

A digital therapy to address the anxiety associated with pulmonary fibrosis

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Background

Pulmonary fibrosis (PF) is often associated with significant psychological distress. 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^{1,2}. The multiple medical and non-medical needs require holistic care of the patient³.

Objectives

A 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 digital CBT and additional modules accessed through a smartphone or tablet, to encourage empowerment in areas of activity, diet, sleep, and breathing exercises. Almee content was custom built in collaboration with PF patient groups, caregivers and ILD specialists, specifically to meet the emotional and psychological needs of people who know the disease best. The device has been granted Breakthrough Device status by the US FDA. A randomized controlled study was conducted in 2023 with the objective to investigate effects on anxiety and health-related quality of life compared with no intervention (treatment as usual).

Methods

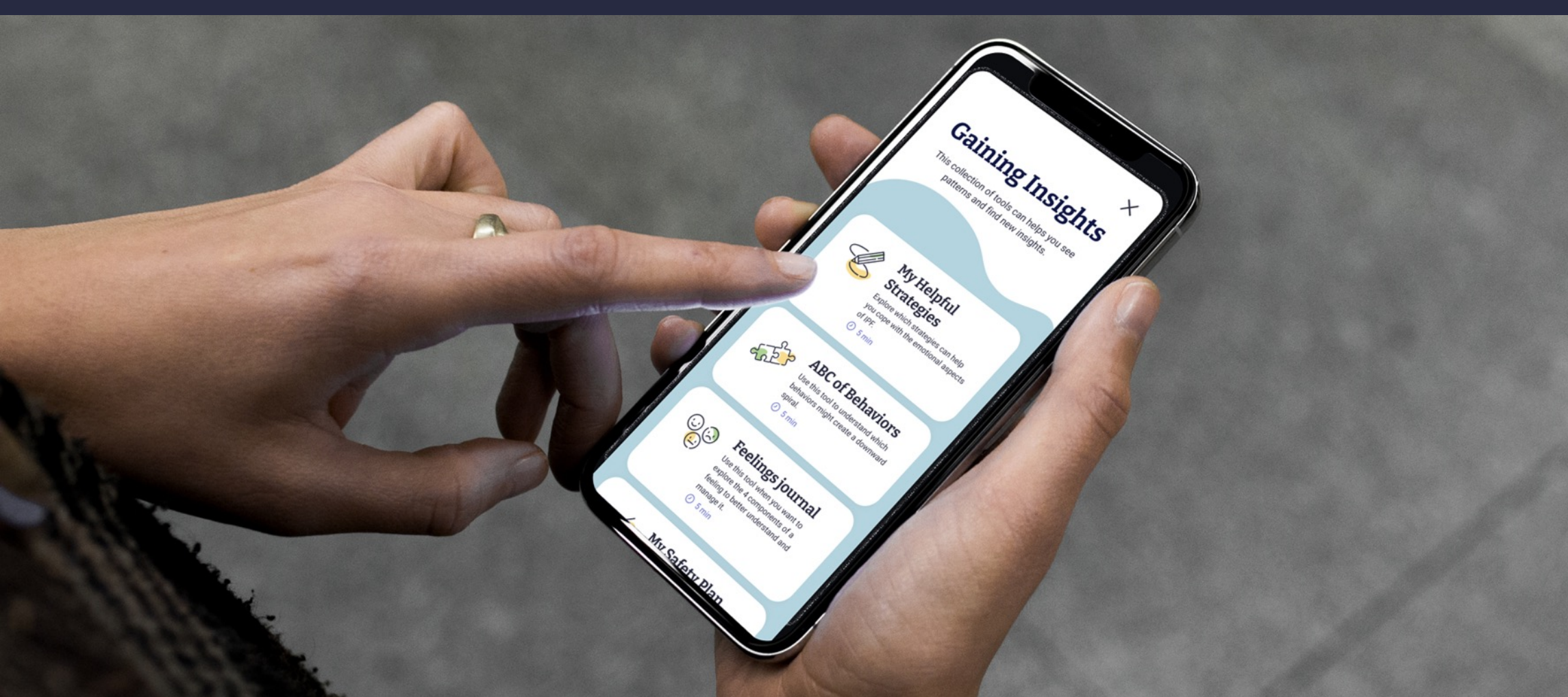
The COMPANION study was a 9-week, randomized, controlled, parallel-group clinical investigation with a 3-week follow-up period, which enrolled 108 participants from across the United States, completing in December 2023. Patient-reported outcomes of anxiety (GAD-7⁴) and health-related quality of life (KBILD⁵) were collected at 0, 3, 6, 9, and 12 weeks. The GAD-7 questionnaire is widely used in clinical practice as an assessment tool for anxiety, scoring ranges from 0 to 21 with four levels spanning minimal anxiety (0 to 4) to severe (15 to 21). KBILD is a validated and widely used tool for assessing ILD-specific quality of life⁵.

Results

The study met its primary endpoint, change from baseline in GAD-7 anxiety scores to week 9, with a statistically significant 2.7-point improvement of anxiety symptoms in the group treated with Almee compared to control, where a change in GAD-7 score of more than 1.8 points is considered clinically meaningful. The observed 2.7-point improvement reflects promising efficacy in reducing anxiety levels and offering tangible relief to individuals coping with pulmonary fibrosis (PF). Quality of life, measured by the K-BILD, was a key secondary endpoint and improved by 4.4 points compared to control, and the K-BILD psychological domain improved by 6.5 points. Changes of at least 3.9 in the total score and at least 5.4 in the psychological domain scores are considered clinically meaningful⁵.

Conclusion

Almee is intended to provide personalized tools to create a sense of control for the person as a whole. The COMPANION data indicate that the interactive content of Almee provides meaningful effects on both anxiety and quality of life in people with pulmonary fibrosis.



1. Lindell et al. *Heart Lung* 2010;39:304-313.
2. Akthar et al. *Chronic Respiratory Disease* 2013;10:127-133.
3. Delameillieure et al. *Respiratory Research* 2022;23:124.
4. 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.

5. King's Brief Interstitial Lung Disease (KBILD) is a 15-item validated health-related quality of life (HRQOL) questionnaire. Nolan CM, Biring SS, Maddocks M, Maher TM, Patel S, Barker RE, Jones SE, Walsh JA, Wynne SC, George PM, Man WD. *King's Brief Interstitial Lung Disease questionnaire: responsiveness and minimum clinically important difference.* *Eur Respir J.* 2019 Sep 5;54(3):1900281. doi: 10.1183/13993003.00281-2019. PMID: 31221807.
6. Kounali D, Button KS, Lewis G, Gilbody S, Kessler D, Araya R, Duffy L, Lanham P, Peters TJ, Wiles N, Lewis G. How much change is enough? Evidence from a longitudinal study on depression in UK primary care. *Psychol Med.* 2022 Jul;52(10):1875-1882. doi: 10.1017/S0033291720003700. *Epub* 2020 Nov 3. PMID: 33138872; PMCID: PMC9340848.

