



A digital therapeutic for anxiety symptoms in patients with IPF: An open-label pilot clinical investigation

Maureen Horton¹, Elin Rosendahl², Cecilia Ganslandt², Rohit Batta², Jessica Shull²

¹Johns Hopkins University School of Medicine, Baltimore, MD, USA ²Vicore Pharma AB, Stockholm, Sweden

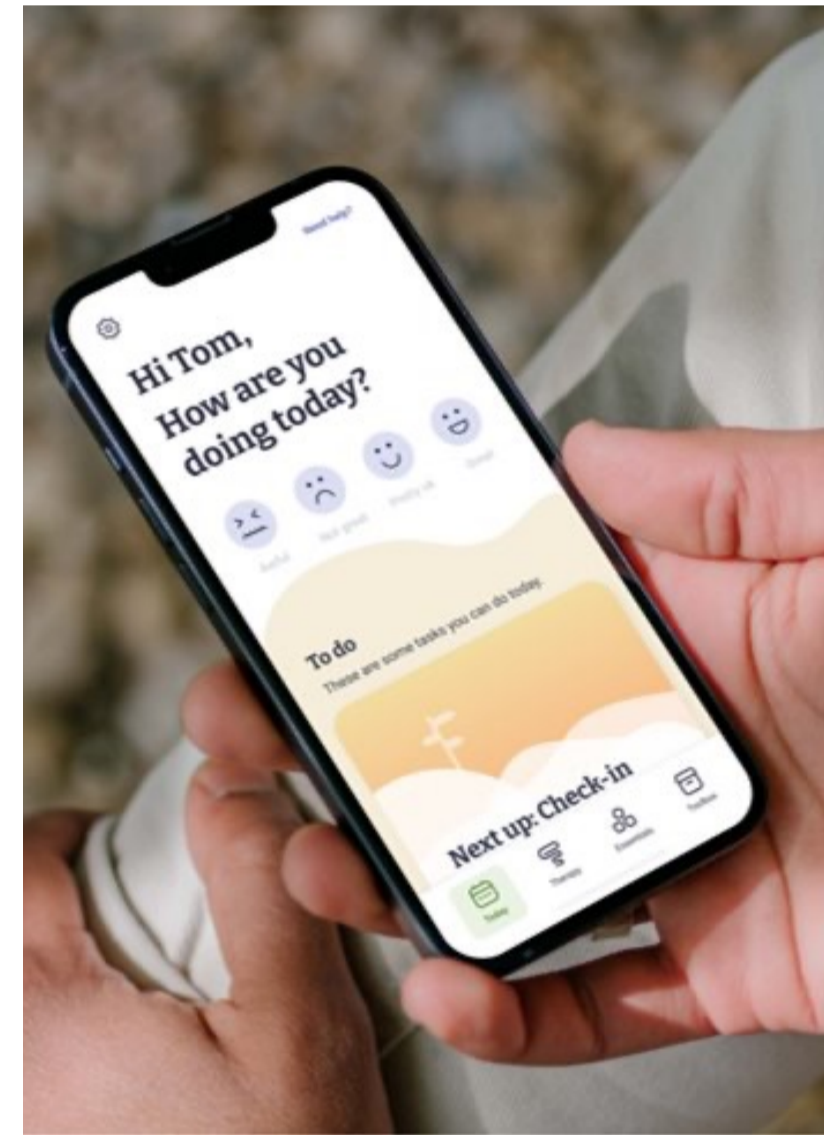
Background

- 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^{1,2}
- 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 patient³

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

Digital therapeutics (DTx)

- Digital therapeutics (DTx) are software-as-a-medical-device products; evidence-based interventions cleared by FDA
- Several DTx products are available in the US for a variety of diseases
- Cognitive behavioral therapy (CBT) is a recommended first-line treatment for anxiety disorders¹
- CBT has been proposed beneficial in managing anxiety in pulmonary fibrosis²
- CBT through a DTx provides easy-access home-based CBT without the need for making appointments, spending time on travel and reduces the risk of contracting infections during consultations



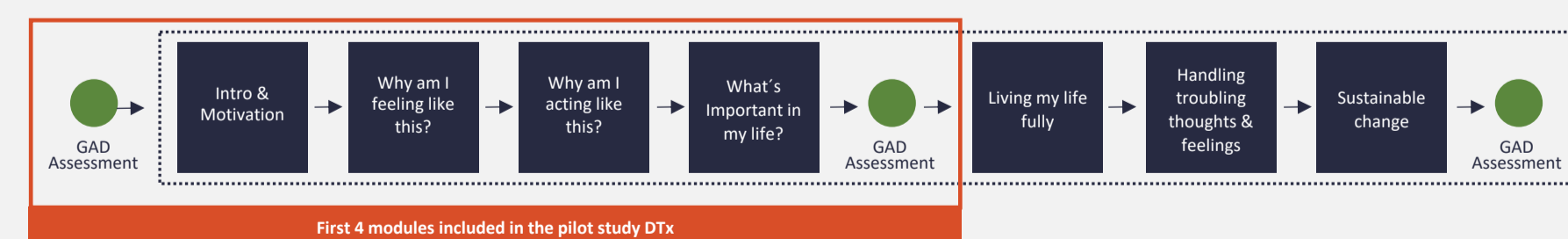
¹ Powers et al. 2015. <https://adaa.org/resources-professionals/practiceguidelines-gad>
² Wijsenbeek et al. 2019. *Am J Respir Crit Care Med* 2019;200:152-159.

The study DTx



- A digital Cognitive Behavioral Therapy accessed through a smartphone or tablet
- Specifically developed to address triggers of anxiety in patients with pulmonary fibrosis in collaboration with ILD specialists, psychologists, and pulmonary fibrosis patients
- Four modules were included in the 4-week pilot investigation
- Recommended use approximately 10 minutes per day for 4 weeks

Therapy modules



PF Essential modules



Aiming to address multiple patient needs



Vicore Pharma developing a range of therapy candidates for pulmonary fibrosis

C21 (AT2 receptor agonist) in IPF – phase 2 clinical trial ongoing

- AIR phase 2a in IPF – updated interim analysis
- Sunday, May 21 at 2:15 -4:15 pm (Prof Toby Maher)
- Mini Symposium: A99. Clinical trials in chronic lung disease

Inhaled formulation of thalidomide for IPF cough – preclinical formulation

Horton et al. *Thalidomide for the treatment of cough in idiopathic pulmonary fibrosis: a randomized trial.* *Ann Intern Med* 2012;157:398-406

Digital therapeutic for the treatment of PF-related anxiety – pivotal clinical investigation ongoing

Pilot study design

- A 4-week, single-arm, decentralized, open-label clinical investigation (COMPANION, NCT05330312)
- Fully virtual trial setting
- Including patients (planned n=10) with self-reported IPF and a GAD-7 composite score of ≥5
- Significant psychiatric conditions, suicidal ideation or behavior, and alcohol/drug abuse were exclusionary
- Intervention: Study DTx for 4 weeks
 - Objectives: Functionality and user experience
 - Safety
 - Change in patient-reported outcomes baseline to end-of-treatment:
 - Generalized Anxiety Disorder (GAD-7)
 - Patient Health Questionnaire (PHQ-9)

Inclusion

ANXIETY SEVERITY (GAD-7)	
Minimal	≤4
Mild	5-9
Moderate	10-14
Severe	≥15

DEPRESSION SEVERITY (PHQ-9)	
Minimal	≤4
Mild	5-9
Moderate	10-14
Moderately/severe	15-19
Severe	≥20

Baseline characteristics, functionality & safety

11 SUBJECTS ENROLLED

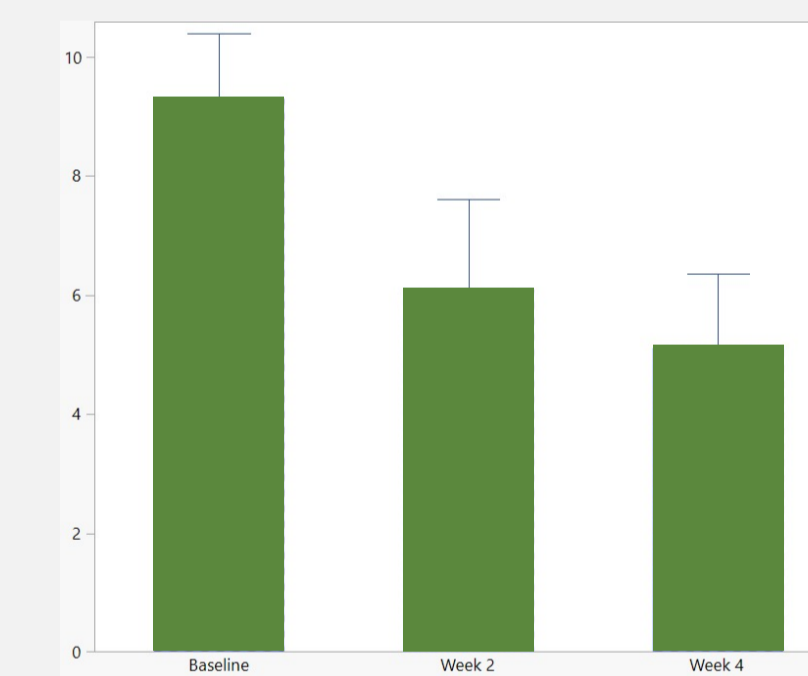
- 6 males, 5 females
- Mean age: 71.1 years
- Mean baseline GAD-7: 8.9 (SD 3.53; range 5 to 15)
- Mean baseline PHQ-9: 11.1 (SD 3.83; range 4 to 16)

10 SUBJECTS COMPLETED INVESTIGATION

- Mean daily use of the DTx: 16.5 (SD 13.24) minutes
- Functionality & user acceptance: positive - intuitive and easy to use
- No adverse events related to the intervention

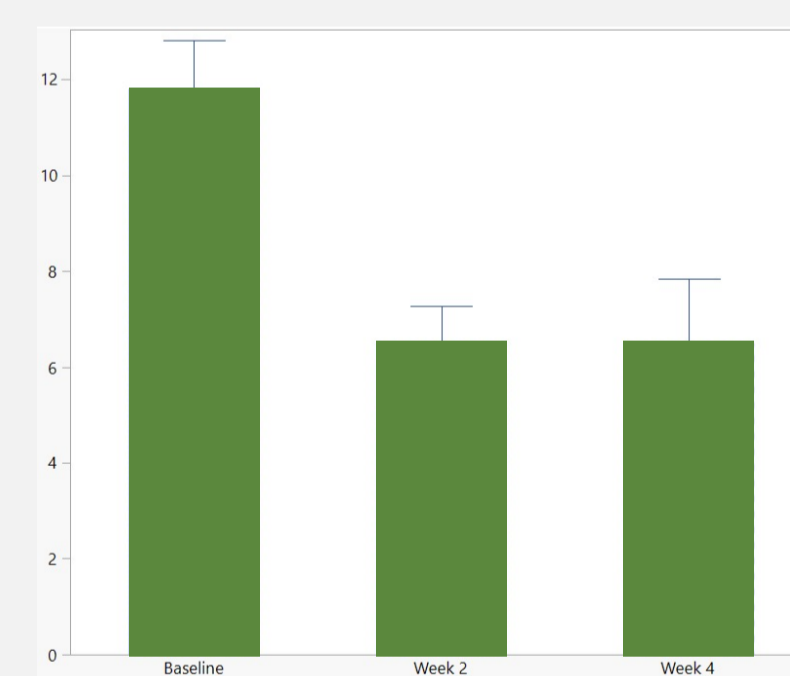
Results - efficacy

Anxiety (GAD-7): Mean +/- SEM (n=10)



MCID GAD-7: 2.2*

Depression (PHQ-9): Mean +/- SEM (n=10)

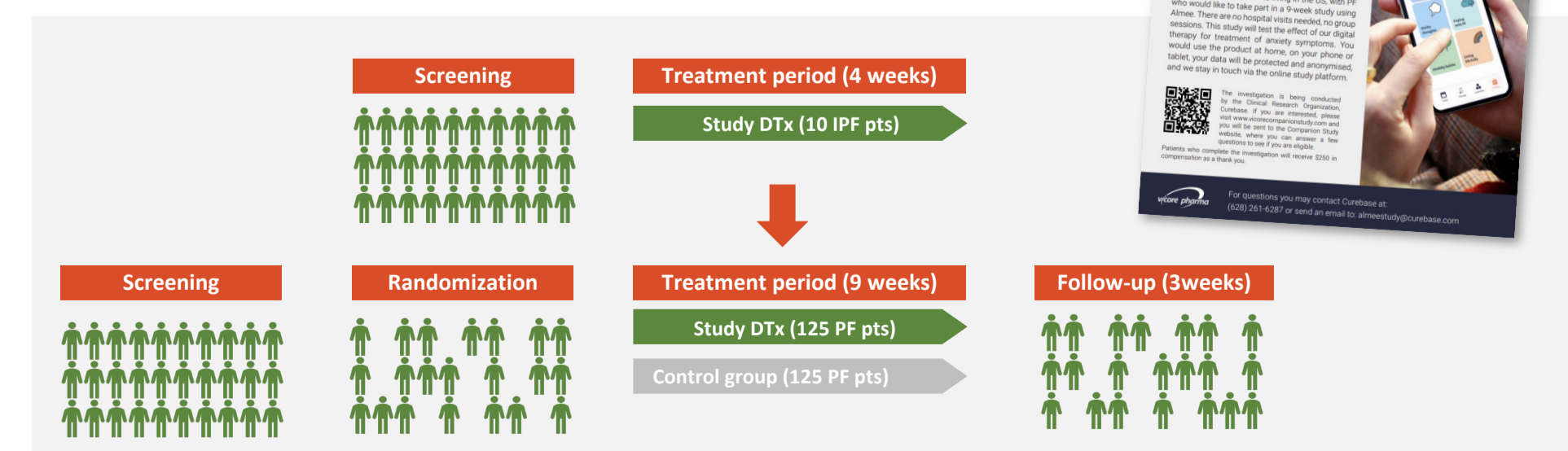


MCID PHQ-9: 2.0*

*Kounali et al. 2020. *Psychological Medicine* 1-8. <https://doi.org/10.1017/S0033291720003700>

Path forward

- For the pivotal, controlled study phase the population has been expanded to include up to 250 patients with pulmonary fibrosis and anxiety
- Recruitment for the pivotal phase is currently ongoing <http://www.vicorecompanionstudy.com/>



Conclusions:

- Four weeks use of the study DTx reduced anxiety symptoms by 49% - a clinically meaningful improvement
- The study DTx has a good safety profile.
- The study DTx was appreciated as functional and user-friendly