

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

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

### Protocol serial number

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

## **Study type(s)**

Quality of life

## **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(s)**

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

**Key secondary outcome(s)**

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)

**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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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)

**ROR**

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

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**

Abertawe Bro Morgannwg University Health Board (UK)

## **Results and Publications**

## 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](mailto: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?
<a href="#">Results article</a>	results	01/02/2019	12/06/2019	Yes	No