Background

More than 50% of intensive care patients report serious psychological morbidity after their stay in the intensive care unit and hospital. 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) Study 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?

Intervention

The intervention being evaluated is a nurse-led preventative psychological intervention comprising the following four elements:

1. an education package (and associated materials) to train intensive care unit staff to carry out elements 2-4;
2. promoting a therapeutic environment to promote calm and minimise stress in intensive care (all intensive care staff);
3. screening for acute psychological stress and psychosis-like symptoms in intensive care patients using the Intensive Care Psychological Assessment Tool (IPAT) (all intensive care staff); and
4. carrying out three, one-to-one stress support sessions for patients screened as distressed and at high risk of psychological morbidity (delivered by specially trained POPPI nurses).

What is POPPI?

The POPPI Study consists of two phases:

Phase I: Feasibility and Pilot Studies – 18 months

Phase II: Cluster-Randomised Controlled Trial (RCT) – 28 months

Primary outcomes

- Clinical evaluation
  Patient-reported post-traumatic stress disorder (PTSD) symptom severity at six months

- Economic evaluation
  Incremental costs, quality-adjusted life years (QALYs) and net monetary benefit.

Patient Population

- age 18 years or greater
- receipt of Level 2 or Level 3 critical care for 48 hours or more
- between +1 and -1 on the Richmond Agitation Sedation Scale
- English-speaking and ability to communicate orally

Phase I: Feasibility and Pilot Studies

The objectives of Phase I are:

1. to develop an education package as part of the proposed intervention;
2. to test the feasibility of the intervention;
3. to refine the intervention;
4. to pilot test the proposed processes and procedures for the cluster-RCT;
5. to set up the cluster-RCT; and
6. to formally evaluate the feasibility of the intervention (and progression to the cluster-RCT) at a pre-specified stop point.
Phase II: Cluster-RCT

The objectives of Phase II are:

1. to evaluate, using a parallel groups cluster-RCT design, the effect of the nurse-led preventative psychological intervention on patient-reported PTSD symptom severity (primary outcome) and other psychological morbidities (secondary outcomes) 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.

Sites/Patients

- **Feasibility and Pilot Studies**
  4 adult, general critical care units
  (2 intervention, 2 control: 110 patients)

- **Cluster-RCT**
  24 adult, general critical care units
  (12 intervention, 12 control: 2,904 patients)

Research Governance/Funding

- NRES Committee number: 14/SC/0149
- NIHR HS&DR Project: 12/64/124
- NIHR CRN Portfolio number: 16479

For further information

**Paul Mouncey (Senior Trial Manager)**

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