

# The effect of exercise on patient fitness and quality of life after intensive care admission

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<b>Registration date</b> 30/09/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 18/03/2014	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
2008010

# Study information

## Scientific Title

The impact of an aerobic exercise rehabilitation programme on fitness and quality of life in intensive care unit survivors: an exploratory trial

## Study objectives

To evaluate the effect of an 8-week supervised exercise programme on patient fitness (as judged by AT [anaerobic threshold] measurement) and quality of life (as judged by 36-item short form health survey [SF-36] and Euroqol EQ-5D), following critical illness and discharge from intensive care unit (ICU).

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Ethics approval received from the Newcastle and North Tyneside 1 Research Ethics Committee on the 16th January 2008 (ref: 07/H0906/137)

## Study design

Multi-centre, parallel group randomised controlled trial

## 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 the contact details below to request a patient information sheet

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

Quality of life after ICU admission

## Interventions

Eligible patients will be asked to attend for a baseline AT measurement and QoL questionnaires 8 - 16 weeks post-discharge from hospital. Patients will be then be randomised into intervention or control groups. The 'usual care' group will be the control.

We have elected to adapt the process of simple random allocation of subjects to groups by using a minimisation method. Minimisation will be performed using Minim software. Initially, a permuted block design (1:1 ratio) will be employed with block sizes of 2, 4, and 6 selected at random. Thereafter, minimisation will be incorporated to ensure a good balance between trial

arms. We intend to minimise on three factors; age (18 - 39 years versus 40 - 65 years), sex (male versus female), and diagnosis on entry to ICU (sepsis versus trauma). The allocation sequence will be generated and held by a statistician who is not involved in enrolment or assessment of outcomes, and will be concealed from the investigators until baseline AT has been measured and baseline questionnaires completed.

The patients in the intervention group will be required to perform a 40 minute exercise session, twice a week for 8 weeks under supervision by trained staff with resuscitation equipment available. and one unsupervised session per week (brisk 40 minute walk). All exercise sessions will be of appropriate intensity and duration to provide a sufficient exercise challenge to test our hypothesis.

All patients will be asked to return at week 9 to retest their AT measurement as well as complete the four questionnaires. This will also be repeated at week 26 of the study for both arms. Patients allocated to the control groups will be seen at weeks 0, 9 and 26 for AT measurement and completion of questionnaires.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome measure**

Changes in AT and quality of life (QoL). QoL will be measured using the SF-36 (Version 2) and EQ-5D questionnaires.

The primary outcome will be assessed in intervention and control groups at baseline, week 9 (post 8-week intervention period), and at 26 weeks. The primary comparison is the change in AT and QoL scores from baseline to week 9 (post 8 week exercise program).

### **Secondary outcome measures**

Secondary outcome analysis will include:

1. Time of return to work
2. Assessment of mental health (Hospital Anxiety and Depression Scale [HADS] questionnaire)
3. Habitual physical activity outside of (and following) the intervention period. Habitual physical activity will be monitored using a validated self-report instrument.

This will be completed after enrolment at baseline, week 9, and at 26 weeks, providing exploratory data for the association between the exercise training and physical activity levels.

Other data collection:

In addition to the outcome measures above the following data will be collected:

4. Demographic data - age, sex, reason for ICU admission
5. Duration of ICU and hospital stay
6. Medication
7. Time of study enrolment
8. Premorbid quality of life analysis - we accept that this element may be subject to patient recall bias with subjects forgetting their "true" premorbid QoL. Accurate recall may be affected by the ICU experience leading to "over-estimation" of premorbid QoL.

**Overall study start date**

01/03/2008

**Completion date**

01/03/2010

## Eligibility

**Key inclusion criteria**

1. Aged between 18 and 65 years, either sex
2. Have had a traumatic or primary sepsis event
3. Emergency admission to the ICU
4. Required ventilatory support for a minimum duration of 3 days
5. Must have been discharged home within 6 months of admission
6. Not be currently involved in a rehabilitation programme
7. Must be able to climb a flight of stairs unaided to participate in this study

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

64

**Key exclusion criteria**

1. Lack of consent
2. Aged less than 18 or greater than 65 years
3. Hospitalised greater than 6 months post-ICU discharge
4. Enrolment in current exercise or rehabilitation programme (this includes stroke and cardiac rehabilitation)
5. Inability to climb a flight of stairs
6. Inability to complete the initial cardiopulmonary exercise test
7. Contraindication to cardiopulmonary exercise (CPX) testing

**Medical exclusions:**

1. New York Heart Association functional classification greater than or equal to Class III
2. Canadian Cardiovascular Society Angina Grading Scale greater than or equal to Class III
3. European Society of Hypertension Classification Grades greater than or equal to III
4. Aortic stenosis greater than or equal to moderate (i.e. valve area less than  $1.0 \text{ cm}^2$ )
5. Hypertrophic cardiomyopathy
6. Symptomatic arrhythmias
7. Severe disability as defined by the Glasgow Outcome Score greater than 2

8. Spinal cord injury
9. Primary muscular disorder (excluding critical illness neuropathy)
10. Uncontrolled epileptic seizures
11. Pregnancy (confirmed with urine sample after consent has been taken)
12. Body mass index (BMI) greater than 40

**Date of first enrolment**

01/03/2008

**Date of final enrolment**

01/03/2010

## **Locations**

**Countries of recruitment**

England

United Kingdom

**Study participating centre**

**Cheriton House**

Cleveland

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## **Sponsor information**

**Organisation**

The James Cook University Hospital (UK)

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**Sponsor type**

Hospital/treatment centre

**Website**

<http://www.southtees.nhs.uk>

ROR

<https://ror.org/02vqh3346>

## Funder(s)

### Funder type

Government

### Funder Name

National Institute for Health Research (UK) - Research for Patient Benefit (RfPB) programme  
(ref: PB-PG-04074-13274)

## 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?
<a href="#">Results article</a>	results	01/07/2014		Yes	No