

Does a six week supervised Exercise programme improve fitness and well-being in Post Intensive Care patients? (EPIC)

Submission date 09/11/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 07/02/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 12/06/2019	Condition category Other	<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims

There is a lot of research that tells us that people who have been in the Intensive Care Unit (ICU) in hospital can often (but not always) experience ongoing problems such as loss of general fitness, balance and strength, or experience higher levels of anxiety and depression. Our study aims to investigate whether a six-week exercise programme can improve any of these possible difficulties experienced by patients who have been discharged home from hospital, after having been in the ICU for more than 48 hours.

Who can participate?

Patients aged 18 or over who have been in the ICU for longer than 48 hours.

What does the study involve?

The study involves attending the physiotherapy department in Morriston Hospital for about 30 minutes, where the patient will carry out three simple fitness tests and complete a short questionnaire. The fitness tests include the Six Minute Walk Test which involves walking for six minutes if the patient is able, a series of simple balance exercises and a test where the patient squeezes their hands into a fist as tight as possible to measure grip strength. Following these tests, the patients will be randomly allocated to either the control group or the exercise group. The control group will be given a general advice sheet on exercise and will then re-attend the physiotherapy department seven weeks later to complete the same series of tests. The exercise group will be asked to attend the physiotherapy gym in Morriston Hospital twice a week for six weeks where they will carry out an exercise programme with a physiotherapist either on their own or with one other patient. The programme will include exercises such as using the treadmill, rowing machine, static bike or stepper and simple strengthening and balance exercises. These sessions will last between 40 minutes and one hour. At the end of the six weeks, the patient will complete the same series of tests that were completed at the start of the programme. Both groups of patients will be asked to complete the tests at 6 months and one year after the study in order to assess any longer lasting benefits of the programme.

What are the possible benefits and risks of participating?

There are no risks associated with this study. The patient may feel slight muscle soreness the day after they have exercised but they will be warmed up and cooled down properly in order to minimise this risk.

Where is the study run from?

Morrison Hospital (UK).

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

November 2011 to October 2013.

Who is funding the study?

This study is receiving no funding from any external source. The ICU physiotherapy team are completing the study as part of their normal daily work.

Who is the main contact?

Miss Ceri Battle

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Contact information

Type(s)

Scientific

Contact name

Miss Ceri Battle

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

A randomised controlled trial examining the effect of a six week supervised exercise programme on patient fitness and hospital related anxiety and depression following an intensive care length of stay of greater than 48 hours

Acronym

EPIC

Study objectives

1. What is the impact of a six week supervised exercise programme on cardiopulmonary fitness in patients who have been discharged home from hospital following an intensive care unit (ICU) length of stay of greater than 48 hours?
2. What is the impact of a six week supervised exercise programme on balance, muscle strength, anxiety and depression levels in patients who have been discharged home from hospital following an ICU length of stay of greater than 48 hours?
3. What is the impact of a six week supervised exercise programme on mortality, return to work and primary and secondary care utilisation at six month and one year follow up?

Ethics approval required

Old ethics approval format

Ethics approval(s)

South West Wales Research and Ethics Committee, October 2011, ref: 11/WA/0216

Study design

Single-centre pragmatic blinded randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Quality of life

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

Any patient who has been a patient on ICU (general) for 48 hours or more

Interventions

Six week, twice weekly, supervised exercise programme which includes:

1. Cardiovascular exercise on treadmill, cycle ergometer, rowing machine and stepper
2. Balance exercises
3. Strengthening exercises

Control group:

No treatment

Tested at baseline, 7 weeks, 6 months and 1 year.

Intervention Type

Behavioural

Primary outcome measure

Cardiopulmonary fitness: Six minute walk test (Guyatt et al 1985)

Secondary outcome measures

1. Balance: measured by the Berg Balance Score (Berg et al 1989)
2. Grip strength as measured by JAMAR grip dynamometer
3. Anxiety and depression as measured by the Hospital Anxiety and Depression Scale (Zigmond and Snaith 1983)

Overall study start date

01/07/2011

Completion date

30/08/2017

Eligibility

Key inclusion criteria

1. Male or female patients who are aged 18 years or more (no upper age limit)
2. Patients who have had a length of stay on ICU for more than 48 hours
3. Patients who have been discharged home and are attending follow up clinic within 6 months of their discharge from ICU
4. Patients who can follow instructions
5. Patients who are not already enrolled in a rehabilitation programme
6. Patients who live within commutable distance

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

60 patients

Total final enrolment

60

Key exclusion criteria

1. Patients who do not consent to participation in the study
2. Patients aged less than 18 years
3. Patients hospitalised for longer than 6 months since their discharge from ICU
4. Patients who lack capacity to follow instructions
5. Patients who are already enrolled in a rehabilitation programme
6. Patients who live outside of commutable distance
7. Patients with any medical contraindications to exercise, including:
 - 7.1. Unstable angina or myocardial infarction in the preceding month
 - 7.2. Unmanaged valvular problems
 - 7.3. Patients awaiting further definitive treatment (e.g. open abdominal wound)
 - 7.4. Pregnancy where the patient has been advised against exercise

Date of first enrolment

01/11/2011

Date of final enrolment

30/03/2015

Locations**Countries of recruitment**

United Kingdom

Wales

Study participating centre**Morrison Hospital**

Morrison

Swansea

United Kingdom

SA6 6NL

Sponsor information**Organisation**

Abertawe Bro Morgannwg University (ABMU) Health Board (UK)

Sponsor details

Research and Development Department
Morriston Hospital
Morriston
Swansea
Wales
United Kingdom
SA6 6NL

Sponsor type

Hospital/treatment centre

Website

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

ROR

<https://ror.org/04zet5t12>

Funder(s)

Funder type

Hospital/treatment centre

Funder Name

Abertawe Bro Morgannwg University Health Board (UK)

Results and Publications

Publication and dissemination plan

We plan to publish our trial in an international peer-reviewed journal by the end of 2018. Preliminary results have been presented at ICS State of the Art Winter Meeting in December 2017. Other documents are available on request by individuals from Ceri Battle on ceri.battle@Wales.nhs.uk

Intention to publish date

31/12/2018

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Ceri Battle on ceri.battle@wales.nhs.uk

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
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[Results article](#)

results

01/02/2019

12/06/2019

Yes

No