first to comprehensively study CGs. We applied a rigorous scoping review methodology, and used duplicate processes (screening, data extraction, analysis, CERT assessments). We prospectively registered our protocol, and reported results according to established guidelines (15).

CONCLUSIONS

We identified heterogeneity and underreporting of CGs in ICU-based studies of PR, which may contribute to discordant results observed in the field. While this is the first study to characterize CGs in ICU-based PR, these findings are not unique from other fields of rehabilitation research, suggesting a common barrier (23, 24). Given that we did not assess fidelity, there is a need for future work to assess the PR received by patients in CGs relative to what was planned. Overall, there is a need for researchers to standardize reporting essential CG details and justify the selection of CG type and content. Use of the RTSS may aid in standardization and improved reporting of PR treatments. By improving CG reporting, future studies can advance the field of critical care rehabilitation by helping researchers to design better trials and clinicians to understand the applicability of trial results in their own settings.

ACKNOWLEDGMENTS

We are grateful to the following individuals for their important contributions to this review (in alphabetical order): Laura Childerhose, Selina Chow, Devin McCaskell, Vanessa Ng, Ebuka Osuji, Stacey Priest, and Daniela Russo.

1 *School of Rehabilitation Sciences, Faculty of Health Sciences, McMaster University, Hamilton, ON, Canada.*

2 *Department of Health Research Methods, Evidence, and Impact, Faculty of Health Sciences, McMaster University, Hamilton, ON, Canada.*

3 *Physiotherapy Department, St. Joseph's Healthcare, Hamilton, ON, Canada.*

4 *School of Physical Therapy, Faculty of Health Sciences, Western University, London, ON, Canada.*

5 *Department of Pediatric Critical Care Medicine, The Hospital for Sick Children, University of Toronto, Toronto, ON, Canada.*

Supplemental digital content is available for this article. Direct URL citations appear in the printed text and are provided in the HTML and PDF versions of this article on the journal's website (http://journals.lww.com/ccejournal).

Dr. Kho holds a Canada Research Chair in Critical Care Rehabilitation and Knowledge Translation from the Canadian Institutes of Health Research. The remaining authors have disclosed that they do not have any potential conflicts of interest.

For information regarding this article, E-mail: ogradyh@mcmaster.ca

Registration: https://doi.org/10.17605/OSF.IO/BS342.

REFERENCES

1. Esteban A, Frutos-Vivar F, Muriel A, et al: Evolution of mortality over time in patients receiving mechanical ventilation. *Am J Respir Crit Care Med* 2013; 188:220–230
2. Desai SV, Law TJ, Needham DM: Long-term complications of critical care. *Crit Care Med* 2011; 39:371–379
3. Herridge MS, Tansey CM, Matté A, et al; Canadian Critical Care Trials Group: Functional disability 5 years after acute respiratory distress syndrome. *N Engl J Med* 2011; 364:1293–1304
4. Kortebein P: Rehabilitation for hospital-associated deconditioning. *Am J Phys Med Rehabil* 2009; 88:66–77
5. Stucki G: International classification of functioning, disability, and health (ICF): A promising framework and classification for rehabilitation medicine. *Am J Phys Med Rehabil* 2005; 84:733–740
6. Cuthbertson BH, Roughton S, Jenkinson D, et al: Quality of life in the five years after intensive care: A cohort study. *Crit Care* 2010; 14:R6
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; 373:1874–1882
8. Burtin C, Clerckx B, Robbeets C, et al: Early exercise in critically ill patients enhances short-term functional recovery*. *Crit Care Med* 2009; 37:2499–2505
9. Castro-Avila AC, Serón P, Fan E, et al: Effect of early rehabilitation during intensive care unit stay on functional status: Systematic review and meta-analysis. *PLoS One* 2015; 10:e0130722
10. 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 Heidelb* 2017; 43:171–183
11. Reid JC, Unger J, McCaskell D, et al: Physical rehabilitation interventions in the intensive care unit: A scoping review of 117 studies. *J Intensive Care* 2018; 6:80
12. Arksey H, O'Malley L: Scoping studies: Towards a methodological framework. *Int J Soc Res Methodol* 2005; 8:19–32
13. Levac D, Colquhoun H, O'Brien KK: Scoping studies: Advancing the methodology. *Implement Sci* 2010; 5:69
14. O'Grady HK, Kho ME: Comparator groups in studies of physical rehabilitation in the intensive care unit: A scoping review. *OSF* 2022
15. Tricco AC, Lillie E, Zarin W, et al: PRISMA extension for scoping reviews (PRISMA-ScR): Checklist and explanation. *Ann Intern Med* 2018; 169:467–473
16. Freedland KE, King AC, Ambrosius WT, et al; National Institutes of Health Office of Behavioral and Social Sciences Research Expert Panel on Comparator Selection in Behavioral and Social Science Clinical Trials: The selection of comparators for randomized controlled trials of health-related behavioral interventions: Recommendations of an NIH expert panel. *J Clin Epidemiol* 2019; 110:74–81
17. McGowan J, Sampson M, Salzwedel DM, et al: PRESS peer review of electronic search strategies: 2015 guideline statement. *J Clin Epidemiol* 2016; 75:40–46
18. Slade SC, Dionne CE, Underwood M, et al: Consensus on Exercise Reporting Template (CERT): Explanation and elaboration statement. *Br J Sports Med* 2016; 50:1428–1437
19. Negrini S, Arienti C, Pollet J, et al; REREP study participants: Clinical replicability of rehabilitation interventions in randomized controlled trials reported in main journals is inadequate. *J Clin Epidemiol* 2019; 114:108–117
20. Burgess LC, Wainwright TW, James KA, et al: The quality of intervention reporting in trials of therapeutic exercise for hip osteoarthritis: A secondary analysis of a systematic review. *Trials* 2021; 22:388
21. Hoffmann TC, Glasziou PP, Boutron I, et al: Better reporting of interventions: Template for intervention description and replication (TIDieR) checklist and guide. *BMJ* 2014; 348:g1687
22. Kleinheksel AJ, Rockich-Winston N, Tawfik H, et al: Demystifying content analysis. *Am J Pharm Educ* 2020; 84:7113
23. Levack WM, Martin RA, Graham FP, et al: Compared to what? An analysis of the management of control groups in Cochrane reviews in neurorehabilitation. *Eur J Phys Rehabil Med* 2019; 55:353–363
24. Arienti C, Buraschi R, Pollet J, et al: A systematic review opens the black box of "usual care" in stroke rehabilitation control groups and finds a black hole. *Eur J Phys Rehabil Med* 2022; 58:520–529
25. McGregor G, Powell R, Finnegan S, et al: Exercise rehabilitation programmes for pulmonary hypertension: A systematic review of intervention components and reporting quality. *BMJ Open Sport Exerc Med* 2018; 4:e000400
26. Braga LH, McGrath M, Easterbrook B, et al: Quality of reporting for randomized controlled trials in the hypospadias literature: Where do we stand? *J Pediatr Urol* 2017; 13:482.e1–482.e9
27. Hadi MA, McHugh GA, Conaghan PG: Quality of reporting of harms in randomised controlled trials of pharmacological interventions for rheumatoid arthritis: A systematic review. *Evid Based Med* 2017; 22:170–177
28. Angelopoulos E, Karatzanos E, Dimopoulos S, et al: Acute microcirculatory effects of medium frequency versus high frequency neuromuscular electrical stimulation in critically ill patients - a pilot study. *Ann Intensive Care* 2013; 3:39
29. Thomas P, Paratz J, Lipman J: Seated and semi-recumbent positioning of the ventilated intensive care patient – effect

on gas exchange, respiratory mechanics and hemodynamics. *Heart Lung* 2014; 43:105–111

30. Collings N, Cusack R: A repeated measures, randomised cross-over trial, comparing the acute exercise response between passive and active sitting in critically ill patients. *BMC Anesthesiol* 2015; 15:1
31. Coutinho WM, Santos LJ, Fernandes J, et al: Acute effect of the use of cycle ergometer during physical therapy treatment in mechanically ventilated critically ill patients. *Fisioter E Pesqui* 2016; 23:278–283
32. Hickmann CE, Montecinos-Munoz NR, Castanares-Zapatero D, et al: Acute effects of sitting out of bed and exercise on lung aeration and oxygenation in critically ill subjects. *Respir Care* 2021; 66:253–262
33. Nakamura K, Kihata A, Naraba H, et al: Efficacy of belt electrode skeletal muscle electrical stimulation on reducing the rate of muscle volume loss in critically ill patients: A randomized controlled trial. *J Rehabil Med* 2019; 51:705–711
34. Nakanishi N, Oto J, Tsutsumi R, et al: Effect of electrical muscle stimulation on upper and lower limb muscles in critically ill patients: A two-center randomized controlled trial. *Crit Care Med* 2020; 48:e997–e1003
35. Sarfati C, Moore A, Pilorge C, et al: Efficacy of early passive tilting in minimizing ICU-acquired weakness: A randomized controlled trial. *J Crit Care* 2018; 46:37–43
36. Hodgson CL, Bailey M, Bellomo R, et al; Trial of Early Activity and Mobilization Study Investigators: A binational multicenter pilot feasibility randomized controlled trial of early goal-directed mobilization in the ICU*. *Crit Care Med* 2016; 44:1145–1152
37. Yang PH, Wang CS, Wang YC, et al: Outcome of physical therapy intervention on ventilator weaning and functional status. *Kaohsiung J Med Sci* 2010; 26:366–372
38. Gruther W, Kainberger F, Fialka-Moser V, et al: Effects of neuromuscular electrical stimulation on muscle layer thickness of knee extensor muscles in intensive care unit patients: A pilot study. *J Rehabil Med* 2010; 42:593–597
39. Kho ME, Truong AD, Zanni JM, et al: Neuromuscular electrical stimulation in mechanically ventilated patients: A randomized, sham-controlled pilot trial with blinded outcome assessment. *J Crit Care* 2015; 30:32–39
40. Frazzitta G, Zivi I, Valsecchi R, et al: Effectiveness of a very early stepping verticalization protocol in severe acquired brain injured patients: A randomized pilot study in ICU. *PLoS One* 2016; 11:e0158030
41. Iwashyna TJ: Survivorship will be the defining challenge of critical care in the 21st century. *Ann Intern Med* 2010; 153:204–205
42. James Lind Alliance: Intensive Care Top 10. 2014. Available at: https://www.jla.nihr.ac.uk/priority-setting-partnerships/intensive-care/top-10-priorities/. Accessed December 5, 2022
43. Zhang F, Xia Q, Zhang L, et al: A bibliometric and visualized analysis of early mobilization in intensive care unit from 2000 to 2021. *Front Neurol* 2022; 13:848545
44. Byrd-Bredbenner C, Wu F, Spaccarotella K, et al: Systematic review of control groups in nutrition education intervention research. *Int J Behav Nutr Phys Act* 2017; 14:91
45. Mohr DC, Spring B, Freedland KE, et al: The selection and design of control conditions for randomized controlled trials of psychological interventions. *Psychother Psychosom* 2009; 78:275–284
46. Parker A, Tehranchi KM, Needham DM: Critical care rehabilitation trials: The importance of "usual care.". *Crit Care* 2013; 17:183
47. Karlsson P, Bergmark A: Compared with what? An analysis of control-group types in Cochrane and Campbell reviews of psychosocial treatment efficacy with substance use disorders. *Addiction* 2015; 110:420–428
48. PhysiotherapyEvidenceDatabase.PEDro: #PEDroTacklesBarriers to Evidence-Based Physiotherapy: Lack of Statistical Skills. 2022. Available at: https://www.youtube.com/watch?v=1T2f9gdDZSg. Accessed October 12, 2022
49. Yu AM, Balasubramanaiam B, Offringa M, et al: Reporting of interventions and "standard of care" control arms in pediatric clinical trials: A quantitative analysis. *Pediatr Res* 2018; 84:393–398
50. Whyte J, Hart T: It's more than a black box; It's a Russian doll: Defining rehabilitation treatments. *Am J Phys Med Rehabil* 2003; 82:639–652
51. Dijkers MP: An end to the black box of rehabilitation? *Arch Phys Med Rehabil* 2019; 100:144–145
52. Zorko DJ, Reid JC, Unger J, et al: Measurement and reporting of physical rehabilitation interventions in pediatric critical care: A scoping review. *Disabil Rehabil* 2021; 43:3417–3424
53. Abell B, Glasziou P, Hoffmann T: Reporting and replicating trials of exercise-based cardiac rehabilitation. *Circ Cardiovasc Qual Outcomes* 2015; 8:187–194
54. Chalmers I, Glasziou P: Avoidable waste in the production and reporting of research evidence. *Lancet* 2009; 374:86–89
55. Craig P, Dieppe P, Macintyre S, et al: Developing and evaluating complex interventions: The new Medical Research Council guidance. *BMJ* 2008; 337:a1655
56. Nicholls SG, Zwarenstein M, Taljaard M: The importance of describing as well as defining usual care. *Am J Bioeth* 2020; 20:56–58
57. Kwakman RCH, Voorn EL, Horn J, et al: Steps to recovery: Body weight-supported treadmill training for critically ill patients: A randomized controlled trial. *J Crit Care* 2022; 69:154000
58. Segers J, Vanhorebeek I, Langer D, et al: Early neuromuscular electrical stimulation reduces the loss of muscle mass in critically ill patients – a within subject randomized controlled trial. *J Crit Care* 2021; 62:65–71
59. Minneci PC, Eichacker PQ, Danner RL, et al: The importance of usual care control groups for safety monitoring and validity during critical care research. *Intensive Care Med* 2008; 34:942–947
60. World Medical Association: World Medical Association Declaration of Helsinki: Ethical principles for medical research involving human subjects. *Bull World Health Organ* 2001; 79:373–374
61. Denehy L, Lanphere J, Needham DM: Ten reasons why ICU patients should be mobilized early. *Intensive Care Med* 2017; 43:86–90

62. Paton M, Chan S, Tipping CJ, et al: The effect of mobilization at 6 months after critical illness — meta-analysis. *NEJM Evid* 2023; 2
63. Critical Care Information Advisory Group (CCIAG). Critical Care Minimum Data Set. Available at: https://www.datadictionary.nhs.uk/data_sets/supporting_data_sets/critical_care_minimum_data_set.html. Accessed October 12, 2022
64. Hart T, Dijkers MP, Whyte J, et al: A theory-driven system for the specification of rehabilitation treatments. *Arch Phys Med Rehabil* 2019; 100:172–180
65. Hart T, Whyte J, Dijkers M, et al: Manual of Rehabilitation Treatment Specification. 2018. Available at: http://mrri.org/innovations/manual-for-rehabilitation-treatment-specification/. Accessed May 15, 2018
66. Boyle M, Gordon JK, Harnish SM, et al: Evaluating cognitive-linguistic approaches to interventions for aphasia within the rehabilitation treatment specification system. *Arch Phys Med Rehabil* 2022; 103:590–598
67. Sikkes SAM, Tang Y, Jutten RJ, et al: Toward a theory-based specification of non-pharmacological treatments in aging and dementia: Focused reviews and methodological recommendations. *Alzheimers Dement J Alzheimers Assoc* 2021; 17:255–270
68. Hodgson CL, Bailey M, Bellomo R, et al; TEAM Study Investigators and the ANZICS Clinical Trials Group: Early active mobilization during mechanical ventilation in the ICU. *N Engl J Med* 2022; 387:1747–1758