Information for Participants

Study title:

Eliciting expert opinion as part of the POPPI trial to enhance the robustness of the clinical and economic evaluations

You are being invited to take part in a research study. Before you decide whether to participate, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and to talk to others about the study, if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

1. What is the purpose of the study?

The aim of this study is to seek your opinions about the health status of POPPI trial patients who did not complete their self-report questionnaires at six months after randomisation.

The overall aim of the POPPI trial is to assess the clinical and cost-effectiveness of a complex nurse-led preventative psychological intervention in reducing patient-reported post-traumatic stress disorder (PTSD) symptom severity, and other reported psychological morbidities, at six months versus usual care. An important health outcome is PTSD symptom severity at six months, but this measure is often missing for some patients. For example, some patients may fail to return the questionnaire used to collect this information or refuse to answer specific questions. Additionally, the cost-effectiveness investigation for this trial is dependent on patient-reported quality of life, which again is missing for some patients for similar reasons. The Chief Investigator is Professor Kathryn Rowan and the trial is managed by the Intensive Care National Audit & Research Centre (ICNARC). Professor Richard Grieve at the London School of Hygiene and Tropical Medicine (LSHTM) is leading the cost-effectiveness investigation.

A key concern is that the patients who fully complete these questionnaires may be systematically different from those who have incomplete information, and inferences based on the complete cases may be misleading. In the primary analysis, we propose to deal with the missing outcomes by using multiple imputation. This approach assumes that patients for whom an outcome is observed are similar to those whose outcome is missing, after adjusting for observed patient characteristics such as age and gender and site level variables. However, there is a general concern that the reasons for incompleteness in self-reported outcomes may be related to unobserved factors. As part of the POPPI study, we propose tackling this issue

by eliciting trial experts' opinion about the likely values and the reasons for the missing outcomes. This information would then be used to inform the assumptions about the missing outcomes in the form of sensitivity analysis of the clinical and cost-effectiveness. Dr Alexina Mason, who works with Professor Grieve at LSHTM, is the person leading this part of the investigation.

2. Why have I been chosen?

The elicitation will be conducted on a representative sample of the clinical staff involved with the POPPI trial and other interested experts, and you have been involved in the POPPI trial or expressed an interest in this research.

3. Do I have to take part?

It is up to you to decide to join the study. If you agree to take part, we will then ask you to sign an electronic consent form. You are free to withdraw at any time, without giving a reason.

4. What will happen to me if I take part?

You will be asked to complete a short on-line questionnaire that should take no longer than 30 minutes. This questionnaire, which has been developed in collaboration with the POPPI trial investigators, asks you for your opinion about fictional patients who were enrolled in the POPPI trial. All your responses will be kept anonymous.

Thank you for taking the time to read this sheet.

Further information

If you have any questions about this elicitation you can contact:

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