A phase I-II feasibility trial of Cancer Carer Medicines Management: an overview

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Introduction

Pain is experienced by 71% of people with cancer approaching end of life (Teunissen et al 2007). It is well established that unpaid carers providing end of life care at home to people with cancer play a significant role in managing medicines for control of pain (Kazanowski 2005; van Ryn 2011). Our scoping exercise of international literature repeatedly found that family carers lack information and confidence, with some holding beliefs that pain cannot be controlled and some having concerns about medication becoming addictive.

A recent systematic search (Meeker et al 2011) found 5 studies reporting interventions involving carer pain management for cancer, with most interventions directed at patient-family carer dyads. Studies’ results indicated that carer education in pain management can improve knowledge & self-efficacy for pain management, reduce attitudinal barriers & carer strain, & benefit carer quality of life. Despite this strong international evidence on carer education and support needs, there has been no UK research to develop and evaluate a tailored carer-focused intervention aimed at helping family carers to manage these medicines better for family members with advanced cancer.

Aims

To conduct a Phase I-II feasibility study to develop a new Cancer Carer Medicines Management intervention; and to test its feasibility, acceptability & efficacy to improve carers’ knowledge, beliefs, skills and self-efficacy for pain management, and decrease carer strain and improve mood state. This feasibility study is being funded by Dimbleby Marie Curie between 2013-2015.

Phase I Methods

A rapid appraisal of research on interventions for carer management of end of life pain medicines is being conducted in early 2013. Views and suggestions of current patients, family carers and pharmacists, specialist nurses and physicians from community, hospice and hospital settings in two UK regions will be sought. This evidence will be synthesised and developed into a prototype intervention, with subsequent refinement through user, educator and researcher collaboration, which will draw on theoretical frameworks from previous community-based nursing interventions.

References


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Phase II Methods

Evaluation of the impact of the intervention will be conducted from autumn 2013 at two UK sites using a two arm, parallel group, cluster randomised control feasibility trial. A total of 12 community nurses and specialist palliative care nurses will provide informed consent to participate at two UK sites. 3 of the nurses at each site will receive training in delivery of the intervention for family carers, which will be offered in face-to-face consultation with telephone follow-up. Each of the 12 nurses (6 in control group; 6 in intervention group) will recruit 5 patient-carer dyads. Carer and patient outcomes at baseline, and at 1 and 4 weeks post intervention will be compared using validated questionnaires measuring carer pain medication knowledge, beliefs and skills; carer strain, self-efficacy and mood state. Secondary outcomes from validated questionnaires and interviews will include perceptions of patient pain, burden of the intervention, and factors inhibiting or facilitating intervention use. A qualitative sub-study of the acceptability of CCMM and trial methods will also be included.

Expected Outcomes and Future Plans

When this Phase I-II feasibility trial ends in 2015, an educational intervention will have been developed for delivery by palliative care nurses during routine care to enable family carers to manage pain medication confidently for family members with advanced cancer. The intervention and study methods will have been tested and evaluated, generating evidence from two sites about their feasibility, acceptability and efficacy. We will then seek funding for a follow-on randomised control trial to fully test the intervention’s impact.