

# A feasibility study of early and enhanced rehabilitation in ICU

<b>Submission date</b> 13/08/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 13/08/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 19/11/2020	<b>Condition category</b> Signs and Symptoms	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Many patients after an illness in the Intensive Care Unit (ICU) are left feeling very weak and struggle to get their strength back. Patients lose muscle mass whilst they are on a breathing machine, which causes muscle weakness. Survivors of critical illness can still be weak many months or even years after hospital discharge which significantly affects quality of life. It is recognized by the National Institute of Health and Care Excellence (NICE) that we need to provide physiotherapy and rehabilitation for patients within the ICU and in the recovery period, but how and when to deliver this is still uncertain. At present, most patients in the UK receive only limited physiotherapy whilst on the ICU. In the United States, it has been demonstrated that providing earlier and more structured physiotherapy on the ICU is safe and can improve a patient's wellbeing and reduce length of stays within the ICU and hospital. However, it is uncertain whether these findings are relevant to the NHS. This study compares two different strategies (types) of rehabilitation and investigates the impact of these strategies on the patient's immune and endocrine (hormone) function. The results will help in the development of another, larger, study.

### Who can participate?

Patients of at least 16 years of age who are critically ill and that have been mechanically ventilated for at least 5 days.

### What does the study involve?

Participants are randomly allocated into one of two groups. Those in group 1 (standard rehabilitation group) are given the physiotherapy routinely provided to all patients in critical care at Queen Elizabeth Hospital Birmingham. Those in group 2 (early rehabilitation group) are given structured physiotherapy earlier within the course of a patient's illness and continuing this programme for as long as the patient is in ICU and carrying on upon their discharge onto the ward. The two approaches are assessed to find out whether one is better than the other by using measures of patient wellbeing, mobility and recovery, and looking at length of stays on the ICU and in hospital. Weekly blood and urine samples are also taken for tests to assess immune and endocrine function.

What are the possible benefits and risks of participating?

Not provided at time of registration

Where is the study run from?

June 2016 to May 2017

When is the study starting and how long is it expected to run for?

University Hospital Birmingham NHS Foundation Trust (UK)

Who is funding the study?

Medical Research Council (UK)

Who is the main contact?

Ms Lauren Cooper

## Contact information

### Type(s)

Public

### Contact name

Ms Lauren Cooper

### Contact details

University Hospital Birmingham NHS Foundation Trust

NIHR SRMRC, Research and Development

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Edgbaston

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

19092

## Study information

### Scientific Title

A feasibility study of early and enhanced rehabilitation in critical care and potential impact on immunoendocrine function

Study objectives

Critical illness causes significant muscle wasting and weakness, and survivors of critical illness suffer from significant physical morbidity for months and sometimes years after hospital discharge. Starting rehabilitation with physiotherapy on the intensive care unit (ICU) has been shown to be effective in the US, but it is unknown whether this is generalisable to the NHS. This is a single site feasibility randomised controlled trial comparing two different strategies of rehabilitation and investigating the impact on immune and endocrine function. The results will inform the design of a larger multicentre study.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

NRES Committee East Midlands - Nottingham 1, 08/04/2015, ref: 15/EM/0114

Ethics approval for extension of study was approved on 20/05/2016. ref: RRK5305, amendment ref: SA 1.31 3/4 18.03.16

### **Study design**

Randomised; Interventional; Design type: Not specified

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Hospital

### **Study type(s)**

Treatment

### **Participant information sheet**

Not available in web format, please use contact details to request a participant information sheet

### **Health condition(s) or problem(s) studied**

Topic: Critical care; Subtopic: Critical care; Disease: All Critical care

### **Interventions**

Patients are randomized to standard care or enhanced rehabilitation.

1. Standard care (control group):

Regardless of the day of admission, all patients are assessed by the physiotherapy team within 24 hours 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 minutes per patient per day Monday to Friday with one physiotherapist. Rehabilitation provision is individually prioritised with no set structure or format for rehabilitation in place, and only limited rehabilitation currently takes place whilst the patient is mechanically ventilated. 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.

## **2. Early and structured rehabilitation (intervention group):**

The process of structured critical care rehabilitation which will be adopted for the management of the treatment group, is shown in Figure 1 and Figure 2 below. To summarise, during the acute phase of a patient's illness whilst they are still sedated and/or paralysed rehabilitation is confined to the bed with daily passive movements and positioning. As soon as patients are stable and awake enough to commence more active mobilisation they are assessed by sitting on the edge of the bed, allowing an assessment to be made of sitting balance, exercise capacity and physiological stability. This is performed with endotracheal tubes or tracheostomies still in situ, and whilst the patient is still on ventilatory and/or renal support and low levels of vasopressor or inotropic support. Following this assessment and as strength increases, a rehabilitation plan is formulated which includes the patient sitting out of bed in a chair using the most appropriate method for transfers. More active rehabilitation is administered as the patient improves to progress to standing, transfers and walking. A key worker will conduct a comprehensive assessment of the patient, which will be completed within 24 hours of randomisation. This will provide background information regarding physical function, any psychological history and pre admission exercise capacity to allow an individually tailored rehabilitation programme to be devised. To facilitate ongoing rehabilitation following critical care discharge both verbal and written handovers will be provided to ward therapy staff. Ongoing rehabilitation will continue to be provided by the critical care team in conjunction with the ward therapists for the first week following discharge from critical care to ensure a seamless handover of care and maximise ongoing rehabilitation.

## **3. Both groups:**

All other medical care will be at the discretion of the responsible intensivist. Rehabilitation interventions by all members of the clinical team at each stage of the patient pathway will be carefully recorded, with analysis of the reasons for missed rehabilitation sessions performed. In accordance with current unit practice, all patients with a length of stay over 14 days will be discussed at weekly multidisciplinary team meetings which include consultant medical staff, senior nursing staff, speech and language therapists and occupational therapists, with collaborative treatment goals set, reviewed and updated.

## **Intervention Type**

Other

## **Primary outcome measure**

Critical care and hospital length of stay

## **Secondary outcome measures**

### **1. Efficacy:**

1.1. Manchester Mobility Score at baseline and critical care discharge – This will highlight any differences seen in baseline mobility at the point of recruitment and track any functional changes achieved within critical care by the intervention strategies

1.2. Ventilator days – To assess whether the intervention and any associated physical improvements lead to an earlier liberation from ventilatory support.

1.3. ICU, Hospital and 2 year mortality – It has been suggested that improving physical status and reducing ICU length of stay may serve to reduce mortality both within critical care and the hospital.

1.4. Total hospital length of stay – To assess whether enhanced rehabilitation services within critical care and continuing onto the wards can also reduce the post-ICU length of stay.

## 2. Patient focused outcomes:

2.1. Functional status: Barthel index score at baseline (estimated), critical care discharge, hospital discharge, 3 and 12 months – To assess the impact of the rehabilitation programmes on function during activities of daily living at hospital discharge and through the post-discharge period.

2.2. Health related quality of life: SF36 at baseline (estimated), critical care discharge, hospital discharge, 3 and 12 months - to assess whether enhanced rehabilitation programmes improve patient-reported measures of health status.

2.3. Anxiety and depression: HADS score – at critical care and hospital discharge – to assess whether structured programmes of rehabilitation improve the psychological impact of critical illness and recovery.

## 3. Mechanism:

3.1. Muscle thickness of quadriceps, thenar eminence, biceps and rectus abdominus – to assess whether enhanced physiotherapy attenuates the reduction in muscle thickness seen in critical illness

3.2. Serum Cortisol:DHEAS ratios – to assess ratios in prolonged critical illness and examine any changes induced by enhanced physiotherapy

3.3. Urinary corticosteroid metabolite profiles and relationship to vitamin D status in prolonged critical illness

3.4. Neutrophil function – to assess neutrophil function in prolonged critical illness and any changes induced by enhanced physiotherapy

3.5. Cytokine flux – to assess whether rehabilitation influences the balance between pro and anti-inflammatory cytokines in chronic critical illness

## Overall study start date

01/06/2015

## Completion date

31/05/2017

# Eligibility

## Key inclusion criteria

1. Age  $\geq 16$  years
2. Patients who have received mechanical ventilation for  $\geq 5$  days

## Participant type(s)

Patient

## Age group

Adult

## Sex

Both

## Target number of participants

Planned Sample Size: 60; UK Sample Size: 60; Description: This is a pilot study and the SS is difficult to determine, CI has confirmed that this is a range 60 - 210 participants

## Total final enrolment

**Key exclusion criteria**

1. Profound neurological deficit
2. Orthopaedic patients with contraindications to mobilise (e.g. pelvic / spinal fractures)
3. Poor prior level of mobility (<10yds)
4. Neuromuscular disease (e.g. Motor Neuron Disease)
5. Mechanical ventilation > 48 hours at another facility prior to admission
6. Expected withdrawal of treatment within the next 24 hours
7. Patients with already established rehabilitation pathways (e.g. amputees)
8. Previous participation in this study

**Date of first enrolment**

01/06/2015

**Date of final enrolment**

31/05/2016

**Locations****Countries of recruitment**

England

United Kingdom

**Study participating centre**

University Hospital Birmingham NHS Foundation Trust

NIHR SRMRC, Research and Development

Queen Elizabeth Hospital

Edgbaston

Birmingham

United Kingdom

B15 2TH

**Sponsor information****Organisation**

University Hospital Birmingham NHS Foundation Trust

**Sponsor details**

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Birmingham & Black Country

United Kingdom

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**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/014ja3n03>

## Funder(s)

**Funder type**

Government

**Funder Name**

Medical Research Council

**Alternative Name(s)**

Medical Research Council (United Kingdom), UK Medical Research Council, MRC

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

Abstract to national and international conferences. Submission to a relevant peer-reviewed journal.

**Intention to publish date**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol article</a>	protocol	17/04/2017		Yes	No
<a href="#">Results article</a>	results	01/04/2018	19/11/2020	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No

