

<b>CareSearch Project</b>		<b>0087</b>
<b>Research Studies Register: Registration Proforma</b>		
<b>Study Title:</b> A double-blind, randomised, placebo-controlled titrated dose pilot study of sertraline in people with refractory breathlessness		
<p><b>Brief description of the study:</b> Breathlessness continues to be a major clinical problem for many people with advanced progressive illnesses such as cancer, end-stage cardiac failure or chronic obstructive pulmonary disease, even when they are receiving the best treatment for the underlying disease. Although there are some interventions that may offer benefit (sustained release low dose morphine, oxygen therapy), there is still a need for a wider range of interventions to meet the needs of people with refractory breathlessness.</p> <p><b>Study design:</b> This is a phase II study of sertraline (titrated to a mid-range dose) or placebo for people with breathlessness despite optimal treatment of the underlying causes of this breathlessness. Their involvement will be for 28 days. Participants will take a capsule every morning, which will contain either sertraline or placebo. Active medication will be titrated from 25mg daily to 100mg daily in the first 7 days of study if tolerated. During these 28 days participants will be carefully monitored by study staff, on a regular basis. People who derive benefit from their study medication will be able to continue on their medication in a double-blind way until data collection is complete. During this time, assessments of breathlessness and adverse effects will be assessed regularly.</p> <p><b>Objectives:</b> To establish feasibility of the study design and inform adequate power calculations for a definitive study of this intervention in the same sites at a later date. It is estimated that to achieve these objectives, data at day 28 is needed on 10 participants for this pilot study.</p> <p><b>Assessments:</b> The primary assessment is a twice daily diary card filled out by participants. There will be measures at 3 time points (1 day prior to d1, d9 d28) for anxiety, depression, quality of life and global impression of change. Potential side effects will be monitored in the daily diary.</p> <p><b>Primary endpoint:</b> Change in a numerical rating scale of average morning and average evening breathlessness in the last 3 days of treatment (d26, d27, d28) with a comparison between arms.</p> <p><b>Definition of response:</b> For people individually to be considered as having responded, a 15% reduction in breathlessness at the end of the study compared to placebo.</p>		
<b>Study Methodology: (Please mark with an x which type of study methodology)</b>		
	Epidemiology	
	Health Services / Health Economics / Quality Improvement	
	Qualitative, Observational or Descriptive	
	Mixed Method	
	Systematic Review	

<b>X</b>	Intervention: RCT				
	Intervention: Comparative or cohort study				
	Intervention: Case series				
<b>Project details:</b>					
Funding source (Optional):					
Has the study received ethics approval?	<b>X</b>	Yes		No	Not applicable
Project starting date: <b>Feb 2008</b>					
Project completion date: <b>Feb 2010</b>					
Multi site:	<b>X</b>	Yes		No	Not applicable
<b>RESEARCHERS</b>					
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Investigator C (Name)	A/Prof Christine McDonald				
Investigator D (Name)	A/Prof Trish Davidson				
Investigator E (Name)	Dr Amy Abernethy				
<b>Associated publications / reports:</b> None					
<b>Topics</b>					
<ul style="list-style-type: none"> <li>• Respiratory symptoms and their treatment</li> <li>• Drug trial</li> </ul>					