

## PACT – Clinician New Clinical Trial and Research

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Trial title	High intensity interval training in fibrotic interstitial lung disease
Trial synopsis	<p>The fibrotic interstitial lung diseases (fILD) are a group of debilitating chronic lung conditions that are characterised by scarring of lung tissue, dyspnoea on exertion and significant physical impairment. Exercise training is recommended for people with fILD in improving breathlessness and exercise tolerance. However, despite the best efforts of patients and clinicians, many of those who participate are not attaining its benefits. The current exercise training strategies of moderate intensity continuous training may not be well suited to fILD. High intensity interval training, short bouts of high-intensity exercise regularly interspersed with periods of rest or light exercise, may be an alternate exercise training option for people with fILD. People with fILD will be recruited and randomly allocated to receive either the traditional PR model of moderate intensity continuous training or high intensity interval training for 8 weeks. Results of this trial will demonstrate whether high intensity interval training is better than the current method of continuous exercise training at moderate intensity, in improving exercise tolerance, breathlessness and quality of life in people with fILD.</p>
Investigational medicinal product, comparator and randomisation	<p>Intervention: High intensity interval training</p> <ul style="list-style-type: none"> <li>• 36 minutes of interval exercise on cycle ergometer alternating every 30 seconds between 100% peak work rate achieved on cardiopulmonary exercise test and unloaded cycling, plus upper and lower body resistance training.</li> </ul> <p>Active Comparator: Traditional pulmonary rehabilitation</p> <ul style="list-style-type: none"> <li>• 30 minutes of continuous exercise on cycle ergometer at 60% peak work rate achieved on cardiopulmonary exercise test, plus upper and lower body resistance training.</li> </ul> <p>The total duration of 36 minutes (18 minutes exercise and 18 minutes recovery), allows the high intensity interval training to be matched in total work with the moderate intensity continuous exercise. This is calculated as the product of exercise time and percentage of WR<sub>peak</sub>.</p>
Disease target	Fibrotic interstitial lung disease
Sponsor	Monash University

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Duration	8 months (8 weeks intervention period plus 6 month follow up)
Trial Status	Recruiting
Trial phase	N/A
Key inclusion criteria	<ul style="list-style-type: none"> <li>• Attended pulmonary rehabilitation within the last 6 months</li> <li>• Severe pulmonary hypertension (WHO class IV)</li> <li>• Comorbidities which preclude exercise training</li> <li>• Clinical instability e.g. syncope, myocardial infarction or exacerbation within the previous 4 weeks</li> <li>• Suffer from cognitive impairment limiting the ability to consent or follow instruction</li> </ul>
Key exclusion criteria	<ul style="list-style-type: none"> <li>• Attended pulmonary rehabilitation within the last 6 months</li> <li>• Severe pulmonary hypertension (WHO class IV)</li> <li>• Comorbidities which preclude exercise training</li> <li>• Clinical instability e.g. syncope, myocardial infarction or exacerbation within the previous 4 weeks</li> <li>• Suffer from cognitive impairment limiting the ability to consent or follow instruction</li> </ul>
Primary endpoint	Change in endurance time on a constant work rate cycle test
Number of participants sought	130
Lead site(s) in Australia	Alfred Hospital, Melbourne VIC
Lead site(s) in New Zealand	N/A
Additional sites	<ul style="list-style-type: none"> <li>• Austin Hospital, Melbourne VIC</li> <li>• Royal Prince Alfred Hospital, Sydney NSW</li> <li>• The Prince Charles Hospital, Brisbane Qld</li> </ul>
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