CareSearch Project Research Studies Register: Registration Proforma	0128

Study Title: The hand held battery operated fan as a self-management strategy: assessing the fan's capacity to increase physical activity in patients with breathlessness and reducing carer anxiety

Short title: Fan Activity and Breathlessness (FAB) Study

Brief description of the study: Breathlessness is a devastating symptom of advanced cancer, heart failure, chronic obstructive pulmonary disease and occurs in over 90% of people with lung cancer and 65% of people with heart failure worsening in intensity as death approaches. It is frightening and disabling for both patient and carer. While the mainstay of treatment for breathlessness focuses on a range of pharmacological and there is increasing interest in exploring the use of various non-pharmacological interventions for the management of breathlessness, such as a tailored exercise program, psycho-educational support for patients and carers, and the use of a handheld battery operated fan ('fan'). Demonstrating whether these self-management strategies can produce incremental benefits to patients is important for building the evidence base for non-pharmacological breathlessness interventions.

Study design: A Phase II multi-site, parallel arm feasibility randomised controlled non-blinded parallel group study comparing the efficacy of a battery operated hand held fan and exercise advice with exercise alone with regard to activity levels in people with intractable breathlessness from any cause. Patients with intractable breathlessness due to cardio-respiratory disease from any cause will be recruited from two UK and two Australian centres.

Aim: To test the feasibility of conducting an adequately powered large, multi-centre, multi-national randomised controlled clinical trial comparing the efficacy of a hand held fan and exercise advice with exercise alone with regard to activity levels in people with optimally treated breathlessness from any cause.

Assessments: The primary assessment is activity levels over 7 days as measured by the activPAL™. This will be measured over the 7 days prior to randomization (Day -8 to 0) and the last 7 days of the study (Days 22-28), with a comparison between arms.

Primary endpoint: Activity levels over 7 days as measured by the activPAL™ monitor.

Study Methodology: (Please mark with an x which type of study methodology)

	Epidemiology
	Health Services / Health Economics / Quality Improvement
	Qualitative, Observational or Descriptive
	Mixed Method
	Systematic Review
X	**Intervention: RCT**
	Intervention: Comparative or cohort study
	Intervention: Case series

Project details:

Funding source (Optional):

Has the study received ethics approval?	**X**	Yes		No		Not applicable

Project starting date: **Jan 2013**						
Project completion date**: In progress**						
Multi site:	**X**	Yes		No		Not applicable

RESEARCHERS

Principal Investigator (name)	**Prof Jane Phillips**
Contact Details	02 8382 9432
Investigator B (Name)	**Prof Miriam Johnson**
Investigator C (Name)	**Dr Sara Booth**
Investigator D (Name)	**Prof David Currow**
Investigator E (Name)	**A/Prof. Lawrence Lam**

Associated publications / reports:

Booth S, Silvester S, Todd C. Breathlessness in cancer and chronic obstructive pulmonary disease: using a qualitative approach to describe the experience of patients and carers 1. Palliative and Support Care 2003 Dec;1(4):337-44.

Booth S, Farquhar M, Gysels M, Bausewein C, Higginson IJ. The impact of a breathlessness intervention service (BIS) on the lives of patients with intractable dyspnea: a qualitative phase 1 study. Palliative and Support Care 2006 Sep;4(3):287-93.

Booth S, Moosavi SH, Higginson IJ. The etiology and management of intractable breathlessness in patients with advanced cancer: a systematic review of pharmacological therapy. Nat Clin Pract Oncol 2008 Feb;5(2):90-100.

Topics (Admin only) Dyspnoea, Non-pharmacological