

# Intensive Care Outcome Network Study - Phase 3

<b>Submission date</b> 24/07/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 01/08/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 26/11/2018	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Research on the effectiveness of intensive care treatment has mainly focused on how many patients survived their treatment. From this research we know that within the five years after intensive care treatment patients are more likely to die when compared to a general population of people of the same age and gender. Also, we know that intensive care unit (ICU) patients experience physical and psychological problems for a long time after discharge from an ICU. This study is gathering information from former ICU patients to try to identify the factors which are more likely to affect the risk of death or long-term physical or mental ill-health of ICU patients in the future. The ultimate aim of the study therefore is to try to improve the long-term quality of life of ICU patients.

### Who can participate?

Patients who have been treated in the ICU at one of the hospitals taking part in the study are eligible to take part if they were at least 16 years of age when admitted to the ICU and experienced at least 24 hours of level three dependency care (ICU care) at any time during their hospital stay.

### What does the study involve?

Patients who agree to help this study will receive a pack of up to six different questionnaires. Each questionnaire will take about 5 minutes to complete. Follow-up questionnaires will be mailed to participants at 12 months and 24 months after the date of discharge from the ICU.

### What are the possible benefits and risks of participating?

There will be no direct benefits to patients taking part. However, we hope your participation will improve the care of patients treated in intensive care units in the future.

### Where is the study run from?

Kadoorie Centre for Critical Care Research and Education at the John Radcliffe Hospital in Oxford (UK).

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

The study began in June 2012 and is expected to run for two years.

Who is funding the study?  
The Bupa Foundation.

Who is the main contact?  
Dr Duncan Young (Chief Investigator)  
icon@nda.ox.ac.uk

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Dr Duncan Young

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## Additional identifiers

**Protocol serial number**  
Version 2 - January 2012

## Study information

**Scientific Title**  
A study of the long term survival, psychological morbidity and health-related quality of life of patients discharged from Intensive Care Units in the United Kingdom

**Acronym**  
ICON3

**Study objectives**  
This study is a continuation of the ICON study (ISRCTN69112866) and its purpose remains the same, i.e. to generate a register of patients discharged from intensive care units (ICUs). The register will be used to study ICU treatment and its relation to mortality and long-term psychological morbidity, as well as changes in health-related quality of life over time after discharge from ICU.

**Ethics approval required**  
Old ethics approval format

## **Ethics approval(s)**

NRES Committee South Central Berkshire, 23/06/2011, ref: 11/SC/0172

## **Study design**

Observational multi-centre study

## **Primary study design**

Observational

## **Study type(s)**

Screening

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

Former intensive care patients of participating hospitals

## **Interventions**

Postal questionnaires at 3, 12 and 24 months after ICU discharge

## **Intervention Type**

Other

## **Phase**

Not Applicable

## **Primary outcome(s)**

Data from the ICON study will allow the identification of risk factors for poor long-term outcomes after patients have been treated on an intensive care unit, which will in turn inform the development of effective treatments and enable earlier recognition of factors related to poor long-term outcome in these patients. This entire process has the ultimate goal of improving the long-term quality of life of patients who have experienced treatment on an intensive care unit.

## **Key secondary outcome(s)**

1. Obtain a response rate of 70% or more
2. To maintain the registry and database from ICON Phases 1 and 2
3. To determine the health-related quality of life of patients at three, twelve and twenty-four months after ICU discharge using SF-36 and EQ-5D and compare this with an age-, sex- and socio-economic status-matched historical control group
4. To determine the number of patients at risk of developing Post Traumatic Stress Disorder (PTSD) at three, twelve and twenty-four months after ICU discharge using PCL-C
5. To determine the number of patients at risk of depression and anxiety disorders at three, twelve and twenty-four months after ICU discharge
6. To assign a health utility index value to each of the first two survivor-years to allow calculation of quality-adjusted life years (QALYs) for all patients and those in specific diagnostic groups
7. To determine differences in health status for broad subgroups of patients based on diagnosis, and calculated (APACHE II and/or ICNARC score) hospital mortality risk
8. To determine the survival of these patients beyond two years after hospital discharge and so determine the relative risk of death over time of all these patients compared with an age and sex matched group drawn randomly from the UK population
9. To determine the relative risk of death over time for broad subgroups based on diagnosis, calculated hospital mortality risk (APACHE II and/or ICNARC score), sex, geography and socio-

economic group (from postcodes) compared with the risk for all patients  
10. To determine the relative risk of death for patients with a similar diagnosis but with or without a specific syndrome characterised by physiological changes (sepsis, ARDS etc)

**Completion date**

31/05/2014

## Eligibility

**Key inclusion criteria**

1. Aged at least 16 years on admission to intensive care
2. Participants must have experienced at least 24 hours of level three dependency care (ICU care) at any time during their hospital stay and survived until the time of hospital discharge

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Key exclusion criteria**

1. Aged under 16 years
2. Unable to complete questionnaires and have no consultee to fill in the forms on their behalf
3. Foreign nationals
4. In residential care
5. In prison
6. Unwilling to consent
7. Life status cannot be traced (i.e. have no GP or NHS numbers)

**Date of first enrolment**

01/06/2012

**Date of final enrolment**

31/05/2014

## Locations

**Countries of recruitment**

United Kingdom

England

**Study participating centre**  
**Kadoorie Centre**  
Oxford  
United Kingdom  
OX3 9DU

## Sponsor information

**Organisation**  
University of Oxford (UK)

**ROR**  
<https://ror.org/052gg0110>

## Funder(s)

**Funder type**  
Charity

**Funder Name**  
Bupa Foundation (UK) ref: 22095028

**Alternative Name(s)**

**Funding Body Type**  
Private sector organisation

**Funding Body Subtype**  
Trusts, charities, foundations (both public and private)

**Location**  
United Kingdom

## Results and Publications

**Individual participant data (IPD) sharing plan**

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

**Study outputs**

<b>Output type</b>	<b>Details</b>	<b>Date created</b>	<b>Date added</b>	<b>Peer reviewed?</b>	<b>Patient-facing?</b>
<a href="#">Results article</a>	results	23/11/2018		Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes