



Provision Of Psychological support
to People in Intensive care

Psychological Outcomes following a nurse-led Preventative Psychological Intervention for critically ill patients

FEASIBILITY STUDY

NRES Committee Number:	14/SC/0149
Trial Sponsor:	ICNARC
Trial Sponsor reference:	01/03/14
Trial funder(s):	NIHR HS&DR Programme
Funder(s) reference:	12/64/124
ISRCTN no:	ISRCTN61088114
NIHR CRN Portfolio no:	16479
CSP reference no:	149095
Protocol version:	1.3
Protocol version date:	16 September 2014

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Funding

National Institute for Health Research – Health Services & Delivery Research Programme
(Project: 12/64/124)

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Abbreviations

CAM-ICU	Confusion Assessment Method for ICU
CBT	Cognitive Behavioural Therapy
CBTp	Cognitive Behavioural Therapy for psychosis
CEA	Cost-effectiveness Analysis
CES-D	Centre for Epidemiological Studies Depression Scale
CMP	Case Mix Programme
CTU	Clinical Trials Unit
DSM-IV	Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition
EQ-5D	European Quality of Life Scale
EPAG	Expert Psychology Advisory Group
GCP	Good Clinical Practice
GLMM	Generalised linear mixed model
GP	General Practitioner
HA	Health Anxiety
HS&DR	Health Services & Delivery Research
ICH	International Conference on Harmonisation
ICNARC	Intensive Care National Audit & Research Centre
ICU	Intensive Care Unit
IPAT	Intensive Care Psychological Assessment Tool
ISF	Investigator Site File
LSHTM	London School of Hygiene & Tropical Medicine
MRC	Medical Research Council
NHS	National Health Service
NICE	National Institute for Health and Care Excellence
NIHR	National Institute for Health Research
PI	Principal Investigator
POPPI	Psychological Outcomes following a nurse-led Preventative Psychological Intervention for critically ill patients
PSS-SR	PTSD Symptom Scale – Self-Report version
PTSD	Posttraumatic Stress Disorder
R&D	Research & Development
QALY	Quality-adjusted life year
RCT	Randomised Controlled Trial
SMG	Study Management Group
SOP	Standard Operating Procedure
TSC	Trial Steering Committee
UCLH	University College London Hospitals NHS Foundation Trust
VAS	Visual Analogue Scale

1 Protocol summary

Title (acronym):	Psychological Outcomes following a nurse-led Preventative Psychological Intervention for critically ill patients (POPPI): Feasibility Study
Public Title	Provision Of Psychological support to People in Intensive care
Short Title:	POPPI Feasibility Study
Sponsor name	ICNARC
Funder name & reference:	NIHR Health Services & Delivery Research Programme, 12/64/124
Design:	Feasibility study, including two prospective cohort studies
Overall aim:	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
Objectives:	<ul style="list-style-type: none"> • to develop an education package (training and associated materials) as part of a complex psychological intervention; • to pilot test the intervention, including the education package; • to refine the intervention, including the education package; • to pilot test the feasibility of proposed processes and procedures for a cluster-RCT; • to set up the cluster-RCT; and • to formally evaluate feasibility of the intervention and progress to the cluster-RCT at a pre-specified stop point.
Target accrual:	110 critical care patients
Inclusion criteria:	<ul style="list-style-type: none"> • 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
Exclusion criteria:	<ul style="list-style-type: none"> • Glasgow Coma Score of less than 15 • Pre-existing chronic cognitive impairment, such as dementia • Pre-existing psychotic illness • Pre-existing chronic post-traumatic stress disorder • Terminally ill/receiving end-of-life care
Planned number of units:	Four adult, general critical care units
Anticipated duration of recruitment:	Intervention Feasibility Study: three months RCT Processes Pilot Study: two months
Duration of follow up:	Intervention Feasibility Study: one month RCT Processes Pilot Study: five months
Definition of end of Study:	Last patient followed-up

2 Background & rationale

Over 100,000 patients are admitted to adult, general critical care units in the National Health Service (NHS) each year and it has been estimated that around two thirds suffer serious emotional distress, and/or hallucinations and delusions, while in the unit.^{1,2} Emotional distress, including severe symptoms of anxiety, low mood and panic, may be caused by a range of stressful, cumulative experiences that are common in critical care: fear of dying; invasive treatments such as mechanical ventilation; pain and discomfort; inability to communicate; and terrifying hallucinatory delusions.^{1,3,4} The characteristic hallucinations and delusions of a critical care patient have been linked to delirium, the provision and withdrawal of sedative and other psychoactive drugs, effects of illness (such as sepsis), immobility, and sensory and sleep deprivation.^{2,4} Hallucinations and delusions are known to be exacerbated by, and co-morbid with, emotional stress; thus a vicious cycle of stress, confusion, and terror is common for critical care patients.

Experiencing acute psychological stress in the critical care unit, or having frequent memories of hallucinations and delusions, are also among the strongest identified risk factors for longer-term post-critical care posttraumatic stress disorder (PTSD), depression or anxiety.⁴⁻⁷ The most recently published systematic review of survivors of critical care³ identified rates of PTSD up to 27%, months or years after leaving critical care, with rates varying by studies' risk of bias. These results are consistent with a previous systematic review, which found a median prevalence of "clinically significant" PTSD symptoms of 22%.⁸ High rates (40%) of onset of depression following critical care have also been reported, as much as two years later.⁹ Patients who develop serious psychological morbidities are at much higher risk of further physical morbidities and mortality¹⁰⁻¹² representing a serious burden to patients, to their carers and to the NHS.^{13,14}

It is more than a decade since the Department of Health explicitly recognised this serious problem, stating in the year 2000 that critical care was extremely distressing for patients and that there was considerable need for psychological support for traumatised patients.¹⁵ In 2009, the National Institute for Health and Care Excellence (NICE) recommended that all critically ill patients should be assessed for risk of non-physical morbidity, and that those at high risk of adverse outcomes such as PTSD, should receive structured psychological support, both during and after their unit stay.¹⁶ NICE guidance on the diagnosis, prevention and management of delirium recommends that patients identified as being at high risk of delirium (including all critically ill patients), should be monitored closely, and strategies for intervention implemented as soon as possible.¹⁷ Even more recently, in 2012, NICE has highlighted the importance of patients being regularly assessed for psychological needs, so that these can be rapidly addressed.¹⁸

Rigorous and relevant evidence is now urgently needed to reduce the burden of serious psychological morbidity on critical care patients and their carers, and cost effective strategies are needed to reduce the burden on the NHS. The modification of clinical risk factors for PTSD such as duration of mechanical ventilation and sedation have been discussed in the literature,^{19,20} but less invasive medical interventions or better drugs are not currently available. Yet little high-quality research has been conducted to evaluate psychological interventions that could alleviate the emotional distress experienced by patients in critical care, with a view to preventing longer-term psychological morbidity.²¹ An unpublished systematic review²² of 15 studies, found mostly weak and some moderate evidence that non-pharmacological interventions including music therapy, complementary therapy or patient diaries could reduce short-term distress for critical care patients. Only the patient diary intervention was shown to have an effect on longer-term psychological outcomes in a sufficiently large sample. However, this intervention targets critical care patients' memory gaps rather than stress, and has been critiqued for its lack of a solid psychological theoretical underpinning.²³

However, recent advances in the study of critical care psychology have made the evaluation of psychological interventions for the critically ill more feasible. Valid psychological assessment tools now exist for use with critical care patients, including a tool measuring critical care-related distress (the Intensive Care Psychological Assessment Tool ((appendix B)) that was developed and validated by our research team.^{24,25} With respect to the best timing to provide psychological interventions for critical illness survivors, research suggests that post-discharge (e.g. at six weeks²⁶ or at outpatient follow-up clinics¹⁴) may be too late, and earlier intervention could be more beneficial. For example, a study with critically ill trauma patients indicated that considerably fewer individuals experienced PTSD, depression or anxiety a year after critical care, having received psychological interventions while in the

critical care unit.²⁷ In today's NHS, clinical psychologists are a scarce resource, and a more pragmatic approach would be to standardise brief evidence-based psychological interventions to be carried out by existing critical care staff, who would be given the necessary training.

Aiming to develop a nurse-led psychological intervention for critical care unit patients that would commence before they leave the unit, our research team has identified the most relevant, up-to-date evidence concerning psychological techniques that are effective in: a) reducing acute emotional distress; b) reducing the impact of psychosis-like symptoms; and c) preventing PTSD after a trauma (the triad of psychological problems most associated with admission to critical care). The evidence is summarised below:

Interventions comprising Cognitive Behavioural Therapy (CBT) techniques have been found to be effective in reducing many types of emotional distress in both physical and mental health settings. Studies have evaluated CBT as effective even when delivered in brief form, or by non-expert staff (including nurses) who receive specific training. For example, a randomised controlled trial (RCT) showed that twice as many patients with excessive health anxiety (HA) who received brief CBT from newly-trained, non-expert clinical staff in medical clinics, achieved normal HA levels, compared to a control group.²⁸

A specific CBT model has also proved effective in reducing the impact of symptoms such as hallucinations and delusions in patients with psychosis.²⁹⁻³³ CBT for psychosis (CBTp) interventions have proved to be particularly effective in cases of early, first episode or acute psychosis, which equate most closely to the critical care experience.^{34,35} Recent CBTp research has demonstrated the efficacy of brief interventions, targeting specific symptoms such as delusions.³⁶ CBTp has also been successfully delivered by nurses and other non-expert therapists to patients with psychosis in mental health settings.³⁷⁻³⁹

Finally RCTs have shown CBT to be the most effective psychological intervention in reducing existing PTSD symptoms following different types of trauma, including episodes of psychosis.^{40, 41} There is also increasing evidence that *early* interventions soon after a trauma may help to *prevent* PTSD symptoms from developing in the longer-term. A recent update to the NICE PTSD guidelines⁴² states specifically that a brief trauma-focused psychological intervention of three sessions, delivered in the period immediately after a trauma, may reduce the development of subsequent PTSD symptoms.

Given that these existing evidence-based psychological interventions could be modified to reduce the stress and trauma experienced by critical care unit patients, and be delivered by highly trained/motivated critical care nurses, there is an urgent need to evaluate their effectiveness in the critical care setting. Increasing psychological support may also provide a further benefit to patients and the NHS by permitting a reduction in use and duration of pharmacological sedation.

The POPPI Study (Psychological Outcomes following a nurse-led Preventative Psychological Intervention for critically ill patients) is a 46-month project with the aim to evaluate the clinical and cost-effectiveness of a complex psychological intervention to reduce patient-reported PTSD symptom severity and assess other psychological morbidities and quality of life at six months. The POPPI Study consists of two phases – a feasibility study and a cluster-RCT. This protocol is for the POPPI Feasibility Study.

3 Study Overview

The POPPI Feasibility Study has six objectives:

1. to develop an education package (training and associated materials) as part of a proposed complex psychological intervention;
2. to pilot test the intervention, including the education package;
3. to refine the intervention, including the education package;
4. to pilot test the feasibility of all proposed processes and procedures for the cluster-RCT;
5. to set up the cluster-RCT;
6. to formally evaluate the feasibility of the intervention and progress to the cluster-RCT at a pre-specified stop point.

Objective 1

The education package will be developed by Dr Dorothy Wade and the clinical team at UCLH with expert advisors (Dr Vaughan Bell – a clinical psychologist and expert trainer in CBT for psychosis – and Dr Dane Goodman – an expert in medical and nursing education) and Expert Psychology Advisory Group (EPAG) comprising study investigators and independent experts (see: Section 6.3).

Objectives 2 to 4

Objectives 2 to 4 will be addressed in two feasibility sub-studies conducted in four adult, general, critical care units:

- the Intervention Feasibility Study will be conducted in two adult, general critical care units and will address objectives 2 to 3 (see: Section 4); and
- the RCT Processes Pilot Study will be conducted in two adult, general critical care units and will address objective 4 (see: Section 5).

Objective 5

An application to the Health Research Agency National Research Ethics Service for the cluster-RCT (with an integrated process evaluation and economic evaluation), following preparation of a protocol and related study documentation, will be submitted. Twenty four critical care units will be invited to participate in the cluster-RCT, excluding the two units taking part in the Intervention Feasibility Study. Following approval from the Research Ethics Committee, applications will be made to the research & development (R&D) departments of each Trust for each of the 24 critical care units. Investigator Site Files (ISFs) containing all essential documents (including standard operating procedures) and other supportive materials (e.g. posters, pocket cards) for the cluster-RCT will be prepared. A dedicated, secure web-based data entry system will be set up to enable local data entry and validation.

Objective 6

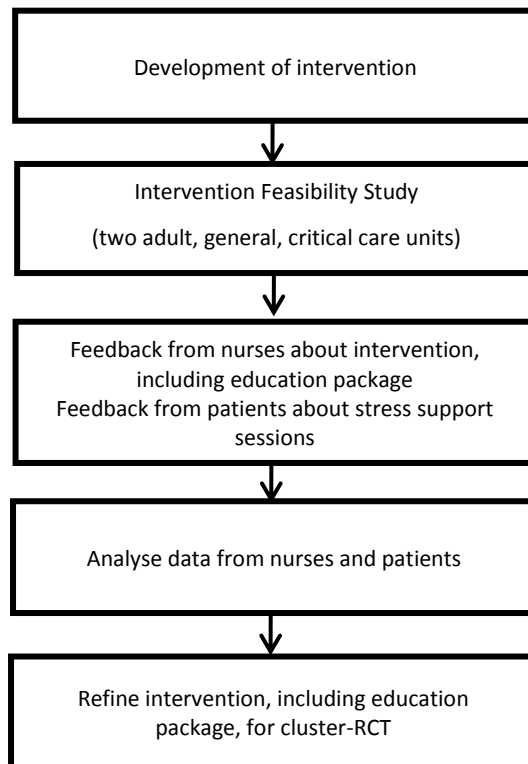
At the end of the Feasibility Study, there is a formal stop point at which a decision will be made whether to progress to the cluster-RCT based on the feasibility of the intervention and feasibility of the processes and procedures for the cluster-RCT have been demonstrated. A formal feasibility report will be prepared for the NIHR HS&DR programme and submitted at the end of the Feasibility Study. Feasibility will be assessed against the following reported criteria for continuation:

- development of all required materials for the intervention, including the education package;
- delivery of the education package to participating sites;
- completion of the Intervention Feasibility Study to pilot test the intervention (confirmation of acceptability and feasibility of the intervention);
- enrolment into the RCT Processes Pilot Study;
- collection of outcome data in the RCT Processes Pilot Study;
- confirmation of excess treatment costs for the cluster-RCT; and
- sign-up of the required sites for the cluster-RCT, including satisfactory progress with obtaining governance approvals.

4 Intervention Feasibility Study

4.1 Study design

Figure 1. Overview of study design



4.2 Study setting

Two NHS adult, general, critical care units.

4.3 Eligibility criteria

Inclusion

- 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 Scale⁴³
- English-speaking and ability to communicate orally

Exclusion

- Glasgow Coma Score of less than 15
- Pre-existing chronic cognitive impairment, such as dementia
- Pre-existing psychotic illness
- Pre-existing chronic PTSD
- Terminal illness/receiving end-of-life care

4.4 Screening and informed consent

All patients in participating critical care units will be routinely screened for eligibility by unit staff. Patients who meet the eligibility criteria will be invited by an authorised staff member (on the POPPI Delegation Log) to take part in the study. The patient will be provided with written information about the study which will be supplemented with information provided orally. The information provided will include details about the purpose of the study, how the study is being funded, the consequences of taking part or not and data security. The contact details for the local Principal Investigator (PI) will be included on the Patient Information Sheet. Patients will be given copies of both the Information leaflet and the Patient Information Sheet. Given the severity of their illness, it is likely that most patients will find it easier to read or have read to them the Information Leaflet initially, which will refer them to the Patient Information Sheet for full details of the study. Patients will be given the opportunity to ask questions and to discuss the study with family or friends.

Patients who agree to take part in the study, after the authorised staff member is satisfied that the Patient Information Sheet has been read and understood, will be invited to sign the Consent Form. Once the patient has signed the Consent Form, the person taking informed consent will add their own name and countersign in the presence of the patient. A copy of the signed Consent Form will be given to the patient, a copy placed in the ISF, and a copy placed in the medical notes.

Patients assessed as being at high risk of psychological morbidity (see section 4.5.2) will be approached with a second Patient Information Sheet/Consent Form asking if they agree to their stress support sessions being audio-taped to assess the fidelity of the intervention. This is optional and will not preclude the patient taking part in the study. Audio tapes will be reviewed by the training team and used to provide constructive feedback to the nurses to help with their training. Audio tapes will only be made available to the training team, and will be destroyed at the end of the study. This consent form will also be countersigned by the person taking informed consent and a copy given to the patient, a copy placed in the ISF, and a copy placed in the medical notes. If a patient withdraws consent for use of their audio-tape then the audio file will be deleted and no longer used.

If a patient subsequently withdraws their consent to taking part in the study, all data collected to the point of withdrawal will be retained for the analysis, however no further follow-up or outcome data will be collected unless agreed with the patient.

Standard operating procedures (SOPs) for screening and informed consent will be provided in the ISF.

4.5 Intervention

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).

4.5.1 Education package

The education package consists of two modules.

Module 1 (part A)

Module 1 (part A) is a three-day central training course for three critical care nurses from each participating critical care unit – the POPPI nurses. As part of the module, appropriate materials will be provided that cover:

- understanding and practising therapeutic communication styles and CBT-inspired psychological techniques to deal with distress;
- how to conduct one-to-one stress support sessions for high risk patients (see: Section 4.5.2) - training manuals with clear guidelines on the content of the three stress support sessions will be provided;
- guidance on assessing patient distress using visual analogue scales (VAS) and the IPAT;
- advice on encouraging culture change in their unit by ensuring that all clinical staff complete Module 2 of the education package (an e-learning course) and with information provided on posters and other materials.

On completion of Module 1 (part A), the POPPI nurses will return to their critical care units to oversee delivery of Module 2 of the education package and one-to-one stress support sessions (see: Section 4.5.2) to patients who consent to take part in the study and are assessed as being stressed and at high risk of psychological morbidity.

Module 2

Module 2 is an e-learning course for all critical care staff. The objectives of the course are:

- to learn to create a calm, less stressful environment with good communication in the unit (culture change); and
- to learn to screen patients for psychological distress using the IPAT.

The e-learning course will take approximately 40 minutes to complete and comprises five sections:

1. Understanding intensive care patients' stress (including using the IPAT);
2. Reducing stress and fear in intensive care;
3. Communicating with distressed or fearful intensive care patients;
4. Inspiring intensive care patients with confidence and hope;
5. Online knowledge test and course evaluation.

The POPPI nurses will encourage culture change in their unit to ensure a therapeutic environment is created by ensuring that all critical care staff complete the e-learning course and through micro-teaching clinical staff at the bedside. In addition, they will ensure that POPPI materials are clearly displayed (e.g. posters) and distributed (e.g. clip-on cards) throughout the unit.

Module 1 (part B)

Approximately one month after completing Module 1 (part A), the POPPI nurses will attend the Module 1 (part B), a one-day central course for feedback, supervision and competency testing.

4.5.2 Delivery of one-to-one stress support sessions

All participating patients who are assessed as being distressed and at high risk of psychological morbidity (scoring 7 or more on the IPAT) will receive three one-to-one stress support sessions delivered by the POPPI nurses. The aims of the sessions are:

- to reduce stress, fear and intrusive memories of critical care before the patient leaves hospital; and
- to help patients find a path to psychological recovery and well-being after their stay in critical care.

To achieve these aims, the POPPI nurses' objectives during the stress support sessions will be:

- to develop a trusting relationship with the patient;
- to help the patient open up to discuss worries and fears; and
- to make links between stressful experiences in the critical care unit and the patient's psychological reactions.

The three stress support sessions will be structured as follows:

Session 1: rapport building; normalising common stress responses in the critical care unit; psycho-education about common causes of distress in the critical care unit; identifying patient's individual worries and fears; setting homework to practise coping strategies using a tablet computer.

Session 2: individual normalising of patient's most stressful and unusual experiences and education about likely causes; distinguishing realistic and unrealistic fears; increasing control and information to help coping with realistic fears; re-thinking and re-evaluating unrealistic fears; homework – practising a “test your fears” technique.

Session 3: review of key messages; safe-place imagery exercise; summarising to create context and collaborating on a staying calm plan; providing patient with a “Getting well, staying well” booklet and DVD of materials from the tablet computer; arranging follow-up.

For patients who consent, audio recording of the three one-to-one stress support sessions will be carried out by the POPPI nurse. This is to enable fidelity of delivery of the stress support sessions to be assessed by independent assessors (Appendix N). The aim is for 18 stress support sessions with six patients to be audio recorded for independent assessment.

All patients who receive one-to-one stress support sessions will receive a follow-up call from the POPPI nurse within one month of the first session to see how they are feeling.

4.6 Outcomes

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.

Assessment of feasibility and acceptability for POPPI nurses

- Self-efficacy questionnaire (Appendix C) – completed before the start of the Module 1 (part A), at the end of Module 1 (part A), and at the end of Module 1 (part B);
- Key learning questionnaire (Appendix E) – completed after end of Module 1 (part A) and Module 1 (part B);
- Course feedback questionnaire on Module 1 (part A) (Appendix D) – completed after completion of Module 1 (part A); and
- Focus groups on the feasibility and acceptability of the intervention – completed after the completion of intervention period for last patient recruited.

All critical care staff completing the e-learning course will be asked to complete a short feedback questionnaire (Appendix F) and key learning objectives questionnaire (Appendix G) at the end of the e-learning course.

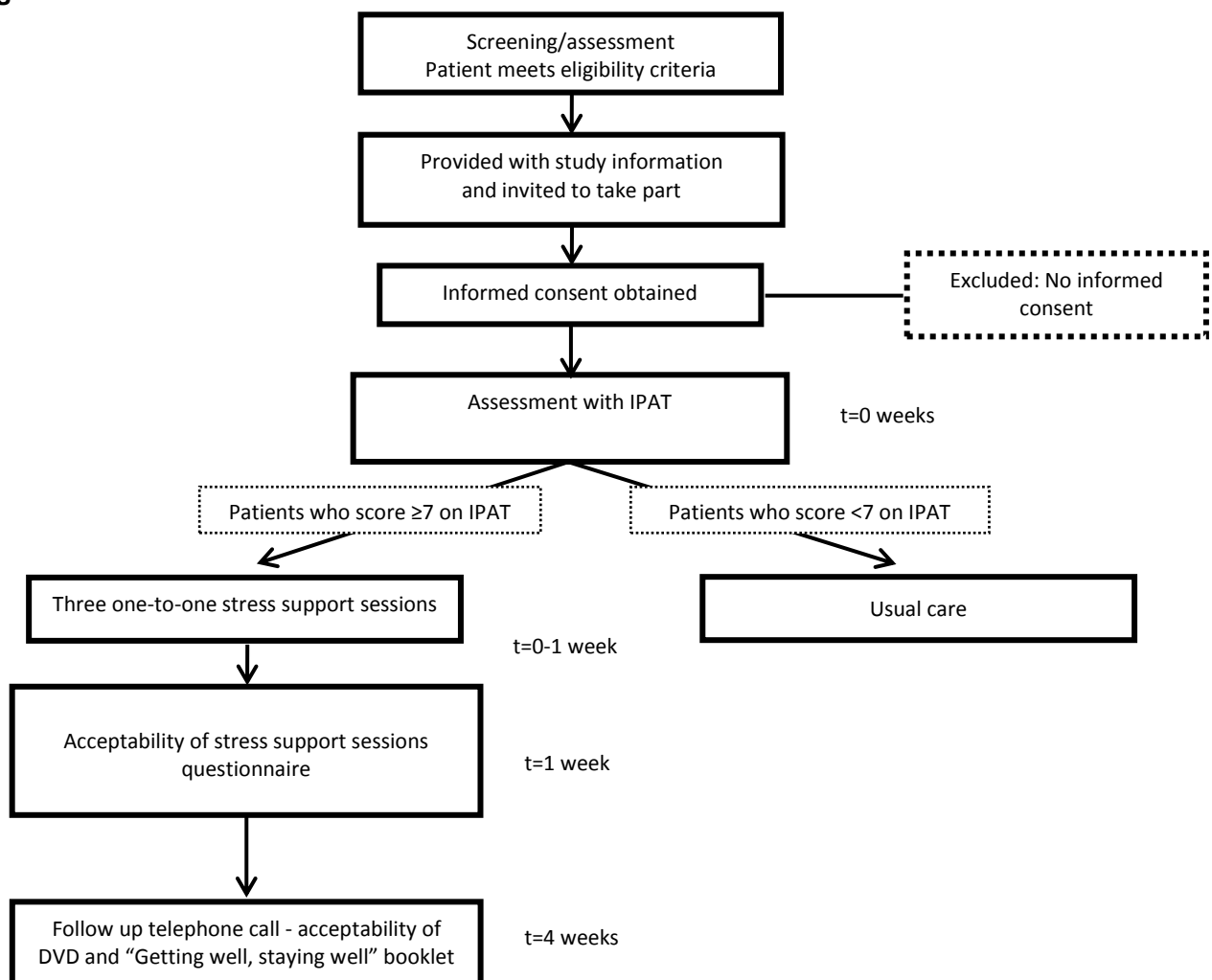
Assessment of feasibility and acceptability for patients

- Satisfaction and acceptability of the one-to-one stress support sessions after they have been delivered (Appendix H); and
- Acceptability of DVD and “Getting well, staying well” booklet one month after the three one-to-one stress support sessions (Appendix I).

4.7 Patient timeline

Eligible patients who have provided informed consent will be assessed for acute psychological stress by trained nurses using the IPAT, and assessment will take place as soon as possible (within 48 hours) following informed consent. If a patient is deemed to be distressed and at high risk of psychological morbidity (scoring 7 or more on the IPAT), and is not currently delirious as assessed by the Confusion Assessment Method for the Intensive Care Unit⁴⁴ (CAM-ICU) they will receive three one-to-one stress support sessions delivered by a POPPI nurse, ideally within one week. Following delivery of the three one-to-one stress support sessions, the patient will be asked to complete a short questionnaire about the acceptability of the stress support sessions by a research nurse. All patients who receive the one-to-one stress support sessions will receive a follow-up call from their POPPI nurse within one month of the first session. During the call the patient will be asked about the acceptability of the DVD and “staying well, getting well” booklet they were given. Patients who were deemed to be at a low risk of psychological morbidity (scoring 6 or less on the IPAT) will receive usual care in the hospital..

Figure 2. Patient timeline



4.8 Sample size

It is anticipated that approximately 66 patients will be recruited into the Intervention Feasibility Study based on an average recruitment rate of 11 patients per month at each of the two participating critical care units. Anticipated recruitment is based on robust data from the Case Mix Programme (CMP), combined with data from previous and ongoing clinical trials among critically ill patients. The CMP is the national clinical audit of adult critical care coordinated by ICNARC, which is ongoing in over 200

adult, general, critical care units in England, Wales and Northern Ireland (over 90%). We are therefore confident that the recruitment rate presented represents a good estimate of the average for a typical critical care unit.

4.9 Data collection methods

Data will be collected from patients, the POPPI nurses and critical care staff during the study period.

Patient data

All patients

- Baseline: basic demographic and clinical data.
- IPAT assessment.

Patients scoring 7 or more on IPAT

- After completion of the three one-to-one stress support sessions: satisfaction and acceptability of the stress support sessions questionnaire.
- One month after the stress support sessions: acceptability of the DVD and “Getting well, staying well” booklet questionnaire.

Clinical critical care staff data

POPPI nurses

- Before Module 1 (part A): basic demographic data and self-efficacy questionnaire – completed by nurses.
- At end of Module 1 (part A): self-efficacy, key learning objectives and course feedback questionnaires – completed by nurses. Competency ratings scale (Appendix N) – completed by assessors.
- During Module 1 (part B): competency ratings scale – completed by assessors.
- At the end of Module 1 (part B): self-efficacy and key learning objectives questionnaires – completed by nurses.
- During the three one-to-one stress support sessions: fidelity ratings scale (audio tapes) (Appendix O) – completed by assessors.
- At the end of recruitment: qualitative data from focus groups on the feasibility and acceptability of the intervention.

Figure 3. POPPI nurses data schedule

	Before Module 1 (part A)	End of Module 1 (part A)	During Module 1 (part B)	End of Module 1 (part B)	During stress support sessions	End of recruitment period
Completed by POPPI nurses						
Demographic data	✓					
Self-efficacy Questionnaire	✓	✓		✓		
Key learning objectives questionnaire		✓		✓		
Course feedback questionnaire		✓				
Attend focus group						✓
Completed by assessors						
Competency ratings scale		✓	✓			

Fidelity ratings scale					✓	
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All staff data

- End of e-learning module: number (%) and demographics of critical care staff completing module; feedback and key learning objectives questionnaire; knowledge test; number of attempts to pass knowledge test and number (%) of those who passed the test.

4.10 Statistical methods

Descriptive analysis will be conducted to assess the objectives of the POPPI Feasibility Study.

Changes in the POPPI nurses' self-efficacy in psychological support skills and key learning objectives will be evaluated to ensure improvement. Based on 66 patients recruited, we anticipate that approximately 33 patients will be assessed as being distressed and at high risk of psychological morbidity, and will therefore receive three one-to-one stress support sessions.

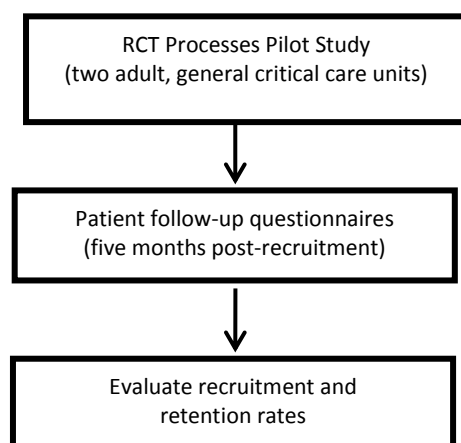
4.11 Post-study care

If a participating patient shows signs of serious distress at the end of the three one-to-one stress support sessions with the POPPI nurse (scoring 7 or more on the IPAT) or on the follow-up phone call at one month, the medical team responsible for the patient will be informed.

5 RCT Processes Pilot Study

5.1 Study design

Figure 4. Overview of study design



5.2 Study setting

Two NHS adult, general critical care units.

5.3 Eligibility criteria

Inclusion

- 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 Scale⁴³
- English-speaking and ability to communicate orally.

Exclusion

- Glasgow Coma Score of less than 15
- Pre-existing chronic cognitive impairment, such as dementia
- Pre-existing psychotic illness
- Pre-existing chronic PTSD
- Terminal illness/receiving end-of-life care

5.4 Screening and informed consent

All patients in participating critical care units will be routinely screened for eligibility by unit staff. Patients who meet the eligibility criteria will be invited by an authorised staff member (on the POPPI Delegation Log) to take part in the study. The patient will be provided with written information about the study which will be supplemented with information provided orally. The information provided will include details about the purpose of the study, how the study is being funded, the consequences of taking part or not and data security. The contact details for the local PI will be included on the Patient Information Sheet. Patients will be given copies of both the Information Leaflet and the Patient Information Sheet. Given the severity of their illness, it is likely that most patients will find it easier to read or have read to them the Information Leaflet initially, which will refer them to the Patient Information Sheet for full details of the study. Patients will be given the opportunity to ask questions and to discuss the study with family or friends.

Patients who agree to take part in the study, after the authorised staff member is satisfied that the Patient Information Sheet has been read and understood, will be invited to sign the Consent Form. Once the patient has signed the Consent Form, the person taking informed consent will add their own name and countersign in the presence of the patient. A copy of the signed Consent Form will be given to the patient, a copy placed in the ISF, and a copy placed in the medical notes.

If a patient subsequently withdraws their consent to taking part in the study, all data collected to the point of withdrawal will be retained for the analysis, however no further follow-up or outcome data will be collected unless agreed with the patient.

SOPs for screening and informed consent will be provided in the ISF.

5.5 Intervention

Recruited patients will continue to receive usual care in the critical care unit.

5.6 Outcomes

The main outcomes are feasibility of estimated recruitment and retention rates.

Assessment of feasibility of estimated recruitment rate:

- At the end of the recruitment period: assessment of study screening and recruitment logs for numbers of eligible patients identified and approached, and of these, the number who consented to take part.

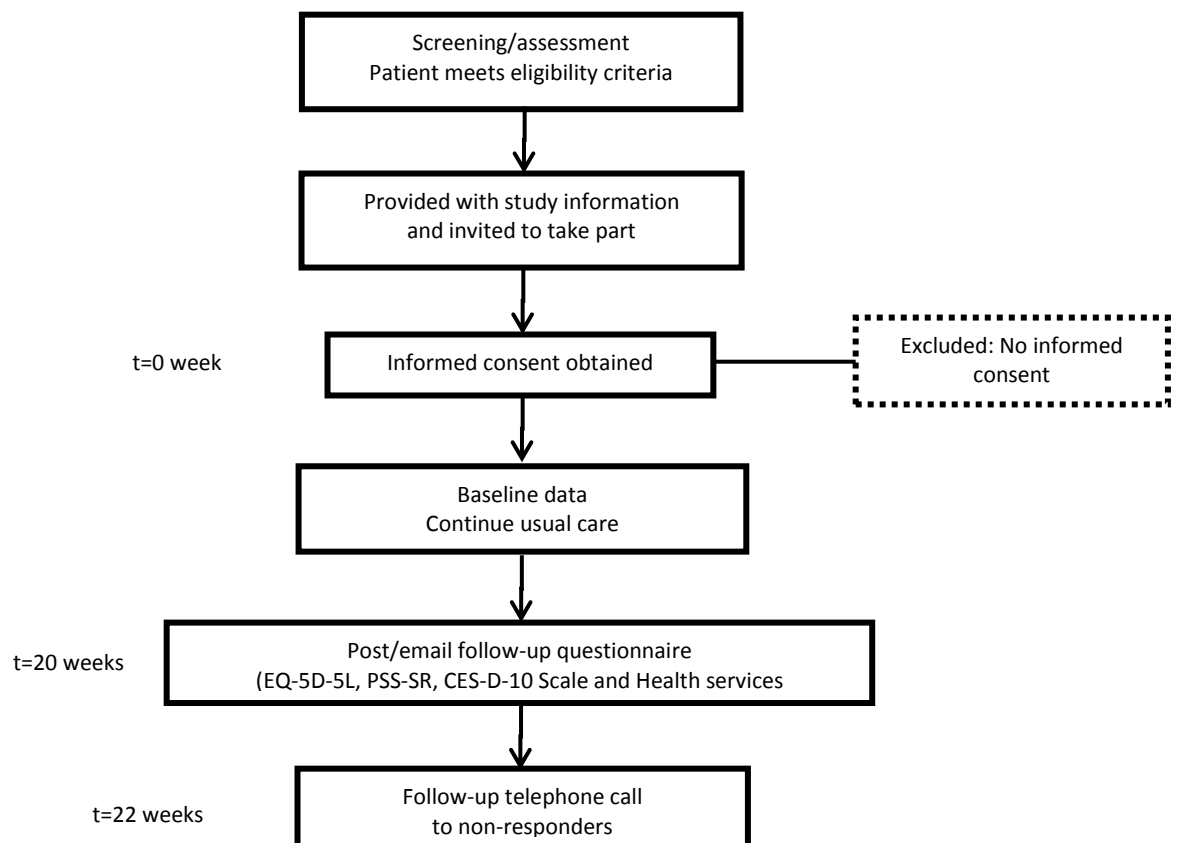
Assessment of feasibility of estimated retention rate:

- At the end of the follow-up period the proportion of patients who returned a follow-up questionnaire and the method of return (e.g. via post, email and/or following a telephone call) will be assessed.
- The completeness of questionnaires will be assessed.

5.7 Patient timeline

Eligible patients who provide informed consent will continue to receive usual care in the critical care unit. Five months after recruitment into the study, a questionnaire will be sent to the patient either via post or email, depending on their preference, from the ICNARC CTU. The questionnaire will include the EuroQoL health questionnaire (EQ-5D-5L) (Appendix K), PTSD Symptom Severity Scale – Self-Report version⁴⁷ (PSS-SR) (Appendix I – Patient emotional reactions questionnaire), Centre for Epidemiologic Studies Depression Scale (short form)⁴⁸ (CES-D-10) (Appendix K – Patient mood questionnaire) and Health Services questionnaire (Appendix M). Questionnaires sent by post will include a pen and a stamped addressed envelope. Non-responders will be telephoned two weeks later to check that the questionnaire has been received. Patients will be given the option to complete the questionnaire over the telephone.

Figure 5. Patient timeline



5.8 Sample size

It is anticipated that approximately 44 patients will be recruited into the RCT Processes Pilot Study based on an average recruitment rate of 11 patients per month at each of the two participating critical care units. Anticipated recruitment is based on robust data from the CMP. We are therefore confident that the recruitment rate presented represents a good estimate of the average for a typical critical care unit.

5.9 Data collection methods

Data will be collected on all participating patients during the study period.

- Baseline: basic demographic and clinical data, contact details (i.e. postal address, email address, telephone number).
- Five months post recruitment: follow-up questionnaire containing the EQ-5D-5L, PSS-SR, CES-D-10 and Health Services questionnaire.

5.10 Statistical methods

A descriptive analysis will be conducted. The feasibility of the anticipated sample size for the cluster-RCT will be assessed using data from the study screening and recruitment logs. Retention in the study will be assessed by examining the proportion of follow-up questionnaires returned and the method of return (via post, email or telephone). The completeness of the questionnaires will be examined to inform the feasibility of follow-up using the EQ-5D-5L, PSS-SR, CES-D-10 and Health Services questionnaire.

5.11 Post-study care

Completed follow-up questionnaires received will be reviewed on receipt at the ICNARC CTU. If the questionnaire data indicates that the patient is showing signs of serious stress or depression, the patient's GP or the site's POPPI Principal Investigator will be informed (using the 'Referral Letter') from Dr Dorothy Wade, Lead Clinical Investigator for the POPPI Study, depending on which method is deemed most appropriate for the site and individual.

6 Monitoring and oversight

6.1 Study Management Group

As Chief investigator, Professor Kathy Rowan will take overall responsibility for study management and overseeing progress against timelines/milestones. Professor Rowan will work closely with Dr Wade, as Lead Clinical Investigator, and Dr Sheila Harvey, as CTU Manager and Senior Research Fellow.

All day-to-day management of the POPPI Feasibility Study will be the responsibility of the Study Management Group (SMG which will include Dr Wade, Dr Harvey, Mr John Welch, Ms Deborah Smyth, Mr Paul Mouncey (POPPI Trial Manager) and the POPPI Research Assistants based at UCLH and ICNARC. The SMG will meet regularly to review progress of the study against timelines/milestones.

6.2 Expert Psychology Advisory Group

The Expert Psychology Advisory Group (EPAG) will oversee the POPPI Feasibility Study and comprise study investigators (Dr Wade, Professor Chris Brewin, Professor John Weinman, Miss Deborah Smyth, Mr John Welch and Dr Sheila Harvey), independent experts (Dr Vaughan Bell and Dr Dane Goodson) and patient representatives (Nicole Als and Margaret Harvey). The EPAG will be chaired by an independent expert in CBT for psychosis, Professor Daniel Freeman. The EPAG will meet every two months to provide expert advice on refinement and piloting of the intervention and to monitor progress of the study against timelines/milestones.

7 Ethical Approval

7.1 Research ethics approval

This protocol, patient information sheets, informed consent forms and other study-related documents will be reviewed and approved by the Sponsor and Research Ethics Committee with respect to scientific content and compliance with applicable research regulations involving human subjects.

7.2 Protocol amendments

Any modification to the protocol and/or study-related documents which may impact on the conduct of the study, potential benefit to patients or patient safety will require a formal amendment to the protocol. Such amendments will be agreed by the Sponsor, SMG and EPAG and approved by the Research Ethics Committee. Administrative changes of the protocol, which have no impact on the conduct of the study or patient safety, will be agreed by the Sponsor, SMG and EPAG. The Research Ethics Committee will be notified but formal approval will not be required.

8 Confidentiality

The POPPI Feasibility Study will be managed according to the Medical Research Council's (MRC) Guidelines for Good Clinical Practice in Clinical Trials and Good Research Practice: Principles and Guidelines, which are based on the principles of the International Conference on Harmonisation (ICH) Good Clinical Practice (GCP). The ICNARC CTU has developed its own policies and procedures, based on these MRC guidelines, for the conduct of all its research activities. In addition, ICNARC has contractual confidentiality agreements with all members of staff. Policies regarding alleged scientific misconduct and breach of confidentiality are reinforced by disciplinary procedures.

Identifiable patient data, including full name, postal address, email address (if applicable), date of birth and NHS number will be required by the ICNARC CTU to successfully follow-up patients at five months post-recruitment. The ICNARC CTU will act to preserve patient confidentiality and will not disclose or reproduce any information by which patients could be identified. Any patient identifiable data leaving the hospital will be encrypted to ensure anonymity. All procedures for handling, processing, storing and destroying data are compliant with the Data Protection Act 1998.

9 Declaration of interests

None.

10 Sponsorship and Indemnity

ICNARC is the Sponsor for the POPPI Feasibility Study and holds professional indemnity insurance (Markel International Insurance Co Ltd) to meet the potential legal liability of the Sponsor and employees for harm to participants arising from the design and management of the research.

Indemnity to meet the potential legal liability of investigators/collaborators for harm to participants arising from the conduct of the research is provided by the NHS indemnity scheme or through professional indemnity.

11 Dissemination policy

The progress and results of the POPPI Feasibility Study will be widely and actively disseminated.

11.1 Progress of study

To ensure all stakeholders are kept aware and informed, ongoing progress of the POPPI Feasibility Study will be disseminated to: participating units through newsletters, emails and telephone; to the wider critical care community through relevant professional newsletters, professional meetings and national and international conferences; and to consumers via the ICNARC website.

11.2 Study results

A formal report of the POPPI Feasibility Study will be prepared and submitted to the NIHR HS&DR programme at the end of the feasibility phase detailing feasibility, assessed against the predefined criteria detailed in Section 3, for continuation to the cluster-RCT.

The results of the POPPI Feasibility Study will be submitted to relevant peer-review journals for publication.

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Appendix A: Protocol version history

Protocol:		Amendments:		
Version no.	Date	Amendment no.	Protocol Section (no./title)	Summary of main changes from previous version.
v1.0	21/02/2014	N/A	N/A	N/A
v1.1	14/04/2014	N/A	N/A	Update of sections in response to NRES committee requests
v1.2	07/05/2014	1	5: RCT Processes Pilot Study	Increase of follow up period from two to five months
v1.3	16/09/2014	2	4: Intervention Feasibility Study 4.4 Screening and informed consent 4.7 Patient timeline	Introduction of a two stage consent process. STAI and PHQ-2 assessments removed

Appendix B: Intensive Care Psychological Assessment Tool (IPAT)

I would like to ask you some questions about your stay in intensive care, and how you've been feeling in yourself. These feelings can be an important part of your recovery. To answer, please circle the answer that is closest to how you feel, or answer in any way you are able to, e.g. by speaking or pointing.

	Since you've been in intensive care:	A	B	C
1	Has it been hard to communicate?	No	Yes, a bit	Yes, a lot
2	Has it been difficult to sleep?	No	Yes, a bit	Yes, a lot
3	Have you been feeling tense?	No	Yes, a bit	Yes, a lot
4	Have you been feeling sad?	No	Yes, a bit	Yes, a lot
5	Have you been feeling panicky?	No	Yes, a bit	Yes, a lot
6	Have you been feeling hopeless?	No	Yes, a bit	Yes, a lot
7	Have you felt disorientated (not quite sure where you are)?	No	Yes, a bit	Yes, a lot
8	Have you had hallucinations (seen or heard things you suspect were not really there)?	No	Yes, a bit	Yes, a lot
9	Have you felt that people were <i>deliberately</i> trying to harm or hurt you?	No	Yes, a bit	Yes, a lot
10	Do upsetting memories of intensive care keep coming into your mind?	No	Yes, a bit	Yes, a lot

Do you have any comments to add in relation to any of the answers?

SCORING

Any answer in column A = 0 points

Any answer in column B = 1 point

Any answer in column C = 2 points

Sum up the scores of each item for a total I-PAT score out of 20

Cut-off point ≥ 7 - indicates patient at risk

Appendix C: POPPI nurse training - self-efficacy questionnaire (skills)

To answer each question please circle a number between 1 and 5, where 1 = not at all confident, and 5 = completely confident.

How confident do you feel about:

1. Establishing rapport and a supportive relationship with awake intensive care patients?

1	2	3	4	5
Not confident at all		Moderately confident	Completely confident	

2. Encouraging patients to open up about their worries and fears?

1	2	3	4	5
Not confident at all		Moderately confident	Completely confident	

3. Helping patients to talk about unusual psychological experiences (e.g., hallucinations or delusions)?

1	2	3	4	5
Not confident at all		Moderately confident	Completely confident	

4. Educating patients about common psychological responses to intensive care and possible causes?

1	2	3	4	5
Not confident at all		Moderately confident	Completely confident	

5. Helping patients to use strategies for coping with acute stress in intensive care?

1	2	3	4	5
Not confident at all		Moderately confident	Completely confident	

6. Helping critical care patients to feel calm, confident, safe, hopeful and connected to others?

1	2	3	4	5
Not confident at all		Moderately confident	Completely confident	

7. Preparing patients to deal with any worries and concerns they may face in their recovery period after leaving intensive care?

1	2	3	4	5
Not confident at all		Moderately confident	Completely confident	

Appendix D: POPPI nurse training - course feedback questionnaire

For every item please give a score that most closely represents how you feel about the training course.

1. The training course was:

Stimulating	5	4	3	2	1	Boring
Useful in my role as a POPPI nurse	5	4	3	2	1	Useless
Relevant to my work as POPPI nurse	5	4	3	2	1	Irrelevant
Well conducted	5	4	3	2	1	Poorly conducted

2. Now you have completed the course, how motivated are you to use what you have learned in your new role as a POPPI nurse?

A lot	5	4	3	2	1	Not at all
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3. What did you like best about the course?

4. What did you like least about the course?

5. Do you have any suggestions about how the course could be improved?

Appendix E: POPPI nurse training – key learning questionnaire (knowledge)

The next 8 questions assess how much knowledge you have acquired during the training course:

How much have you learned about:

1. Common stressful experiences, including hallucinations and delusions in intensive care patients?

A lot	5	4	3	2	1	Nothing
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2. Methods of screening for acute distress and unusual psychological experiences in intensive care?

A lot	5	4	3	2	1	Nothing
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3. The background and aims of the three POPPI stress support sessions?

A lot	5	4	3	2	1	Nothing
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4. The use of “guided discovery” to enable patients to find their own solutions, rather than “telling” them or “giving advice”?

A lot	5	4	3	2	1	Nothing
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5. The value of “psychoeducation” and “normalising” to increase patient’s understanding of common psychological reactions and possible causes in intensive care?

A lot	5	4	3	2	1	Nothing
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6. The connection between negative ways of thinking, and feeling more stressed?

A lot	5	4	3	2	1	Nothing
--------------	----------	----------	----------	----------	----------	----------------

7. The theory behind the “test your fear” technique?

A lot	5	4	3	2	1	Nothing
--------------	----------	----------	----------	----------	----------	----------------

8. The rationale for using relaxation, mindfulness, or music as coping strategies for intensive care patients?

A lot	5	4	3	2	1	Nothing
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Appendix F: E-learning course – feedback questionnaire

For every item please give a score that most closely represents how you feel about the POPPI e-learning course.

1. The e-learning package was:

Stimulating	5	4	3	2	1	Boring
Useful for my everyday role	5	4	3	2	1	Useless for my everyday role
Relevant to my work	5	4	3	2	1	Irrelevant to my work
Well designed	5	4	3	2	1	Poorly designed
Just the right length	5	4	3	2	1	Too long

2. What did you like best about the course?

Factual information	Patient videos
Videos of staff-patient interactions	The quizzes and assessment
Nothing	

3. What did you like least about the course?

Factual information	Patient videos
Videos of staff-patient interactions	The quizzes and assessment
Nothing	

Do you have any comments or suggestions on how this e-learning course could be improved?

Appendix G: E-learning Course – learning objectives questionnaire

Please answer the following questions about how much you learned from the course.

To what extent have you learned about:

1. Causes of delusions and hallucinations in intensive care patients?

A lot	5	4	3	2	1	Not at all
--------------	----------	----------	----------	----------	----------	-------------------

2. Informal methods of detecting patients' distress, e.g., how to ask about patients' concerns?

A lot	5	4	3	2	1	Not at all
--------------	----------	----------	----------	----------	----------	-------------------

3. Identifying and reducing stressors and triggers of fear in the intensive care environment?

A lot	5	4	3	2	1	Not at all
--------------	----------	----------	----------	----------	----------	-------------------

4. Using the five elements of "psychological first aid" to help Intensive care patients feel calm and safe?

A lot	5	4	3	2	1	Not at all
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5. Communicating well with hallucinating/delusional patients?

A lot	5	4	3	2	1	Not at all
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Appendix H: Patient Satisfaction - acceptability of stress support sessions questionnaire

We would like to know your opinions about the stress support sessions you received from your POPPI nurse. For every item (1-10) please circle the answer in the box below it, that is closest to how you feel.

1. The sessions have helped me to express my worries and fears about my experience in intensive care.

Strongly agree	Agree	not sure	Disagree	Strongly disagree
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2. I felt the nurse understood me and was sensitive to my feelings

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
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3. The nurse told me about normal psychological experiences in intensive care, in words that I could understand

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
-----------------------	--------------	-----------------	-----------------	--------------------------

4. The sessions allowed me to think of my experience in intensive care in a different way, which made me feel less upset

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
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5. After talking to the nurse, I felt less stressed about my experience in intensive care

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
-----------------------	--------------	-----------------	-----------------	--------------------------

6. The sessions gave me useful ideas about coping with any worries and fears after leaving intensive care

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
-----------------------	--------------	-----------------	-----------------	--------------------------

7. How did you feel about the number of stress support sessions you had?

Definitely too many	Maybe too many	just right	Maybe too few	Definitely too few
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8. How did you feel about the length of the sessions?

Much too short	A bit too short	just right	A bit too long	Much too long
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9. I found the music/relaxation exercises provided on the tablet easy to use

Strongly agree	Agree	Not sure	Disagree	Strongly disagree
-----------------------	--------------	-----------------	-----------------	--------------------------

10. Overall, I think this treatment was...

Very useful	Useful	Somewhat useful	Not very useful	Not at all useful
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Comments – please feel free to provide any other comments you have below

Appendix I: Patient satisfaction - acceptability of DVD and booklet package questionnaire

1. Have you used the relaxation DVD you were given in hospital?

Not at all	Somewhat	A lot
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2. Have you found any materials from the DVD helpful?

- Breathing exercise **yes/no**
- Relaxation practices **yes/no**
- Mindfulness meditation **yes/no**
- Nature sounds **yes/no**
- Patient recovery stories **yes/no**

3. Have you read the booklet?

No	Yes, some of it	Yes, all of it
-----------	------------------------	-----------------------

4. Have you found any of the following sections of the booklet useful?

- Going to the ward/returning home **yes/no**
- The staying well programme (e.g., boosting positive feelings, improving sleep, and confidence) **yes/no**
- Advice on coping with difficulties (e.g., worries, panic, low mood, memories) **yes/no**
- Information about relaxation package **yes/no**
- Your personal staying well plan **yes/no**
- Further information and psychological support **yes/no**

Appendix J: Patient Emotional Reactions Questionnaire (PSS-SR)

These questions are about reactions people may have after intensive care.

Please circle how often a problem has bothered you **in the past month**.

1. Have you had upsetting thoughts or images about intensive care that came into your head when you didn't want them to?

Not at all	Once per week or less	2 – 4 times per week	5 or more times per week
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2. Have you had bad dreams or nightmares about intensive care?

Not at all	Once per week or less	2 – 4 times per week	5 or more times per week
-------------------	----------------------------------	---------------------------------	-------------------------------------

3. Have you relived your time in intensive care, acting or feeling as if it were happening again?

Not at all	Once per week or less	2 – 4 times per week	5 or more times per week
-------------------	----------------------------------	---------------------------------	-------------------------------------

4. Have you felt emotionally upset when you were reminded of your time in intensive care (e.g. feeling scared, angry, sad, guilty)?

Not at all	Once per week or less	2 – 4 times per week	5 or more times per week
-------------------	----------------------------------	---------------------------------	-------------------------------------

5. Have you had physical reactions when you remember your time in intensive care (e.g. breaking into a sweat, heart beating fast?)

Not at all	Once per week or less	2 – 4 times per week	5 or more times per week
-------------------	----------------------------------	---------------------------------	-------------------------------------

6. Have you tried not to think about, talk about, or have feelings about your time in intensive care?

Not at all	Once per week or less	2 – 4 times per week	5 or more times per week
-------------------	----------------------------------	---------------------------------	-------------------------------------

7. Have you tried to avoid activities, people or places that remind you of your time in intensive care?

Not at all	Once per week or less	2 – 4 times per week	5 or more times per week
-------------------	----------------------------------	---------------------------------	-------------------------------------

8. Have you found that you were not able to remember an important part of your time in intensive care?

Not at all	Once per week or less	2 – 4 times per week	5 or more times per week
-------------------	----------------------------------	---------------------------------	-------------------------------------

9. Have you had much less interest in important activities?

Not at all	Once per week or less	2 – 4 times per week	5 or more times per week
-------------------	----------------------------------	---------------------------------	-------------------------------------

10. Have you felt distant or cut off from people around you?

Not at all	Once per week or less	2 – 4 times per week	5 or more times per week
-------------------	----------------------------------	---------------------------------	-------------------------------------

11. Have you felt emotionally numb (unable to cry or have loving feelings?)

Not at all	Once per week or less	2 – 4 times per week	5 or more times per week
-------------------	----------------------------------	---------------------------------	-------------------------------------

12. Have you felt as if your future plans or hopes would not come true?

Not at all	Once per week or less	2 – 4 times per week	5 or more times per week
-------------------	----------------------------------	---------------------------------	-------------------------------------

13. Have you had trouble falling or staying asleep?

Not at all	Once per week or less	2 – 4 times per week	5 or more times per week
-------------------	----------------------------------	---------------------------------	-------------------------------------

14. Have you felt irritable or had fits of anger?

Not at all	Once per week or less	2 – 4 times per week	5 or more times per week
-------------------	----------------------------------	---------------------------------	-------------------------------------

15. Have you had trouble concentrating (e.g. forgetting what you read, losing track of a story on television)?

Not at all	Once per week or less	2 – 4 times per week	5 or more times per week
-------------------	----------------------------------	---------------------------------	-------------------------------------

16. Have you been too alert (for example, checking to see who is around you, not being comfortable with your back to a door)?

Not at all	Once per week or less	2 – 4 times per week	5 or more times per week
-------------------	----------------------------------	---------------------------------	-------------------------------------

17. Have you been jumpy or easily startled (for example, when someone walks up behind you)?

Not at all	Once per week or less	2 – 4 times per week	5 or more times per week
-------------------	----------------------------------	---------------------------------	-------------------------------------

The next two questions are about the timing of emotional reactions people may have after intensive care.

Please circle the answer that is closest to your experience.

18. If you reported any problems in your answers to questions 1-17, how long have you experienced these problems?

Not at all	Less than 1 month	1 to 3 months	More than 3 months
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19. If you reported any problems in your answers to questions 1-17, how long after leaving Intensive care did these problems begin?

I have not had these type of problems	Less than 1 month	1 to 3 months	More than 3 months
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Appendix K: Patient Mood Questionnaire (CES-D-10)

How often you have felt any of the following during **the past week**?
Please circle one answer for each item.

1. I was bothered by things that usually don't bother me

Less than 1 day	1- 2 days	3-4 days	5-7 days
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2. I had trouble keeping my mind on what I was doing

Less than 1 day	1- 2 days	3-4 days	5-7 days
-----------------	-----------	----------	----------

3. I felt depressed

Less than 1 day	1- 2 days	3-4 days	5-7 days
-----------------	-----------	----------	----------

4. I felt that everything I did was an effort

Less than 1 day	1- 2 days	3-4 days	5-7 days
-----------------	-----------	----------	----------

5. I felt hopeful about the future

Less than 1 day	1- 2 days	3-4 days	5-7 days
-----------------	-----------	----------	----------

6. I felt fearful

Less than 1 day	1- 2 days	3-4 days	5-7 days
-----------------	-----------	----------	----------

7. My sleep was restless

Less than 1 day	1- 2 days	3-4 days	5-7 days
-----------------	-----------	----------	----------

8. I was happy

Less than 1 day	1- 2 days	3-4 days	5-7 days
-----------------	-----------	----------	----------

9. I felt lonely

Less than 1 day	1- 2 days	3-4 days	5-7 days
-----------------	-----------	----------	----------

10. I could not "get going"

Less than 1 day	1- 2 days	3-4 days	5-7 days
-----------------	-----------	----------	----------

Appendix L: Patient Health Questionnaire (EuroQoL - EQ-5D-5L)

Under each heading, please tick the ONE box that best describes your health TODAY

MOBILITY

- I have no problems in walking about ☐
- I have slight problems in walking about ☐
- I have moderate problems in walking about ☐
- I have severe problems in walking about ☐
- I am unable to walk about ☐

SELF-CARE

- I have no problems washing or dressing myself ☐
- I have slight problems washing or dressing myself ☐
- I have moderate problems washing or dressing myself ☐
- I have severe problems washing or dressing myself ☐
- I am unable to wash or dress myself ☐

USUAL ACTIVITIES *(e.g. work, study, housework, family or leisure activities)*

- I have no problems doing my usual activities ☐
- I have slight problems doing my usual activities ☐
- I have moderate problems doing my usual activities ☐
- I have severe problems doing my usual activities ☐
- I am unable to do my usual activities ☐

PAIN / DISCOMFORT

- I have no pain or discomfort ☐
- I have slight pain or discomfort ☐
- I have moderate pain or discomfort ☐
- I have severe pain or discomfort ☐
- I have extreme pain or discomfort ☐

ANXIETY / DEPRESSION

- I am not anxious or depressed ☐
- I am slightly anxious or depressed ☐
- I am moderately anxious or depressed ☐
- I am severely anxious or depressed ☐
- I am extremely anxious or depressed ☐

We would like to know how good or bad your health is **TODAY**.

This scale is numbered from 0 to 100.

100 means the **best** health you can imagine.

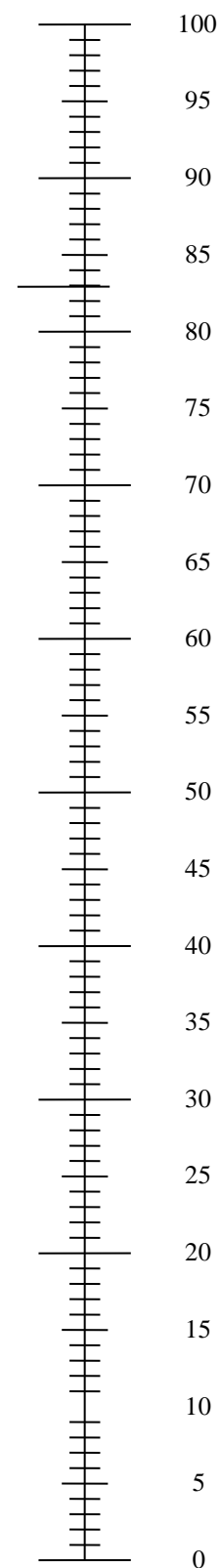
0 means the **worst** health you can imagine.

Mark an **X** on the scale to indicate how your health is **TODAY**.

Now, please write the number you marked on the scale in the box below.

YOUR HEALTH TODAY =

The best health
you can imagine



The worst health
you can imagine

Appendix M: Health Services Questionnaire

HEALTH SERVICES QUESTIONNAIRE

We would be grateful if you would complete this questionnaire. It will help us understand the care you needed after leaving the hospital.

Please answer multiple choice questions by putting a ✓ in ONE BOX for each question.

Where are you now?

<input type="checkbox"/>	At home (your own home, or a relative's home)
<input type="checkbox"/>	In residential care (e.g. nursing home or hospice)
<input type="checkbox"/>	In short-term rehabilitation
<input type="checkbox"/>	In long-term rehabilitation
<input type="checkbox"/>	In hospital
<input type="checkbox"/>	Other (please specify): <input type="text"/>

The questions refer to ALL health services that you have used since leaving the hospital on **XX/XX/XXXX**

Part 1. Hospital Stay

A Since you left hospital on **XX/XX/XXXX** have you stayed overnight in hospital for any reason?

- ☐ No - Go to Part 2
- ☐ Yes - Please give details about the number of stays below

B For EACH TIME you stayed in hospital please answer the following

	Number of nights		1-3 nights	4-10 nights	11 or more nights	Did you spend any part of your stay in critical care?
1 st Stay	<input type="text"/>	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2 nd Stay	<input type="text"/>	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
3 rd Stay	<input type="text"/>	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4 th Stay*	<input type="text"/>	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**If you have stayed in hospital overnight more than 4 times, please could you provide information on these further hospital stays in Part 6 of the questionnaire.*

Part 2. Hospital outpatient visits

Outpatient visits are when a patient comes to the hospital to see a specialist (e.g. consultant) but does not stay overnight.

A Since you left the hospital on **XX/XX/XXXX** have you visited hospital outpatients about ANY ASPECT of your health?

☐

No - Go to Part 3

☐

Yes - Please give details about the number of outpatients visit(s) below

B	Number of visits		1-3 visits		4-10 visits		11 or more visits
	<input type="text"/>	or...	<input type="checkbox"/>		<input type="checkbox"/>		<input type="checkbox"/>

Part 3. Visits to health care providers

A Since you left the hospital on **XX/XX/XXXX** have you visited any of the health care providers listed below?

☐

No - Go to Part 4

☐

Yes - Please give details about your visits below

B For EACH PROVIDER please answer the following

Did you visit this provider?	Number of visits		1-3 visits	4-10 visits	11 or more visits
GP	<input type="checkbox"/>	<input type="text"/> or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Nurse at your GP clinic	<input type="checkbox"/>	<input type="text"/> or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Nurse at hospital or elsewhere	<input type="checkbox"/>	<input type="text"/> or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Health visitor	<input type="checkbox"/>	<input type="text"/> or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Part 4. Visits to your home by health care providers

A Since you left the hospital on **XX/XX/XXXX** have you had home visits from any the following health care providers about ANY ASPECT of your health?

☐

No - Go to Part 5

☐

Yes - Please give details about your visits below

B For EACH HOME VIST please answer the following

Were you visited at home by this provider?	Number of visits		1-3 visits	4-10 visits	11 or more visits
GP	<input type="checkbox"/>	<input type="text"/> or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Nurse from your GP clinic	<input type="checkbox"/>	<input type="text"/> or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Occupational Therapist	<input type="checkbox"/>	<input type="text"/> or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Health visitor or District nurse	<input type="checkbox"/>	<input type="text"/> or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Part 5. Visits to other service providers

A Since you left the hospital on **XX/XX/XXXX** please indicate whether you have had contact (either visits to the provider or home visits) with any of the following service providers about any aspect of your health?

☐

No - Go to Part 6

☐

Yes - Please give details below

B For EACH PROVIDER please answer the following

Have you had contact with any of these providers?	Number of visits		1-3 visits	4-10 visits	11 or more visits
Occupational therapist <input type="checkbox"/>	<input type="text"/>	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Psychologist <input type="checkbox"/>	<input type="text"/>	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Speech and Language therapist <input type="checkbox"/>	<input type="text"/>	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Physiotherapist <input type="checkbox"/>	<input type="text"/>	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Dietician <input type="checkbox"/>	<input type="text"/>	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Psychiatrist <input type="checkbox"/>	<input type="text"/>	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Psychiatric nurse <input type="checkbox"/>	<input type="text"/>	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Counsellor <input type="checkbox"/>	<input type="text"/>	or...	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

Part 6. Other services not listed so far

- A Since you left the hospital on **XX/XX/XXXX** have you had further hospital stays or used ANY OTHER health care services for any aspect of your health that you haven't included above?

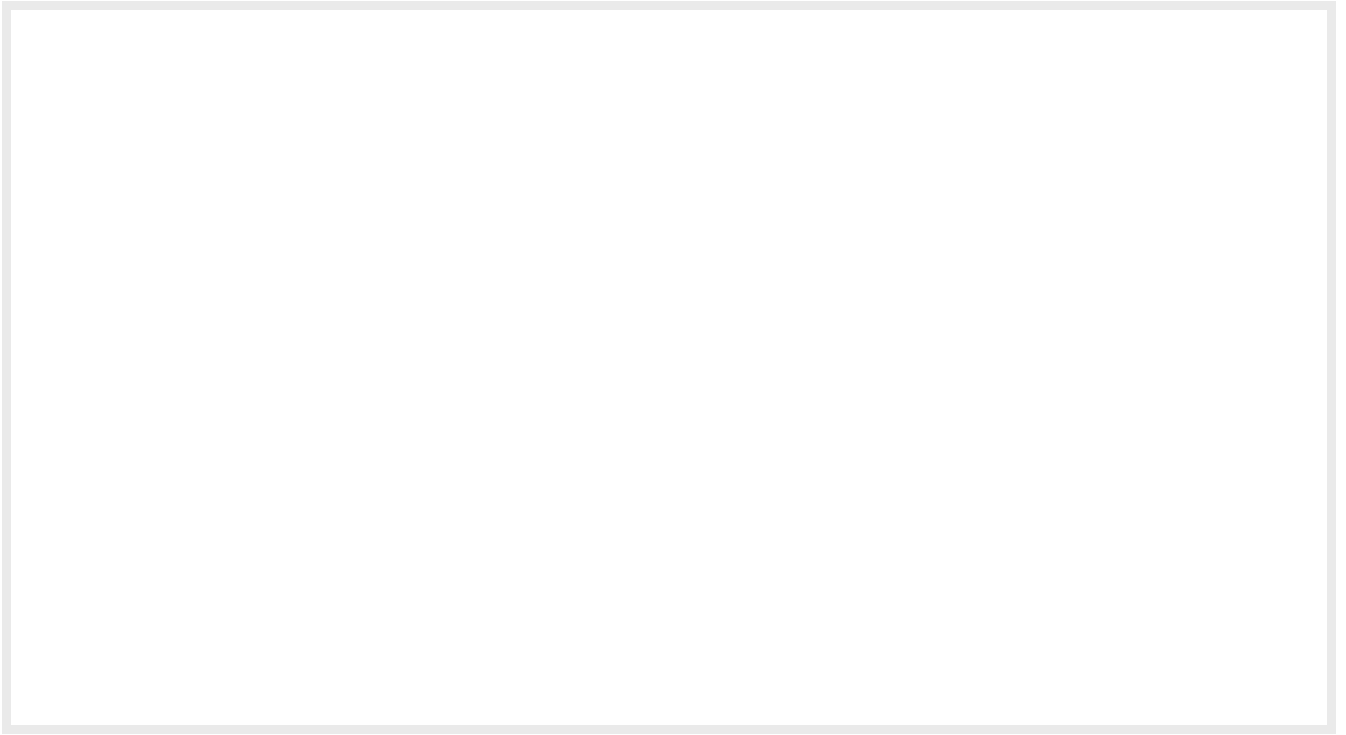
- ☐ No - Go to Part 7
- ☐ Yes - Please give details below

- B For EACH PROVIDER please answer the following

Type of service provider	Number of visits	Reason

Part 7. Comments

Your views are important to us. Please feel free to provide any other comments you have in the box below.



Appendix N: Stress support sessions - competency ratings scale

Each session is rated separately. Each item scores on a 3-point Likert scale: 0 (poor), 1 (fair), 2 (good). Items are summed to give a total competency score for each session.

Rater _____

Trainee _____

For each item rate the trainee's performance	Poor (0)	Fair (1)	Good (2)
SESSION I			
1. Provided a proper introduction to the POPPI treatment (aims, duration)			
2. Adopted an empathic, positive and supportive therapeutic style			
3. Provided a clear description of normal psychological reactions to being in to critical care			
4. Provided a clear explanation of possible causes of common psychological reactions to being in critical care			
5. Helped the patient to open up about worries and fears			
6. Guided the patient to use the safe place technique and explore the relax and recover package			
Total competency score (session I)			
SESSION II			
1. Adopted an empathic, positive and supportive therapeutic style			
2. Encouraged the patient to discuss his/her disturbing psychological experiences			
3. Normalised the patient's personal disturbing psychological experiences (including hallucinations and delusions, if relevant)			
4. Helped the patient re-evaluate stressful interpretations of their experiences			
5. Helped the patient to test his/her fears			
6. Encouraged the continued use of relaxation programme/adaptive coping strategies			
Total competency score (session II)			

SESSION III			
1. Adopted an empathic, positive and supportive therapeutic style			
2. Reviewed key messages of previous sessions (normalising, rethinking, “test your fears” method)			
3. Asked permission to share information with staff and family, to encourage “connectedness”.			
4. Summarised the work done together with the patient, putting their experience in context			
5. Created a “staying calm plan” together in an appropriate way			
6. Was able to conclude the final session (including follow-up arrangements) in an appropriate way			
Total competency score (session III)			

Further Comments:

Signed: _____

Date: _____

Appendix O: Stress support sessions - fidelity ratings scale

Each session is rated separately. Each item scores on a 3-point Likert scale, from 0 to 2. Items are summed to give a total fidelity score for each session.

Rater _____

Trainee _____

Please rate to what extent the nurse carried out the elements below during each session:	Did not carry it out (0)	Partly carried it out (1)	Fully carried it out (2)
SESSION I			
1. Provided an introduction to the POPPI treatment (aims, duration)			
2. Adopted an empathic, positive and supportive therapeutic style			
3. Provided a clear description of normal psychological reactions to being in critical care			
4. Provided a clear explanation of possible causes of common psychological reactions to being in critical care			
5. Helped the patient to open up about worries and fears			
6. Guided the patient to use the safe place technique and to explore the "relax and recover package"			
Total fidelity score (session I)			
SESSION II			
1. Adopted an empathic, positive and supportive therapeutic style			
2. Created a 'safe space' for the patient's self-disclosure of thoughts and feelings			
3. Encouraged the patient to discuss his/her disturbing psychological experiences			
4. Normalised the patient's personal disturbing psychological experiences (including hallucinations and delusions, if relevant)			

5. Helped the patient re-evaluate stressful interpretations of their experiences			
6. Helped the patient to test his/her fears			
7. Encouraged the continued use of relaxation programme/adaptive coping strategies			
Total fidelity score (session II)			
SESSION III			
1. Adopted an empathic, positive and supportive therapeutic style			
2. Reviewed key messages of previous sessions (normalising, rethinking, "test your fears" method)			
3. Asked permission to share information with staff and family, to encourage "connectedness".			
4. Summarised the work done together with the patient, putting their experience in context			
5. Created a "staying calm plan" together in an appropriate way			
6. Concluded the final session (including follow-up arrangements) in an appropriate way			
Total fidelity score (session III)			

Further Comments:

Signed: _____

Date: _____