Centre of Research Excellence in Pulmonary Fibrosis

Lung Foundation Australia Pulmonary Fibrosis Clinical Trials

PACT – Clinician
New Clinical Trial and Research

Trial title	A Randomised Clinical Trial of a digital Self-Management package for people with Interstitial Lung Disease (REBUILD-SM trial)
Trial synopsis	To compare the clinical efficacy and cost-effectiveness of REBUILD-SM (a purpose-built smartphone application and digital self-management package) with standard care in people with Interstitial Lung Disease; and to understand the barriers and facilitators to its implementation in clinical practice.
Investigational medicinal product, comparator and randomisation	The intervention is a bespoke smartphone application and integrated self-management website. The intervention group will have access to learning modules on the website and will be supported by clinicians specialising in management of patients with ILD, who will engage with the participant at regular intervals. The comparator is standard of care with the addition of a reduced functionality version of the app (i.e. without educational resources). Patients in the control group will also receive phone calls at the same frequency to control for the effects of attention. Randomisation will be in a 1:1 allocation (intervention vs control) and will be stratified for FVC (51% or more; 50% or less); site; and diagnosis (IPF or other).
Disease target	Interstitial Lung Disease
Sponsor	The University of Sydney
Duration	Intervention period of 12 weeks, with follow-up at 26 and 52 weeks.
Trial Status	Not yet recruiting
Trial phase	Non-pharmaceutical trial
Key inclusion criteria	• 18 years or older • Able to provide consent • Able to read and write adequately in English • Owns a smartphone / tablet • Digitally literate • Has an email address • On stable treatment for ILD for the previous 30 days prior to enrolment

Key exclusion criteria	• Less than 18 years • Unable to consent • Unable to read and write adequately in English • Not on stable ILD treatment for the previous 30 days prior to enrolment • Acute exacerbation in the 30 days prior to enrolment • Participating in pulmonary rehabilitation at enrolment or during the 12-week intervention period • Death or transplant expected within the trial period
Primary endpoint	Change in HRQoL as measured by the Kings' Brief Interstitial Lung Disease (K-BILD) at 12 weeks
Number of participants sought	400
Lead site(s) in Australia	Royal Prince Alfred Hospital
Lead site(s) in New Zealand	N/A
Additional sites	• The Alfred (VIC) • Austin Health (VIC) • The Prince Charles Hospital (QLD)
Contact	pactcoordinator@cre-pf.org.au