



Earlier and enhanced rehabilitation of mechanically ventilated patients in critical care: A feasibility randomised controlled trial

David McWilliams^{a,*}, Charlotte Jones^a, Gemma Atkins^a, James Hodson^b, Tony Whitehouse^c, Tonny Veenith^c, Emma Reeves^d, Lauren Cooper^d, Catherine Snelson^c

^a Therapy Services, University Hospitals Birmingham NHS Foundation Trust, Queen Elizabeth Hospital Birmingham, Mindelsohn Way, Edgbaston, Birmingham B15 2WB, United Kingdom

^b Department of Statistics, University Hospitals Birmingham NHS Foundation Trust, Queen Elizabeth Hospital Birmingham, Mindelsohn Way, Edgbaston, Birmingham B15 2WB, United Kingdom

^c Department of Critical Care, University Hospitals Birmingham NHS Foundation Trust, Queen Elizabeth Hospital Birmingham, Mindelsohn Way, Edgbaston, Birmingham B15 2WB, United Kingdom

^d National Institute for Health Research Surgical Reconstruction and Microbiology Research Centre, University Hospitals Birmingham NHS Foundation Trust, Queen Elizabeth Hospital Birmingham, Mindelsohn Way, Edgbaston, Birmingham B15 2WB, United Kingdom

ARTICLE INFO

Available online xxxx

Keywords:

Rehabilitation

Critical care

Physiotherapy

Exercise

ICU

ABSTRACT

Background: Systematic reviews of early rehabilitation within intensive care units have highlighted the need for robust multi-centre randomised controlled trials with longer term follow up. This trial aims to explore the feasibility of earlier and enhanced rehabilitation for patients mechanically ventilated for ≥ 5 days and to assess the impact on possible long term outcome measures for use in a definitive trial.

Methods: Patients admitted to a large UK based intensive care unit and invasively ventilated for ≥ 5 days were randomised to the rehabilitation intervention or standard care on a 1:1 basis, stratified by age and SOFA score. The rehabilitation intervention involved a structured programme, with progression along a functionally based mobility protocol according to set safety criteria.

Results: 103 out of 128 eligible patients were recruited into the trial, achieving an initial recruitment rate of 80%. Patients in the intervention arm mobilized significantly earlier (8 days vs 10 days, $p = 0.035$), at a more acute phase of illness (SOFA 6 vs 4, $p < 0.05$) and reached a higher level of mobility at the point of critical care discharge (MMS 7 vs 5, $p < 0.01$).

Conclusion: We have demonstrated the feasibility of introducing a structured programme of rehabilitation for patients admitted to critical care.

© 2018 The Authors. Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

1. Introduction

Approximately 270,000 patients are admitted annually to general critical care units in England, with around a third of this requiring mechanical ventilation [1]. A strong correlation between muscular weakness and prolonged mechanical ventilation has been observed, with survivors experiencing significant physical, cognitive and mental health impairments. The muscle weakness experienced by ICU patients is multifactorial, with sarcopenia from pre-morbid conditions, disuse atrophy from bed rest [2] and ICU acquired weakness (ICUAW) all contributing factors [3]. Muscle wasting occurs early and rapidly during the first week of critical illness, correlates with the degree of organ failure [4], and is associated with failure to wean from the ventilator and increased in-hospital mortality [5,6]. Preventing the physical consequences of critical illness and supporting recovery from intensive care has therefore been identified as a high priority area for critical care research [7].

Early and progressive mobilisation has been demonstrated to be both safe and feasible for patients admitted to critical care [8]. When implemented, programmes of early mobility have demonstrated improvements in physical function and mobility levels, alongside significant reductions in both ICU and hospital length of stay, ventilation days and a reduction in both the incidence and duration of delirium [9–12]. Despite this, point prevalence surveys have shown rehabilitation levels within critical care to remain low, particularly for patients still requiring mechanical ventilation and with ongoing organ dysfunction [13,14]. Recently published randomised controlled trials of early rehabilitation within the ICU have failed to show long term significant benefits, but they have been limited by recruiting patients with short lengths of stay in the ICU and therefore lower levels of ICUAW, or mismatches in the baseline characteristics [15–18].

An important consideration when interpreting the results of such trials remains the use of the term “early”, which in itself has yet to be defined and onset of interventions varying by as much as 1 week [19]. The patients most at risk of prolonged sequelae are often still too acutely unwell for active mobilisation to be commenced safely in the first few days of critical illness. For these patients the important factor may instead be

* Corresponding author.

E-mail address: David.McWilliams@uhb.nhs.uk (D. McWilliams).

the implementation of “earlier” interventions, whereby mobilisation can be initiated at a more acute stage of the patient’s illness than would otherwise occur rather than simply focussing on a one size fits all approach. After 10 days in the ICU, the admission diagnosis and physiological derangement become less important than simple antecedent patient characteristics such as age, sex and chronic health status in determining outcome and although only representing 5% of all ICU admissions, these patients with “persistent critical illness” consume significant resource and require dedicated future research [20]. Older ICU survivors in particular suffer prolonged and persistent decline in cognitive and physical function with those with a length of stay >2 weeks at highest risk for 1-year mortality and disability [21].

Our group has previously published the results of a quality improvement project, where a new supportive rehabilitation team was created with a focus on promoting early and enhanced rehabilitation for patients at high risk of prolonged ICU and hospital stays [11]. The introduction of the team led to a significant improvement in mobility at ICU discharge, and this was associated with a significant reduction in ICU length of stay (LOS), ventilator days and in-hospital mortality. However, only a minority of the eligible ICU patients was treated by the team and unmeasured confounding factors may have impacted on results seen. In a before and after design, it was difficult to define on an individual patient level the constituent parts of standard and enhanced care. The rehabilitation intervention therefore required further evaluation prior to a multicentre trial.

The aim of this trial was to explore the feasibility of delivery of earlier and enhanced rehabilitation for patients mechanically ventilated for ≥ 5 days and to assess the impact on possible long term outcome measures for use in a future definitive trial. Specifically, the objectives were to:

- Estimate rates of recruitment and consent from eligible patients and to describe the baseline characteristics of the participants in terms of co-morbidities, physical function and illness severity.
- Test the rehabilitation intervention in terms of compliance, differentiation from standard care and ability to increase mobility levels at ICU discharge.
- Estimate retention of participants and response rates to follow-up questionnaires.
- Evaluate a range of clinical and patient-reported outcome measures to aid selection of the most appropriate primary outcome measure for a definitive trial, with estimates of variance for sample size calculation.

2. Material and methods

The protocol for this trial has been previously published in full [22]. Ethical approval was obtained from the Research Ethics Committee East Midlands – Nottingham 1 (reference 15/EM/0114) on the 8th April 2015 and trial was registered with ISRCTN registry (ISRCTN90103222). Written informed consent was obtained from all participants, a personal consultee or a Registered Medical Practitioner. The conduct and reporting of the trial conforms to CONSORT extension guidelines [23]. This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

3. Design

We conducted a single centre, 1:1 randomised controlled feasibility trial of earlier and enhanced rehabilitation for patients admitted to critical care. There was no *a priori* calculation of sample size, with a target recruitment of 100 patients specified to allow adequate assessment of outcome measures.

4. Participants

Patients admitted to the critical care unit of a large tertiary referral university teaching hospital were recruited between June 2016 and September 2017. Inclusion criteria were adults (≥ 16 years of age) who had been invasively ventilated for at least 4 days and expected to continue for at least 24 h. Patients were not eligible for the trial if they had a profound neurological deficit (defined as unlikely to return to a Glasgow Coma Score of at least 14), an orthopaedic injury with contraindications to mobilise (e.g. pelvic fracture), were unable to mobilise at least 10 m prior to admission (with or without an aid), had pre-existing neuromuscular disease, had been invasively ventilated at another facility for >48 h prior to admission or in hospital for >7 days prior to the onset of mechanical ventilation. Patients were also excluded if withdrawal of treatment was expected within 24 h of potential recruitment.

5. Randomisation and blinding

Participants were randomised on a 1:1 basis to enhanced rehabilitation or standard care using a computer based stratified blocked randomisation, stratified for age (<50 years vs ≥ 50 years) and SOFA score on the day of recruitment (<9 versus ≥ 9). Recruitment and completion of assessments was undertaken by the research nursing team who were independent from the therapy team delivering rehabilitation. Given the nature of the intervention, it was not possible to blind physiotherapists or participants to group allocation.

6. Study interventions

6.1. Standard care

All patients within our institution are assessed by the physiotherapy team within 24 h of admission to critical care to obtain background information on reason for admission, as well as any pre-existing conditions that may be relevant. They then continue to be seen on a daily basis on weekdays, with rehabilitation commencing based on the individual physiotherapists own clinical reasoning. Physiotherapy provision is funded at a ratio of 1 physiotherapist to 10 patients, with an average treatment time of 30–45 min per patient per day Monday to Friday with one physiotherapist. When discharged to the ward environment, a telephone handover is provided to the receiving therapist who then continues the rehabilitation until the patient is deemed safe for discharge, with no further input provided by the critical care team.

6.2. Enhanced rehabilitation (intervention group)

Physiotherapy sessions for subjects assigned to the intervention group were delivered by members of a specialist critical care rehabilitation team who were separate to the normal physiotherapy team, aiming to minimise contamination between groups. Following recruitment and randomisation subjects in the intervention group were assigned a physiotherapy key worker who completed a standardized comprehensive assessment. This was used to gain additional background information regarding pre-existing physical function, any psychological history and pre admission exercise capacity. Following this assessment an individually tailored rehabilitation programme was devised, with the rehabilitation plan displayed in the subjects’ bed space to aid communication and track daily achievements. Weekly goal setting meetings were held to review progress and update treatment plans as required. To facilitate ongoing rehabilitation following critical care discharge both verbal and written handovers were provided to ward therapy staff. For patients achieving a Manchester Mobility Score (MMS) of ≤ 4 at critical care discharge (unable to stand independently), ongoing rehabilitation was provided by the key worker in conjunction with the ward therapists for the first week following discharge from critical care. This aimed to ensure a seamless handover of care and maximise ongoing

Download English Version:

<https://daneshyari.com/en/article/8620484>

Download Persian Version:

<https://daneshyari.com/article/8620484>

[Daneshyari.com](https://daneshyari.com)