Marie Curie Research Grants Scheme

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ENeRgy: Exercise and Nutritional Rehabilitation in patients with advanced cancer: a single centre, randomised (1:1), open label, feasibility study of a rehabilitation programme (exercise and nutrition) versus wait list control, in patients with advanced cancer.

Duration of project: 24 months

Start date: 1st August 2017

Budget: £118,135*

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Abstract

Background

In 2015, Hospice UK published a report advocating that "Rehabilitative Palliative Care is an essential component of palliative care". In essence a challenge was set that palliative care should refocus its approach to care, advancing the doctrines set by Cicely Saunders of maximising the potential of patients to live fully, until they die.

However there is limited robust evidence on which to base this approach. A systematic review examining rehabilitation in advanced cancer, published in 2015, identified only a limited number of studies in this area. It was suggested that rehabilitation may be feasible for patients with advanced cancer but key components were not clear and no recommendations could be given.

In addition, the majority of the work to date has focused on exercise as a single intervention rather than as part of a comprehensive rehabilitation programme. Whilst there is evidence of the benefits of rehabilitation in some non-malignant conditions, such as chronic respiratory disease, extrapolating these models to advanced cancer care needs evaluation.

Although exercise is important, it has been argued that any rehabilitation programme in advanced cancer should also focus on nutritional aspects. This would seem logical as approximately 20% of cancer deaths are directly attributable to cancer cachexia (loss of muscle +/- fat and impaired physical function). Optimising nutrition is also fundamental to facilitate post-prandial anabolism, which is key to maintaining muscle and thus physical function. There is now a persuasive argument that exercise and nutrition should be considered as the cornerstones of any rehabilitation programme in patients with advanced cancer. However this remains to be demonstrated in clinical practice.

Pilot Work

Work by our group has demonstrated the detrimental effect of deteriorating physical function on survival. It therefore follows that optimising physical function may even have positive survival benefits. At the very least it should enable patients to remain independent for longer periods. Pilot work by our group has examined an exercise and nutrition based intervention in oncology outpatient's patients with lung and pancreatic cancer undergoing chemotherapy. We have demonstrated that such an intervention was feasible and had beneficial effects on

physical function and weight. These findings are encouraging however the potential benefits of an exercise and nutrition based rehabilitation programme in the general advanced cancer population and within the hospice setting remains unclear. The first step in assessing this is to conduct a feasibility trial examining an exercise and nutrition based rehabilitation programme in advanced cancer patients.

Hypothesis

An exercise and nutrition based rehabilitation programme improves physical function and quality of life in patients with advanced cancer in a hospice context.

Research Question

Is it feasible to deliver an exercise and nutrition based rehabilitation programme in patients with advanced cancer within the hospice context?

Methods

Design: Single centre, randomised (1:1), open label, feasibility study of a rehabilitation programme versus wait list control, in patients with advanced cancer.
Population: Patients with advanced cancer, KPS>60, not undergoing anti-cancer therapy, outpatients.
Intervention: A personalised exercise and nutritional programme delivered over 9 weeks incorporating weekly review.
Comparison: Wait list control, with standard care.
Outcome(s):
Primary:
Feasibility of recruitment, retention, compliance, and contamination of the control arm.
Exploratory:
Patient Reported Outcome Measures (PROMs) including function and quality of life – this will be assessed using the EORTC QLQ-C15-PAL.
Physical function assessed using the two minute walk test and ActivPAL physical activity meter.
Nutritional assessment – assessed using the Patient Generated Subjective Global Assessment (PG-SGA).
Statistical Aspects
Forty patients (20 in each arm) are required to assess the primary outcome measures of feasibility. Randomisation will incorporate stratification using the following factors: age group, performance status and gender. Descriptive statistics will be used to demonstrate feasibility and provide an estimate of effect size at 9 weeks that can be used for sample size estimation for future studies. Outcomes will be assessed at study baseline (pre-randomisation), study mid-point (5 weeks) and end-point (9 weeks).
Study Site
The study will be conducted in St Columba's Hospice, Edinburgh UK. Patients will be recruited across Edinburgh and Lothian, and will include those patients under the care of Marie Curie Hospice, Edinburgh and St Columba's Hospice, Edinburgh.