ISRCTN53448131 https://doi.org/10.1186/ISRCTN53448131

Provision of psychological support to people in intensive care (v1.0)

Submission date	Recruitment status	[X] Prospectively registered
15/07/2015	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[X] Statistical analysis plan
16/07/2015	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
18/08/2023	Mental and Behavioural Disorders	

Plain English summary of protocol

Background and study aims
Many patients suffer distress whilst in an intensive care unit (ICU) and can have a poor psychological recovery after leaving hospital. This could include suffering from frightening flashbacks to intensive care, a symptom of post-traumatic stress disorder (PTSD). POPPI investigates whether a nurse-led psychological intervention (program) can improve patients' psychological recovery after a stay in an ICU and see if this approach is cost-effective.

Who can participate?
Adult patients from ICUs having spent over 48 hours in critical care.

What does the study involve?
ICUs taking part in the study are allocated randomly into one of two groups. Patients attending ICUs in group 1 receive the intervention. Patients attending ICUs in group 2 receive usual care. For the first five months, all sites deliver usual care. The intervention group then undergo training before delivering the intervention for the remaining 6 months. The control group continues to deliver usual care for the entire study period (11 months). At the end of the study, the psychological recovery of patients in the two groups (intervention and control) are compared by measuring patient-reported PTSD symptom severity six months after recruitment onto the study. The costs of the intervention and patients' quality of life are also compared to measure the cost-effectiveness.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Intensive Care National Audit & Research Centre (UK)

When is the study starting and how long is it expected to run for?
September 2015 to July 2017

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Mr Paul Mouncey

Contact information

Type(s)
Public

Contact name
Mr Paul Mouncey

Contact details
Intensive Care National Audit & Research Centre
Napier House
24 High Holborn
London
United Kingdom
WC1V 6AZ

Additional identifiers

Protocol serial number
18940

Study information

Scientific Title
Psychological Outcomes following a nurse-led Preventative Psychological Intervention for critically ill patients (POPPI) cluster-randomised controlled trial

Acronym
POPPI

Study objectives
Many patients suffer distress whilst in an intensive care unit (ICU) and can have a poor psychological recovery after leaving hospital. This could include suffering from frightening flashbacks to intensive care, a symptom of post traumatic stress disorder (PTSD). POPPI aims to assess whether implementing a nurse-led psychological intervention can improve patients' psychological recovery after a stay in an ICU and see if this approach is cost-effective.

Ethics approval required
Old ethics approval format

Ethics approval(s)
NRES Committee South Central - Oxford B, 15/05/2015, ref: 15/SC/0287

Primary study design
Interventional

Study design
Randomized; Interventional; Design type: Screening, Treatment

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Topic: Mental Health, Critical care; Subtopic: Anxiety, Critical care; Disease: Anxiety, All Critical care

Interventions
1. An education package (two training courses and associated materials) to train critical care unit staff to carry out parts 2-4 below
2. Creating a less stressful environment in the ICU
3. Assessing patients' psychological distress in the ICU using the Intensive care Psychological Assessment Tool; and
4. Carrying out three stress support sessions for very distressed patients (delivered by specially trained POPPI nurses).

Intervention Type
Behavioural

Primary outcome(s)
PTSD symptom severity measured using the PTSD Symptom Scale (Self-report version) (PSS-SR) Timepoint(s): 6 months

Key secondary outcome(s)
1. Cost-effectiveness; Timepoint(s): 6 months
2. Days alive and free from sedation; Timepoint(s): Day 30
3. Depression measured using the Hospital Anxiety and Depression Scale (HADS); Timepoint(s): 6 months
4. Duration of critical care unit stay; Timepoint(s): End of critical care unit stay
5. Health-Related Quality of Life; Timepoint(s): 6 months
6. PTSD Symptom Scale (Self-Report version) (PSS-SR) >18; Timepoint(s): 6 months
7. Anxiety measured using the HADS; Timepoint(s): 6 months (added 04/04/2016)

Completion date
29/12/2017

Eligibility

Key inclusion criteria
1. Age 18 years or greater
2. Greater than 48 hours in critical care
3. Receipt of Level 3 critical care (for any period of time) during the first 48 hours
4. Between +1 and 1 on the Richmond Agitation Sedation Scale
5. Glasgow Coma Scale score of 15
6. Englishspeaking and ability to communicate orally

Participant type(s)

Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
All

Key exclusion criteria
1. Pre-existing chronic cognitive impairment, such as dementia
2. Pre-existing psychotic illness, such as schizophrenia
3. Pre-existing chronic PTSD
4. Receiving end-of-life-care
5. Previously recruited into POPPI

Date of first enrolment
01/09/2015

Date of final enrolment
03/02/2017

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Intensive Care National Audit & Research Centre
Napier House
24 High Holborn
London
United Kingdom
WC1V 6AZ

Sponsor information

Organisation

Intensive Care National Audit & Research Centre

ROR
https://ror.org/057b2ek35

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research, Health Services and Delivery Research (HS&DR) Programme

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

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?
Results article	6-month follow-up results	19/02/2019	25/02/2019	Yes	No
Results article	results	01/08/2019	13/09/2019	Yes	No
Protocol article	protocol	08/02/2018		Yes	No
HRA research summary			28/06/2023	No	No
Other publications	statistical analysis plan	17/03/2020	18/08/2023	Yes	No

Statistical Analysis Plan	01/11/2018	No	No