ISRCTN61088114 https://doi.org/10.1186/ISRCTN61088114

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

Submission date
05/06/2014

Recruitment status
No longer recruiting

Registration date
05/06/2014

Overall study status
Completed

Last Edited
13/09/2019

Condition category
Mental and Behavioural Disorders

[X] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] 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
-
paul.mouncey@icnarc.org

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Prevention

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

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 measure
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.

Secondary outcome measures
Not provided at time of registration

Overall study start date
01/06/2014

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 110; UK Sample Size: 110

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
England

United Kingdom

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)

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

Sponsor type
Research organisation

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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	results	23/07/2018		Yes	No
Results article	results	01/08/2019	13/09/2019	Yes	No
HRA research summary			28/06/2023	No	No