To be printed on local hospital headed paper

Provision Of Psychological support to People in Intensive care

Patient Information Sheet

We are inviting you to take part in a research study by nurses and doctors who work in the intensive care unit. Before you decide, we would like to explain why the study is being done and what it would involve for you. **One of our team will go through this information with you and answer any questions you have.**

Section 1 (below) tells you why we are doing this study and what will happen if you take part. Section 2 explains about your legal rights if you take part in this study. Please take the time to decide whether or not you wish to take part. Feel free also to talk to your friends and family about this study.

Section 1

Why are we doing this study?

We know that the intensive care unit can be a scary, unusual and unfamiliar environment for someone to be in. This environment may be particularly hard to get used to when critically ill and receiving a lot of medicines/treatments. Quite understandably, some patients may become distressed or upset during their stay. The POPPI study aims to test one idea which may reduce this and improve the well-being of patients during and after their stay in the intensive care unit.

As part of the study, the intensive care unit team at 12 hospitals are being trained to create a calmer, less stressful environment for patients in the intensive care unit. We do not know whether this training will benefit patients – so in another 12 hospitals, the intensive care unit team have not received this training. At the end of the study, we will compare both of the groups of patients from these hospitals to see if well-being improves or not. The intensive care unit team at your hospital are providing care following their standard practice.

What will happen if I take part, and what do I have to do?

All we need from you are some contact details, and in six months' time we will post you a questionnaire. This will contain a few questions on your health and well-being. It should only take a short time (no more than 15 minutes) to complete. We will provide a stamped addressed envelope for ease of return and so there is no cost to you. If we haven't received it back after three weeks, we will telephone you to check if it

has been received. We will also ask you a few questions to see how you are feeling at the moment.

Our research team will also record a few items of information about you and your medical treatment. These will be kept completely secure and confidential.

Why have I been asked to take part in the study?
We are asking patients like you, who have stayed more than 48 hours in the intensive care unit, to take part. We are running this study with nearly 2,000 patients in 24 hospitals across the UK.

Why should I take part?
You will be part of an important study aiming to improve the well-being of intensive care unit patients.

Do I have to take part?
It is up to you if you want to take part in the study. We will leave this information sheet with you so you can discuss it with your friends and family. If you agree, then we will confirm your eligibility for the study and ask you to sign a Consent Form.

You are free to leave the study at any time, without giving a reason. This would not affect your medical care now, or in future, and no further information about you will be collected (unless you agree otherwise).

What if there is a problem?
We will take any complaint about the way you have been dealt with during the study very seriously. If you wish to complain about any aspect of the way you have been approached or treated during the course of this study, please contact the Principal Investigator (the person leading the study at this hospital) or the Hospital's Patient Advice & Liaison Service (PALS) – details on the last page.

Section 2

Involvement of the General Practitioner (GP)
We will let your GP know that you are taking part in this study. Your GP will be asked to inform the Intensive Care National Audit & Research Centre (ICNARC) if you have any significant medical events in the six months following your hospital admission. If your questionnaire shows that you are feeling very distressed, we will send another letter to your GP who should contact you to arrange an appointment.

If I take part in this study, then will it be kept confidential?
Yes. We will follow the law by making sure all your information is kept secure and never given out. To ensure that you can be contacted by the Intensive Care National Audit & Research Centre (ICNARC) in six months (as outlined in section 1), your hospital will pass on your contact details (name, address, telephone number and email address (if applicable)) to ICNARC. These will be protected and accessed only by

authorised people at ICNARC. As some patients may lose touch with their hospital, ICNARC will need to collect important basic information from NHS records held by the Health & Social Care Information Centre. To ensure you are identified correctly, we will pass on your date of birth, postcode and NHS number. These will be protected and accessed only by authorised people at ICNARC. All other details will be removed from all information leaving the NHS, so that nobody can identify you. We will follow the Data Protection Act 1998, which covers the way we handle all your information.

If possible, we would like your permission to keep your contact details you provide on file after the study has ended. This would enable us to contact you if we feel you or your data could contribute to answering other important health questions. Any data would be fully anonymised prior to being published or shared with other researchers. This aspect is completely optional.

What will happen to the results of this study?

The results of the study will appear in scientific journals. You will be able to find them on ICNARC's website (www.icnarc.org) or if you contact ICNARC by telephone (020 7269 9277). It will not be possible to identify any person who has taken part in the study in any reports or articles.

Who is funding and organising the study?

The study is funded by the National Institute for Health Research, Health Services and Delivery Research Programme. The study is being sponsored and managed by the Intensive Care National Audit & Research Centre (ICNARC).

Who has reviewed the study?

All NHS research is reviewed by an independent group of people, called a Research Ethics Committee, to protect your interests. The NRES Committee South Central - Oxford B Research Ethics Committee has checked and approved this study and given it a good report.

Thank you for taking the time to read this information sheet, it is yours to keep.

If you agree to take part in the study, then we'd like you to now sign a Consent Form.

For more information about POPPI, you can contact the Principal Investigator:

[Insert name local Principal Investigator, position]
[Contact number local Principal Investigator]

If you are unhappy with any aspect of the study:

If you do not wish to speak to the research staff listed above, please contact the Patient Advisory and Liaison Service (PALS): [Insert PALS contact details here].

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Section 1 (below) tells you why we are doing this study and what will happen if you take part. Section 2 explains about your legal rights if you take part in this study. Please take the time to decide whether or not you wish to take part. You may wish to talk to your friends and family about this study.

Section 1

Why are we doing this study?

We know that the intensive care unit can be an unusual and unfamiliar environment for someone to be in. This environment may be particularly hard to get used to when critically ill and receiving a lot of medicines/treatments. Quite understandably, some patients may become stressed or upset during their stay. The POPPI study aims to test one idea which may reduce this stress and upset, and improve the well-being of patients during and after their stay in the intensive care unit.

As part of the study, the intensive care unit team at 12 hospitals (including yours) have received training to create a calmer, less stressful environment for patients in the intensive care unit. Additionally, some nurses have received further training to support patients who are feeling particularly stressed. We do not know whether this training will benefit patients – so in another 12 hospitals the intensive care unit team have not received this training. At the end of the study, we will compare both of the groups of patients from these hospitals to see if well-being improves or not.

What will happen if I take part, and what do I have to do?

Experiences and support

If you are willing, we would like to ask you about your experiences during your stay in the intensive care unit. If your responses indicate that you may benefit from further support, one of our specially trained

nurses will offer you three support sessions. These sessions are to discuss any worries or concerns you may have and to help you cope with being in the intensive care unit. You will get to use music and relaxation exercises on a tablet computer (which the nurse will show you how to use), and receive a DVD and a booklet to take home with you.

The sessions will take up to 30 minutes each, but the nurse will be happy to finish early if you feel tired. Usually these sessions will start here on the intensive care unit, but they can continue on another ward if you move. It is up to you if you want to take part in these sessions. Your medical care will not be affected if you choose not to take part in a session.

Questionnaire

All we need from you are some contact details, and in six months' time we will post you a questionnaire. This will contain a few questions on your health and well-being. It should only take a short time (no more than 15 minutes) to complete. We will provide a stamped addressed envelope for ease of return and so there is no cost to you. If we haven't received it back after three weeks, we will telephone you to check if it has been received.

Our research team will also record a few items of information about you and your medical treatment. These will be kept completely secure and confidential.

If you decide against taking part in the 'experiences and support' section we would still like to send you a questionnaire in six months time.

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Why should I take part?

You will be part of an important study aiming to improve the well-being of intensive care unit patients.

Do I have to take part?

It is up to you if you want to take part in the study. We will leave this information sheet with you so you can discuss it with your friends and family. If you agree, then we will confirm your eligibility for the study and ask you to sign a Consent Form.

You are free to leave the study at any time, without giving a reason. This would not affect your medical care now, or in future, and no further information about you will be collected (unless you agree otherwise).

What if there is a problem?

We will take any complaint about the way you have been dealt with during the study very seriously. If you wish to complain about any aspect of the way you have been approached or treated during the course of this study, please contact the Principal Investigator (the person leading the study at this hospital) or the Hospital's Patient Advice & Liaison Service (PALS) – details on the last page.

Section 2

Will my General Practitioner (GP) be informed?

We will let your GP know that you are taking part in this study. Your GP will be asked to inform the Intensive Care National Audit & Research Centre (ICNARC) if you have any significant medical events in the six months following your hospital admission. If your questionnaire shows that you are feeling very stressed, we will send another letter to your GP who should contact you to arrange an appointment with them.

If I take part in this study, then will it be kept confidential?

Yes. We will follow the law by making sure all your information is kept secure and never given out. To ensure that you can be contacted by the Intensive Care National Audit & Research Centre (ICNARC) in six months (as outlined in section 1), your hospital will pass on your contact details (name, address, telephone number and email address to ICNARC. As some patients may lose touch with their hospital, ICNARC will need to collect important basic information from NHS records held by the Health & Social Care Information Centre. To ensure you are identified correctly, we will pass on your date of birth, postcode and NHS number. These will be protected and accessed only by authorised people at ICNARC. All other details will be removed from all information leaving the NHS, so that nobody can identify you. We will follow the Data Protection Act 1998, which covers the way we handle all your information.

If possible, we would like your permission to keep your contact details you provide on file after the study has ended. This would enable us to contact you if we feel you or your data could contribute to answering other important health questions. Any data would be fully anonymised prior to being published or shared with other researchers. This aspect is completely optional.

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[Contact number local Principal Investigator]

If you are unhappy with any aspect of the study:

If you do not wish to speak to the research staff listed above, please contact the Patient Advisory and Liaison Service (PALS): [Insert PALS contact details here].