



## PACT – Clinician New Clinical Trial and Research

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Trial title	SINFONIA: A clinical trial examining the benefits of SingINg For breathing in COPD aNd ILd pAtients
Trial synopsis	<p>SINFONIA is a 12-week trial of guided online group singing for patients with chronic obstructive pulmonary disease or interstitial lung disease who experience breathlessness. The study aims to determine the effects of online group singing classes led by a trained music therapist on breathlessness, wellbeing and symptom management.</p> <p>The study is open to patients and caregivers around Australia as it is an online intervention.</p> <p>SINFONIA is a randomised trial, meaning participants will be assigned to the singing group or the control group at random. Participants randomised to the singing group will attend one 90-minute online singing group per week for 12 weeks. Participants randomised to the control group will continue to receive their normal care during this time. Participants in the control group are also invited to join to singing group at the end of the 12-week period.</p> <p>During the study period, participants will be contacted at 4-weekly intervals and asked to complete a set of short surveys about quality of life, symptoms, and their healthcare usage. Participants may also be invited to participate in a short interview to discuss their experiences of participating in the SINFONIA trial.</p>
Investigational medicinal product, comparator and randomisation	<p><u>Intervention:</u> Participation in 90 minute online singing classes weekly for 12 weeks. Monthly completion of study questionnaires</p> <p><u>Control:</u> 12 weeks of standard care. Monthly completion of study questionnaires. Option to enrol in 12 weeks singing classes at the completion of the study (no data collected)</p>
Disease target	COPD and ILD
Sponsor	St Vincent's Hospital Melbourne
Duration	12 weeks
Trial Status	Recruiting



Trial phase	Phase III
Key inclusion criteria	<ul style="list-style-type: none"><li>• &gt; 18yrs</li><li>• confirmed diagnosis of COPD or ILD (on PFTs and/or CT)</li><li>• on stable treatment for at least 4 weeks (i.e. no new or changed cardiorespiratory medications or hospital admissions for COPD or ILD)</li><li>• breathless: mMRC <math>\geq</math> 2 (i.e., walks slower than someone their own age or has to stop for breath when walking on the level)</li><li>• capable to give informed consent</li><li>• carers aged over 18 years may also participate</li></ul>
Key exclusion criteria	<ul style="list-style-type: none"><li>• NOT currently participating in pulmonary rehabilitation</li></ul>
Primary endpoint	To assess the effects of online singing classes on respiratory health-related QoL as assessed by the 36-item Short Form Survey (SF-36)
Number of participants sought	140
Lead site(s) in Australia	Alfred Health
Lead site(s) in New Zealand	N/A
Additional sites	Royal Melbourne, Austin Health, St Vincent's
Contact	<a href="mailto:pactcoordinator@cre-pf.org.au">pactcoordinator@cre-pf.org.au</a>