**Background**

Studies indicate high rates of serious psychological morbidity amongst patients after their stay in a critical care unit. Early psychological assessment of risk and subsequent intervention/support are both key to reduce longer-term psychological morbidity. Rigorous and relevant evidence is needed to reduce the burden of serious psychological morbidity on patients and their carers. In addition, cost-effective strategies are needed to reduce the burden on the NHS.

The Provision Of Psychological support to People in Intensive care (POPPI) trial sets out to inform the NHS on improving both access to, and delivery of, services to ensure that critically ill patients receive both psychological assessment and intervention/support in a cost-effective manner.

**Aim**

The main research question is:
- can psychological morbidity, and its associated costs, be reduced through delivery of a nurse-led preventative psychological intervention?

**Objectives**

1. to evaluate the effect of a nurse-led preventative psychological intervention on psychological morbidity at six months;
2. to conduct an integrated process evaluation to assess the fidelity and quality of implementation of the intervention, and identify important contextual factors to better understand how the intervention works; and
3. to estimate, in an integrated economic analysis, the cost-effectiveness of the intervention.

**Primary outcomes**

- **Clinical effectiveness evaluation**
  Patient-reported psychological morbidity at six months
- **Cost-effectiveness evaluation**
  Incremental costs, quality-adjusted life years (QALYs) and net monetary benefit at six months

**Patient Population**

- Age 18 years or greater
- Greater than 48 hours in the critical care unit
- Receipt of Level 3 critical care during first 48 hours in the critical care unit
- Between +1 and -1 on the Richmond Agitation Sedation Scale
- Glasgow Coma Scale score of 15
- English-speaking
- Ability to communicate orally

Patient’s must be confirmed eligible and first approached for participation in the critical care unit.
**Patients**

- 1,914 patients

**Site timeline**

- 24 adult, general, critical care units (12 intervention, 12 control)
- Sites open to recruitment in three groups of eight sites at two month intervals
- Eleven month recruitment period for each site
- All sites deliver usual care for the first five months of recruitment (baseline period)
- Sites are randomised in month two
- At month six, sites randomised to the intervention group undergo a transition period in which they undergo training and commence delivery of the intervention
- Sites randomised to the control group continue to deliver usual care

**Research Governance**

- **NHS REC Committee number**: 15/SC/0287
- **NIHR CRN Portfolio number**: 18940
- **ISRCTN Registry number**: ISRCTN53448131

**Funding/support**

- NIHR Health Services & Delivery Research Programme (Project: 12/64/124)
- Samsung Electronics (UK) Ltd – donation of 38 ATIV Tab 3 tablet computers for use by patients as part of a relaxation and recovery programme

**For further information**

**Paul Mouncey (Senior Trial Manager)**

**Email**: poppi@icnarc.org
**Tel**: 020 7269 9277
**Fax**: 020 7831 6879

**ICNARC**
**Sponsor**

**Trial Management**

ICNARC Clinical Trials Unit

**Team**

**Chief Investigator**
Kathy Rowan (ICNARC)

**Lead Clinical Investigator**
Dorothy Wade (UCLH)

**Senior Trial Manager**
Paul Mouncey (ICNARC)

**Research Assistant**
Alvin Richards-Belle (ICNARC)

**Data Manager**
Nick Hudson (ICNARC)

**Statistician**
Jerome Wulff (ICNARC)

**Co-Investigators**
David Aaronovitch (News UK)
Chris Brewin (UCL)
Richard Grieve (LSHTM)
David Harrison (ICNARC)
Sheila Harvey (LSHTM)
David Howell (UCLH)
Michael Mythen (UCLH)
Zia Sadique (LSHTM)
Deborah Smyth (UCLH)
John Weinman (KCL)
John Welch (UCLH)

ICNARC | Intensive Care National Audit & Research Centre
KCL | King’s College London
LSHTM | London School of Hygiene & Tropical Medicine
UCL | University College London
UCLH | University College London Hospitals NHS Foundation Trust