

# A personalized treatment for anxiety and challenges of living with Pulmonary Fibrosis

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## Background:

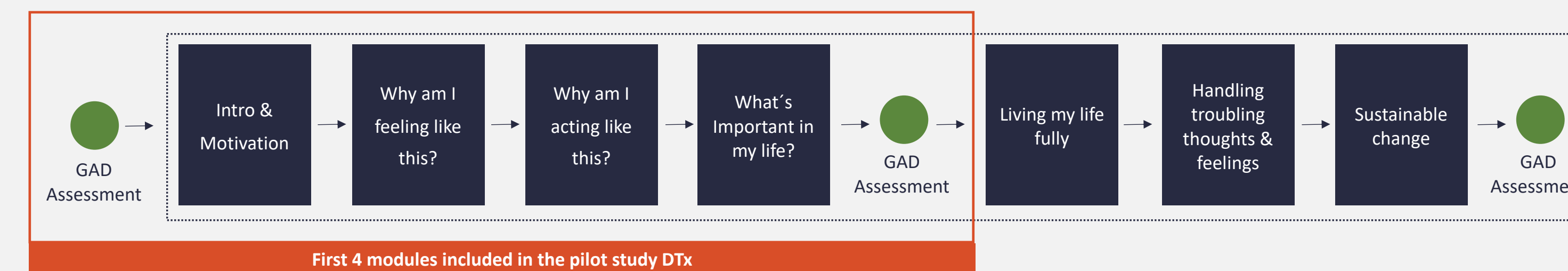
- Idiopathic pulmonary fibrosis (IPF) is often associated with significant psychological distress
- No identified cause and prognosis is poor with an estimated life expectancy of 3-5 years after diagnosis
- Antifibrotics reduce the rate of lung function decline but are associated with significant side effects
- Daily routines are limited by cough, dyspnea, and fatigue with a significant impairment of quality of life
- Symptoms of anxiety and depression have been reported in 58% and 49% of patients, respectively<sup>1,2</sup>
- Despite the profound effects on mental health, referrals for psychotherapy are generally not part of standard of care in IPF
- The multiple medical and non-medical needs require holistic care of the patient<sup>3</sup>



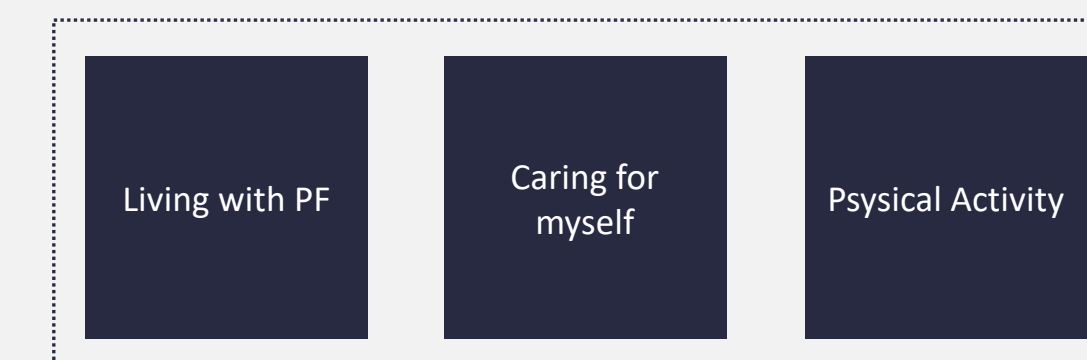
## Methods:

The COMPANION pilot study was a four-week, open label, home-based, clinical investigation in 10 patients with self-reported symptoms of anxiety related to idiopathic PF (IPF), the most prevalent of the diseases within the PF group. GAD-7 scores were collected at 0 and 4 weeks. In collaboration with PF patient groups, caregivers and ILD specialists, Almee™ content was custom built specifically to meet the emotional and psychological needs of people who know the disease best.

### Therapy modules



### PF Essential modules

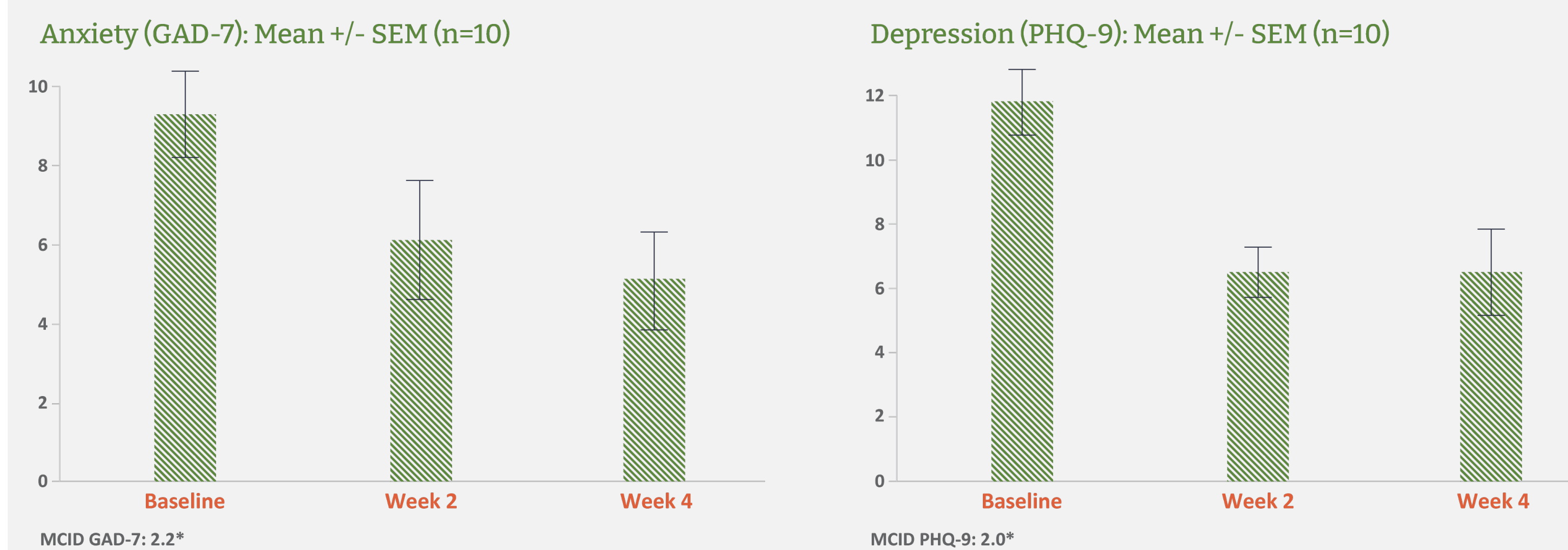


## Objectives:

Living with pulmonary fibrosis, a group of over 200 interstitial lung diseases, can be challenging and burdensome to navigate – through diagnosis, treatment options, changes in lifestyle and capabilities, in addition to the symptoms of increasing dyspnea and cough. The dCBT-PF digital therapy was developed for individuals with all types of pulmonary fibrosis (PF) to offer cognitive behavioral therapy (CBT) and personalized coping mechanisms to address fears and worry instigated by living with PF. Almee™ (an investigational medical device in clinical development), contains dCBT-PF and additional modules accessed through a smartphone or tablet, to encourage empowerment in areas of activity, diet, sleep, and breathing exercises. The core medical device, dCBT-PF, was tested in a pilot study in 2022.

## Results:

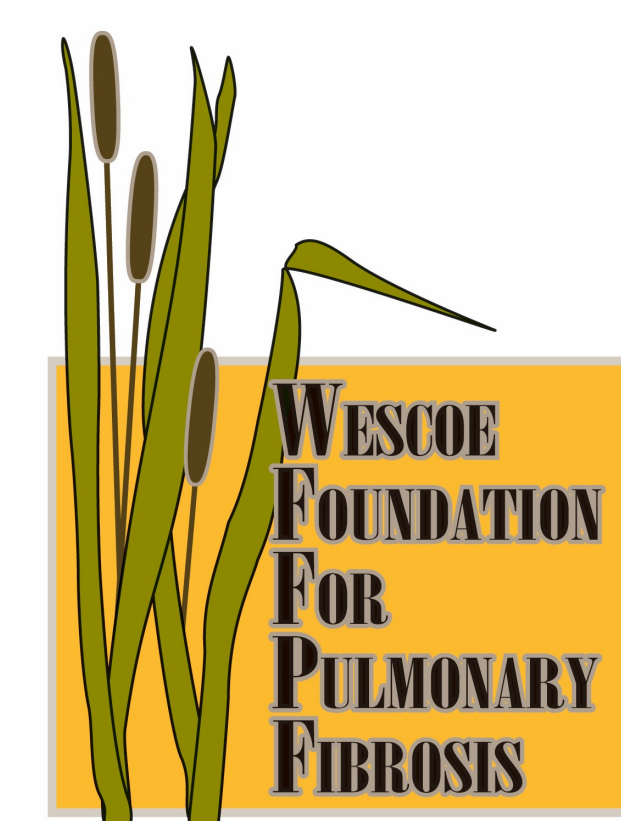
The primary objective of the study, to test the functionality, safety, and user experience of dCBT-PF, was met. There were no adverse events, and the efficacy results were compelling. Four weeks use reduced average GAD-7<sup>1</sup> scores by 4.2 points, a reduction in anxiety level of nearly 50%.



<sup>1</sup> GAD-7 is a self-administered patient questionnaire used as a screening tool and severity measure for generalized anxiety disorder (GAD). Spitzer RL, Kroenke K, Williams JB, et al; A brief measure for assessing generalized anxiety disorder: the GAD-7. Arch Intern Med. 2006 May 22;166(10):1092-7.  
\*Kounali et al. 2020. Psychological Medicine 1–8. <https://doi.org/10.1017/S0033291720003700>

## Conclusions:

Almee™ is intended to provide personalized tools for the person as a whole; at the core of Almee™ is dCBT-PF for anxiety, bundled with additional modules to address all aspects of living with PF. This pilot data indicates that the interactive content provides meaningful effects. The Almee™ pivotal phase study results are to be shared at the end of 2023. Learnings from conducting this decentralized study were incorporated in the ASPIRE trial evaluating the regenerative potential of C21 in IPF.



A special thank you to the people who participated in this study and their caregivers, with particular appreciation for the PF Warriors, Breathe Support Network, and the Wescove Foundation for supporting completion of the COMPANION study.



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