[Abstract] Surveying patients' views on trial information provision and decision making using the 'Accept/Decline' clinical trials questionnaire

Article (Published Version)

Surveying patients' views on trial information provision and decision making using the 'Accept/Decline' clinical trials questionnaire

Kathryn Monson[1], Tom Treasure[2], Chris Brew-Graves[3], Valerie Jenkins[1], Lesley Fallowfield

[1]Sussex Health Outcomes Research & Education in Cancer, Brighton & Sussex Medical School, University of Sussex, [2]Clinical Operational Research Unit, University College London, [3]Surgical & Interventional Trials Unit, University College London

Introduction: The Pulmonary Metastasectomy in Colorectal Cancer (PulMiCC) trial completed its feasibility phase in 2015. Surgically treated colorectal cancer patients, with newly diagnosed lung metastases, were randomised to continued active monitoring or pulmonary metastasectomy followed by active monitoring. Randomisation was a two stage process; Stage 1 investigations assessed fitness for surgery and eligibility for Stage 2 randomisation. A key trial criterion was clinician uncertainty regarding the benefit of surgery in the light of the patient's test results. The trial was anticipated to be challenging for both clinicians and patients. Both patient information, and healthcare professional, training DVDs were produced to assist with trial discussions and decision making. Additionally a patient survey was conducted to examine patients' views about the trial.

Method: Following PulMiCC stage 1 tests, patients eligible for randomisation (PulMiCC stage 2) were offered an 'Accept/Decline' questionnaire to complete following their decision to either proceed to randomisation or decline PulMiCC stage 2. This 16 item, Likert scale, self-report questionnaire explores aspects of trial information provision, patients' concerns about their illness, influence of friends, family and doctor, and concerns regarding randomisation (V Jenkins, L Fallowfield, 2000). It enables the collection of patients' views on key issues surrounding trial information provision and decision-making in a structured, quantitative manner. Patients also identify their most important reason for accepting or declining study participation. The questions are worded generically to enable widespread use in randomised trials.

Results: Questionnaires were returned by 54 randomised patients and 57 who declined randomisation. The majority 106/111 (95%) indicated that they had received sufficient written information about the study and 110/111 (99%) indicated that the doctor had told them what they needed to know about the trial. Of patients who agreed to randomisation, 43/54 (80%) thought the trial offered the best treatment available and 48/54 (89%) were satisfied that either treatment in the trial would be suitable for them. Twenty five patients (44%) who declined randomisation were satisfied that either treatment in the trial would be suitable for them but 40/57 (70%) wanted the doctor to choose their treatment rather than be randomised by a computer. The results did not highlight significant problems such as patients feeling unable to say 'No' or concerns that their illness might get worse unless they joined the study. We have been able to use the information, together with clinicians' views on their experiences of the feasibility phase of the trial, to identify potential barriers to recruitment and enable strategies to be put in place to address these.

Conclusion: We found the questionnaire easy to administer and acceptable to both patients who declined or agreed to join PulMiCC stage 2. It is an efficient tool for collecting relevant views from patients regarding potential drivers and barriers to recruitment.