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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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet

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

Secondary outcome measures
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)

Overall study start date
01/09/2015

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Target accrual: 1,378 patients. During recruitment, in consultation with the TSC and DMEC, a review of assumptions underlying the pre-trial power calculation once outcome data were available for patients recruited during the five-month baseline period in both intervention group and control group sites. This review, undertaken using data available on 9 August 2016, established that the planned design had an anticipated 78% power under the observed parameter estimates (allowing for uncertainty in the between-site variation, between 73% and 85% power). Consequently, the decision was taken to extend recruitment in all sites to the end of planned recruitment in the third group of sites (November 2016). With this extension to recruitment, the planned design had an anticipated 85% power (allowing for uncertainty in the between-site variation, between 79% and 91% power). It was anticipated that, with this extension to recruitment, the estimated total number of patients recruited would be 1,378. Recruitment continued to be monitored to ensure 1,378 or more patients were recruited. A final decision to extend recruitment by an additional two months (until end-January 2017) in all sites was taken to ensure this minimum number was achieved.

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
England

United Kingdom

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

Sponsor details
Napier House
24 High Holborn
London
England
United Kingdom
WC1V 6AZ

Sponsor type
Hospital/treatment centre

Website
https://www.icnarc.org/Our-Research/Studies/Poppi

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date
31/12/2018

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?
Protocol article	protocol	08/02/2018		Yes	No
Statistical Analysis Plan	statistical analysis plan	01/11/2018		No	No
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
HRA research summary			28/06/2023	No	No
Other publications		17/03/2020	18/08/2023	Yes	No