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Evaluation of the description of active mobilisation protocols for mechanically ventilated patients in the intensive care unit: A systematic review of randomized controlled trials

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ABSTRACT

Background: The complete description of exercise interventions is essential to allow for the replication of clinical trials and to the correct application in clinical practice.

Objectives: The aim of this review was to evaluate of the description of the active mobilisation protocols in patients on invasive mechanical ventilation at intensive care units (ICU).

Methods: Systematic review of randomised controlled trials (RCTs) using the Consensus on Exercise Reporting Template.

Results: We identified 16 RCTs (n = 1,850). None sufficiently described the intervention for all items required for replication. The frequency, intensity, time, volume, and progression of active mobilisation as well as other important components of the intervention such as the instructor's qualifications/expertise, the types and incidence of adverse events, and the adherence to the exercise intervention were not adequately reported.

Conclusion: Active mobilisation interventions were only incompletely described in RCTs, which can compromise replication in both, clinical and research settings.

Registration: PROSPERO (CRD42017068762).

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Introduction

Immobilisation and bed rest of patients in intensive care units (ICU) increases their risk for muscle dysfunction and prolonged mechanical ventilation, leading to physical deconditioning and loss of functionality,¹⁻³ which can persist for five years or longer.^{4,5} Active mobilisation is a feasible, safe, and low-cost intervention to improve muscle dysfunction and disability in patients at the ICU.⁶⁻⁸ Active mobilisation is a therapeutic strategy that typically involves exercises in which the patient uses his or her own strength and muscular

control.^{7,8} It has been shown to improve patients' mobility status and muscle strength, increase their days alive and out of the hospital to 180 days,⁸ reduce the mechanical ventilation time, and increase functional capacity as well as the quality of life after hospital discharge.⁶⁻¹⁰

Despite scientific advances, the current description and prescriptions of exercises at the ICU remain incomplete with respect to the control and the description of the variables of training load (volume and intensity), programming, and progression.^{7,8,11} A complete published description of exercise interventions is essential for healthcare professionals and researchers to assess the generalisability of findings, synthesise the literature, design future trials, determine the safe and feasibility of therapeutics interventions, and develop treatment guidelines.^{12,13} The TIDieR checklist and CONSORT guidelines for non-pharmacological interventions provide recommendations for an adequate description of exercise programs in items 4c and 8c¹³ and extensions 4, 4b, and 4c, respectively¹²; however, these are not specific instruments for this purpose. Recently, a more specific guidelines, the Consensus on Exercise

Abbreviations: CERT, Consensus on exercise reporting template; CONSORT, Consolidated Standards of Reporting Trials; ICU, Intensive care units; PEDro, Physiotherapy evidence database; PRISMA, Preferred reporting items for systematic reviews and meta-analyses; RCTs, Randomised controlled clinical trials; TIDieR, Template for intervention description and replication.

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Reporting Template (CERT), has been published to improve the description of the key components of exercise.¹⁴

Exercise interventions comprise several components, all of which interplay to determine the overall training response. Previous work has highlighted deficiencies in the reporting of a range of exercise interventions in published trials.^{15,16} Tipping et al.⁸ performed a systematic review to investigate the effects of active mobilisation and rehabilitation in the ICU. They reported that very limited information regarding the dosage was provided in many studies and suggested that more studies are needed to specifically assess the appropriate dosages and timing of therapy to inform clinicians and assist them in prescribing appropriate therapy in clinical practice.⁸

A complete description of active mobilisation exercises at the ICU can optimise the safety, efficacy, and replication of protocols in both, research and clinical settings. To the best of our knowledge, clinical trials have not yet been evaluated in this perspective to date. Moreover, no systematic review has examined the integrity description of studies on active mobilisation in patients at the ICU. The aim of this review was to evaluate of the description of the active mobilisation protocols in patients on invasive mechanical ventilation at intensive care units (ICU).

Method

Identification and selection of studies

We conducted a systematic review of randomised controlled clinical trials (RCTs) that was registered in PROSPERO (CRD42017068762) and followed the PRISMA-P (The Preferred Reporting Items for Systematic Reviews and Meta-analyses) guidelines.¹⁷

Search terms were selected based on systematic reviews on intensive care mobilisation^{1,6-9} and searches of the Medical Subject Headings (MeSH) of the National Library of Medicine. All searches were performed between June and August, 2017. Initially, an advanced search was performed in PubMed/Medline ([Appendix 1](#)). The descriptors were matched to generate the largest number of results in the Physiotherapy Evidence Database (PEDro), Cochrane Library, and Scientific Electronic Library Online (SciELO). The following international portals of RCT registries were also consulted: Cochrane Central Register of Controlled Trials, [Clinical-trials.gov](#), WHO International Clinical Trials Registry Platform (ICTRP), IFPMA Clinical Trials Portal, and Current Controlled Trials. Reference lists of relevant systematic reviews were manually consulted to identify studies eligible for inclusion in this review.

Two independent researchers evaluated the titles, abstracts, and full-texts of identified studies. In cases of disagreement, a third researcher was consulted.

Eligibility criteria

Only randomized controlled clinical trials that performed active mobilization in adult patients (age >18 years) mechanically ventilated during an ICU stay were eligible. Active mobilization is understood to mean any exercise that relies on conscious muscle activation (e.g – active limb exercises, transfer training, ambulation, cycle ergometer, etc...), except isolated breathing exercises.

Assessment of characteristics of studies

Quality

To evaluate the methodological quality of the studies, the 11 items of the PEDro scale were used.¹⁸ The final score (0 to 10) was obtained by summing the evaluation items, except item 1, according to the scale's guidelines.¹⁸

Data analysis

Two researchers independently extracted the data of interest using a standardised form. In addition to the original articles, supplements, previous duly referenced studies, published protocols, and the websites of equipment manufacturers were consulted.

To evaluate the completeness of the description of the exercise protocols, we used the CERT,¹⁴ which consists of 16 items (items 7, 14 e, and 16 have one sub-item each, resulting in 19 items). Item 9 was excluded because it did not apply to the ICU (as it is related to the prescription of home exercises); therefore, 18 items were evaluated in this study. Each CERT item was rated 0 (not described or description unclear) or 1 (yes, well-described). In studies in which no equipment but only free active exercises were used, the item was classified as 1.

Quantitative variables are expressed as means (SD) or maximum and minimum values, while categorical variables are shown as frequencies and proportions.

Results

Flow of studies through the review

We identified 2,961 potentially eligible studies in PubMed/Medline with the search strategy presented in [Appendix 1](#). After consultation of other databases, removal of duplicates, and application of the inclusion criteria, 17 studies were eligible. One study¹⁹ was excluded because it was a secondary analysis of another clinical trial²⁰; thus, 16 clinical trials were considered for this review ([Figure 1](#)).^{10,20-34}

Characteristics of studies

The included studies were published from 1998 to 2017 and involved 1,850 adults (including elderly patients) of both sexes (intervention, n = 836; control, n = 814) who were admitted to a medical ICU,^{20,33} surgical ICU,¹⁰ or mixed medical-surgical ICU^{25,26,31,34} with conditions including: acute respiratory failure,^{30,33} sepsis syndromes,²⁸ ICU Acquired Weakness,²⁷ severe neurological injuries,²⁹ chronic obstructive pulmonary disease,²¹ prolonged mechanical ventilation,²³ prolonged mechanical ventilation after coronary artery bypass surgery,³² and expected prolonged stay at the ICU.²²

Details of the active mobilisation programs

[Table 1](#) presents the details of the types of exercises and training loads. Seven studies reported a daily frequency of active mobilisation of once daily,^{10,20,22,24,30,33} two studies of once to twice daily,^{21,23,28} and one study of once daily for patients on mechanical ventilation and twice daily for patients weaned from ventilation or who could remain without ventilation for >4 hours.²⁶ Of the studies reporting a frequency of twice daily,^{25,27,32} Wright et al.³⁴ and Hodgson et al.³¹ did not directly report the daily frequency of the exercise but rather stated that the total duration could be completed within a single treatment session or divided into several sessions throughout the day, according to the criteria of the responsible physiotherapist and the tolerance criteria ([Table 1](#)). In ten studies, active mobilisation was performed seven days/week.^{10,20,21,25-28,30,31,33} Schweickert et al.,²⁰ Schaller et al.,¹⁰ and Morris et al.³³ did not report the duration of the exercise programs. Dong et al.³² did not report the walking time, and Yosef et al.²⁷ only described the duration of active limb exercises but did not report the duration of transfer training. Only four studies reported the number of sets/replicates.^{23,25,30,33} To measure exercise intensity, Morris et al.³³ and Moss et al.³⁰ used the colour of an elastic band, while Denehy et al.²⁶ and Dantas et al.²⁵ used target-modified Borg scale scores of 3–5 and 12–13, respectively. Chen et al.²⁴ used

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