ISRCTN20436833 https://doi.org/10.1186/ISRCTN20436833

# Extra physiotherapy in critical care: intensive versus standard physical rehabilitation therapy in the critically ill

| | | |
|---|---|---|
| **Submission date** 20/02/2012 | **Recruitment status** No longer recruiting | [_] Prospectively registered<br>[X] Protocol |
| **Registration date** 20/02/2012 | **Overall study status** Completed | [_] Statistical analysis plan<br>[X] Results |
| **Last Edited** 09/08/2017 | **Condition category** Other | [_] Individual participant data |

## Plain English summary of protocol

Background and study aims
An increased intensity of physiotherapy, including an individualised structured exercise programme, may be beneficial for critically ill patients. The aim of this study is to compare two intensities of physiotherapy in critically ill patients.

Who can participate?
Critically ill surgical or medical patients, over 18 years of age, who have been ventilated for between 48 and 72 hours

What does the study involve?
Participants are randomly allocated to one of two groups. Group 1 (control group) receive usual physical rehabilitation therapy (Monday to Friday), including a once-daily functional retraining session. Group 2 (intervention group) receive a more intensive physical rehabilitation therapy, including at least one functional retraining session per day (Monday to Friday), and an individualised structured exercise programme. Physical quality of life is compared on Critical Care discharge and 3 and 6 months later. Changes in participants' mental health and the economic costs of the interventions are also assessed.

What are the possible benefits and risks of participating?
The possible benefits of participating are that if additional physiotherapy is shown to be beneficial to Critical Care patients, research participants will also benefit. This could be shown as improvements to physical function, longer-term health, exercise capacity and overall quality of life. During physiotherapy sessions, research participants will be monitored closely, and if any specific events occur, the session will be stopped. Research participants are patients who are already critically ill, and so additional precautions will be taken to ensure that the risks of participating are minimised.

Where is the study run from?
The Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
January 2012 to June 2015

Who is funding the study?
National Institute for Health Research (NIHR) Research for Patient Benefit (RfPB)

Who is the main contact?
Miss Gillian Watson
gillian.watson@ncl.ac.uk

# Contact information

### Type(s)
Scientific

### Contact name
Miss Gillian Watson

### Contact details
Newcastle Clinical Trials Unit
Institute of Health & Society
Newcastle University
4th Floor, William Leech Building
Medical School
Framlington Place
Newcastle Upon Tyne
United Kingdom
NE2 4HH
+44 (0)191 222 8813
gillian.watson@ncl.ac.uk

# Additional identifiers

### EudraCT/CTIS number

### IRAS number

### ClinicalTrials.gov number

### Secondary identifying numbers
11389

# Study information

### Scientific Title
A randomised controlled trial of intensive versus standard physical rehabilitation therapy in the critically ill: Extra Physiotherapy In Critical Care

### Acronym
EPICC

## Study objectives
This study aims to compare two intensities of physiotherapy in critically ill patients. The trialists believe that an increased intensity of physiotherapy, including an individualised structured exercise programme, will be beneficial for critically ill patients. To assess this, their physical quality of life will be compared on Critical Care discharge, and at 3 and 6 months following initial recruitment to the study. Changes in participants' mental health and the economic costs of the interventions will also be assessed.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
South Central - Southampton B Research Ethics Committee, first MREC approval date 20/07/2011, ref: 11/NE/0206

## Study design
Randomised; Interventional; Design type: Treatment

## 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 contact gillian.watson@ncl.ac.uk to request a patient information sheet

## Health condition(s) or problem(s) studied
Topic: Generic Health Relevance and Cross Cutting Themes; Subtopic: Generic Health Relevance (all Subtopics); Disease: Critical Care

## Interventions
Group 1 (control group) will receive usual physical rehabilitation therapy (Monday to Friday), including a once-daily functional retraining session.

Group 2 (intervention group) will receive a more intensive physical rehabilitation therapy, including at least one functional retraining session per day (Monday to Friday), and an individualised structured exercise programme.

## Intervention Type
Behavioural

## Primary outcome measure

Physical QoL; Timepoint(s): 6 months

### Secondary outcome measures
1. Changes in mental health; Timepoint(s): 6 months
2. Economic costs of intervention; Timepoint(s): 6 months

### Overall study start date
16/01/2012

### Completion date
04/06/2015

## Eligibility

### Key inclusion criteria
1. Participant has provided written informed consent, or their Personal Consultee has provided a signed Personal Consultee Declaration Form, for participation in the study, prior to any study specific procedures taking place
2. Medical and surgical patients (surgical patients are those admitted to ICU as a direct consequence of an operative procedure, or as a consequence of that procedure. All other patients are termed medical)
3. Age 18 years or over
4. Invasive or noninvasive ventilation for more than 48 hours
Target Gender: Male & Female ; Lower Age Limit 18 years

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
Planned Sample Size: 308; UK Sample Size: 308

### Key exclusion criteria
1. Invasive or non-invasive ventilation for more than 72 hours
2. Under 18 years
3. Patients receiving end-of-life care
4. Patients not expected to survive for more than 48 hours after enrolment
5. Acute brain injury
6. Acute spinal cord injury
7. Spinal surgery
8. Brain surgery
9. Multiple trauma

10. Burns
11. Rapidly progressive neuromuscular disease
12. Enrolment in another clinical trial
13. Post-cardiac arrest

### Date of first enrolment
16/01/2012

### Date of final enrolment
04/12/2014

## Locations

### Countries of recruitment
England

United Kingdom

### Study participating centre
**Newcastle University**
Newcastle Upon Tyne
United Kingdom
NE2 4HH

## Sponsor information

### Organisation
Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

### Sponsor details
Wolfson Unit of Clinical Pharmacology
Institute of Cellular Medicine
Framlington Place
Newcastle Upon Tyne
England
United Kingdom
NE2 4HH

### Sponsor type
Hospital/treatment centre

### ROR
https://ror.org/05p40t847

# Funder(s)

### Funder type
Government

### Funder Name
National Institute for Health Research (NIHR) (UK) - Research for Patient Benefit Programme (RfPB)

### Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### Funding Body Type
Government organisation

### Funding Body Subtype
National government

### Location
United Kingdom

# Results and Publications

### Publication and dissemination plan
Not provided at time of registration

### Intention to publish date

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Protocol article | protocol | 25/05/2015 | | Yes | No |
| Results article | results | 01/03/2018 | | Yes | No |