ISRCTN65176374 https://doi.org/10.1186/ISRCTN65176374

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

Submission date 02/09/2008	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 30/09/2008	**Overall study status** Completed	
Last Edited 18/03/2014	**Condition category** Other	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Gerard Danjoux

Contact details
Cheriton House
James Cook University Hospital
Marton Road
Middlsbrough
Cleveland
United Kingdom
TS4 3BW
gerard.danjoux@stees.nhs.uk

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 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
United Kingdom
TS4 3BW

Sponsor information

Organisation
The James Cook University Hospital (UK)

Sponsor details
Marton Road
Middlesbrough
Cleveland
England
United Kingdom
TS4 3BW
gerard.danjoux@stees.nhs.uk

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?
Results article	results	01/07/2014		Yes	No