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## **The information pathway to randomisation: Patients experience of the Mesothelioma and Radical Surgery (MARS2) feasibility trial**

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**(397 words, Max = 400) (395 with revisions)**

### **Background/Objectives:**

The Mesothelioma and Radical Surgery 2 (MARS 2) trial was established in the UK to evaluate the role of radical surgery, (Pleurectomy decortication), for the treatment of malignant pleural mesothelioma (MPM). It compares chemotherapy and surgery to chemotherapy alone. The feasibility trial included a nested qualitative sub-study. The sub study aimed to 1) understand the patient experience of MARS2 trial process and interventions and 2) Identify any information and support needs required by patients. We present here the results related to MARS2 participant's information experiences and needs at the point of randomisation. Implications for information provision to enhance patient experience and overcome recruitment barriers<sup>1</sup> within MPM trials are considered.

**Methods:** 41 in-depth longitudinal qualitative methods were used with 15 participants following randomisation. 9 participants received chemotherapy and surgery and 6 received chemotherapy alone. Interviews were conducted following randomisation, and at 6 and 12 months after the initial interviews. Participants randomised to surgery also had an interview after post-operative discharge. Data was collected between August 2015 and March 2017 and analysed using Framework analysis<sup>2</sup>.

### **Results**

The findings provide insight into the challenging context within which potential participants have to assimilate knowledge about a trial such as MARS2. Prior to hearing about the trial participants had encountered a diverse range of new and concerning experiences. These included worrying symptoms, diagnostic tests, investigations and the drainage of litres of fluid from the lung. They had to absorb an array of life-changing facts in a short time including that they had a rare incurable cancer with a poor prognosis; their illness was an occupational disease with legal and financial implications due to asbestos exposure. Participants attended their trial consultation soon after this challenging diagnostic information provision. The study reveals variations in understanding of the trial procedures, specifically decision-making regarding treatments, equipoise and the process of randomisation. Motivations for participating in the trial were identified along with preferences for information formats.

### **Conclusion**

This study provides unique insight into the information pathway of MPM trial participants, from diagnosis to randomisation. Results suggest that improvements in presentation of trial information and the development of formats that can be tailored to individual needs and preferred ways of learning, many enhance experience of and recruitment to MPM trials. Working with patients to co-produce information that communicates challenging concepts effectively, (such as randomisation and equipoise), may be a useful approach to meeting this challenge.

1. British Lung Foundation. Patient survey results: barriers to accessing mesothelioma clinical trials. Unpublished. On: <https://fb.me/1E6ReZBi6> Accessed: February 2018
2. Ritchie J and Lewis J (2013) Qualitative research practice: a guide for social science students and researchers 2<sup>nd</sup> edition London.