Marie Curie Cancer Care Research Programme - Project Grant

Project details

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Pilot feasibility randomised trial of a novel non-pharmacological intervention for the management of the respiratory distress symptom cluster (breathlessness, cough, fatigue) in patients with advanced lung cancer

Duration of project: 20 months
Start date: 01/05/2012 (TBC)
Budget: £175k

Abstract

Background
Our previous work has shown the existence of a complex respiratory distress symptom cluster in patients with lung cancer (breathlessness, cough, fatigue). We have developed a non-pharmacological intervention in an effort to manage better this symptom cluster following the MRC Framework for Complex Interventions. Accordingly, we have published 3 systematic reviews identifying the current state of evidence; we conducted interviews with 37 lung cancer patients and 22 informal caregivers exploring which interventions were more appropriate to use and what would make an intervention more successful; we sought the views of health professionals (through focus groups), and we explored preferences of intervention delivery (n= 88).

Aim
The aim of this study is to move to the next stage of the MRC Framework and test the feasibility of delivering the intervention in real practice.

Methods
This will be a feasibility randomised trial using two arms, one receiving best supportive care (standardised for all centres involved) and the other receiving our intervention, focusing both on patients and their carers. The intervention 'package' we have developed through patient and caregiver input will be delivered over two hourly sessions one week apart and will be followed up by a phone call 2 weeks after the face-to-face sessions. It will be delivered after the end of first line treatments close to the patients' home by a specialist nurse with the involvement of caregivers. A number of psychometrical valid scales will be used not only to measure outcomes but also to identify which scales are more sensitive to change and appropriate for use in a full scale trial. Assessments will be taken before randomisation, 4 weeks (end of follow up) and 12 weeks. 100 patients will be recruited from four centres in the North West of England (larger number than usual to accommodate for a 50% attrition due to death or high morbidity).

How the results of this study will be used
This study will provide initial evidence of the intervention and its delivery methods, and will refine the intervention further. The results of this project will lead to testing the intervention in a large population (phase III trial). If successful, the results will influence the provision of care for patients with lung cancer experiencing complex respiratory symptoms, an area that currently we do not manage well in clinical practice and it has a real potential of improving the patients' and caregivers' quality of life.