

# Provision Of Psychological support to People in Intensive care (POPPI): feasibility study

<b>Submission date</b> 05/06/2014	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 05/06/2014	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 13/09/2019	<b>Condition category</b> Mental and Behavioural Disorders	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

It is known that patients may suffer from stress and panic in intensive care. Many patients become fearful and some even see or hear things that are not really happening (hallucinations). Doctors believe these frightening effects are caused by illness, medicine or stressful treatments in intensive care. Research shows that these worries and fears may increase the time it takes for patients to get better. The stress could also lead to future problems like flashbacks or nightmares. The idea of this study is to give intensive care staff special training to help patients who are worried or distressed. All the staff will learn how to make intensive care a calmer, less stressful place. Some nurses will also have training to give patients extra support to help lower their stress. The trialists believe this will improve patients well-being after leaving intensive care.

### Who can participate?

Adult patients receiving treatment in the intensive care can take part.

### What does the study involve?

This study consists of two separate parts. Part one is to check that patients are happy to take part and complete a short questionnaire. If it is shown that patients are happy to do this, they move on to part two. Part two of the study tests whether training intensive care staff to give stress support can improve patients' future well-being. Patients taking part in part one of the study receive a short questionnaire 5 months after their stay in intensive care by email or post. Patients taking part in part two of the study are given a short questionnaire about stress and mood in intensive care. It only takes a few minutes to answer the questions. If the stress score is low, they continue to receive normal care from the intensive care staff. If they have a high score, a specially trained nurse offers three sessions of stress support. These sessions are to discuss any worries they may have and to help them cope with being in intensive care. They also receive music and relaxation tapes, and a booklet.

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

The trialists cannot promise the study will help patients right now. They will be part of an important study aiming to improve the well-being of intensive care patients. If nurses like the training and patients find the stress support helpful, the study will be held in another 24 hospitals.

Where is the study run from?

The study is being run at four sites in the UK: Bristol Royal Infirmary, Medway Maritime Hospital, University College Hospital, and Watford General Hospital.

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

June 2014 to June 2015

Who is funding the study?

National Institute for Health Research (NIHR) (UK)

Who is the main contact?

Mr Paul Mouncey

paul.mouncey@icnarc.org

## Contact information

### Type(s)

Scientific

### Contact name

Mr Paul Mouncey

### Contact details

Napier House

24 High Holborn

London

United Kingdom

WC1V 6AZ

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paul.mouncey@icnarc.org

## Additional identifiers

### Protocol serial number

16479

## Study information

### Scientific Title

Psychological Outcomes following a nurse-led Preventative Psychological Intervention for critically ill patients (POPPI): a feasibility study

### Acronym

POPPI

### Study objectives

The overall aim of the study is to develop and test the feasibility of a complex psychological intervention and to test the feasibility of the processes and procedures for the POPPI cluster randomised controlled trial.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

NRES Committee South Central - Oxford B, 23/04/2014, ref: 14/SC/0149

**Study design**

Non-randomised; Both; Design type: Prevention, Screening, Treatment

**Primary study design**

Interventional

**Study type(s)**

Prevention

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

Topic: Critical Care, Mental Health; Subtopic: Critical Care, Anxiety; Disease: All Critical care, Anxiety

**Interventions**

The intervention to be assessed is a complex psychological intervention comprising four related elements:

1. An education package (two training courses and associated materials) to train critical care unit staff to carry out elements 2-4
2. Creating a therapeutic environment to promote calm and minimise stress in critical care (all critical care staff)
3. Screening for acute psychological stress and psychosis-like symptoms in critical care patients using the IPAT (all critical care staff)
4. Carrying out three, one-to-one CBT-inspired stress support sessions, for patients screened as distressed and at high risk of psychological morbidity (delivered by specially trained POPPI nurses)

**Intervention Type**

Behavioural

**Primary outcome(s)**

The main outcomes of the Intervention Feasibility Study will be the feasibility and acceptability of the intervention for the POPPI nurses and for patients, which will be assessed quantitatively and qualitatively. The main outcomes of the RCT Processes Feasibility Pilot Study are feasibility of estimated recruitment and retention rates.

**Key secondary outcome(s)**

Not provided at time of registration

**Completion date**

01/06/2015

**Eligibility****Key inclusion criteria**

1. Age 18 years or greater
2. Receipt of Level 2 or Level 3 critical care for 48 hours or more
3. Between +1 and -1 on the Richmond Agitation Sedation Scale
4. English-speaking and ability to communicate

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Glasgow Coma Score of less than 15
2. Pre-existing chronic cognitive impairment, such as dementia
3. Pre-existing psychotic illness
4. Pre-existing chronic PTSD
5. Terminal illness/receiving end-of-life care

**Date of first enrolment**

11/06/2014

**Date of final enrolment**

30/03/2015

**Locations****Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Bristol Royal Infirmary**

Upper Maudlin St

Bristol

United Kingdom

BS2 8HW

**Study participating centre**  
**Medway Maritime Hospital**  
Windmill Rd  
Gillingham  
United Kingdom  
ME7 5NY

**Study participating centre**  
**University College Hospital**  
235 Euston Rd  
Fitzrovia  
London  
United Kingdom  
NW1 2BU

**Study participating centre**  
**Watford General Hospital**  
Vicarage Rd  
Watford  
United Kingdom  
WD18 0HB

## **Sponsor information**

**Organisation**  
Intensive Care National Audit & Research Centre (UK)

**ROR**  
<https://ror.org/057b2ek35>

## **Funder(s)**

**Funder type**  
Government

**Funder Name**  
Health Services and Delivery Research Programme (Grant Codes: 12/64/124)

**Alternative Name(s)**

Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research (HS&DR) Programme, NIHR Health Services and Delivery Research Programme, HS&DR Programme, HS&DR

**Funding Body Type**  
Government organisation

**Funding Body Subtype**  
National government

**Location**  
United Kingdom

## Results and Publications

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	23/07/2018		Yes	No
<a href="#">Results article</a>	results	01/08/2019	13/09/2019	Yes	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes