Effects on life satisfaction using a digital therapy in individuals with pulmonary fibrosis -randomised controlled investigation

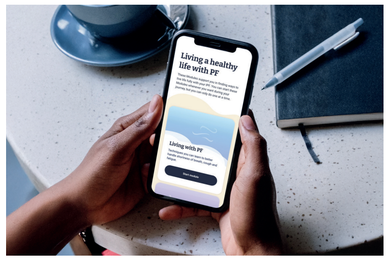
Mary Beth Scholand[1], Joshua J Solomon, MD[2] , Robert W. Hallowell, MD.[3], Mark Hamblin MD[4], Christopher Harden[5], Jessica Shull, PhD.[6], Maureen Horton, MD.[7]

[1]University of Utah Health Salt Lake City, [2] National Jewish Health Denver, [3] Massachusetts General Hospital and Harvard Medical School, [4] University of Kansas, [5] University of Florida, [6] Vicore Pharma. Sweden, [7]Johns Hopkins University School of Medicine

Aims / learning objectives

Pulmonary fibrosis (PF), a manifestation of interstitial lung disease, is a devastating condition with significant impact on quality of life (QoL).

1. Almee, a digital cognitive behavioral therapy (CBT) in development, was designed to alleviate the psychological burden of living with PF.
2. The aim of the current analysis was to evaluate the effect of Almee on general life satisfaction and QoL in patients with PF in the United States.



Methodology of the COMPANION study

Study Characteristics

- A randomized, controlled, open-label, partly reader-blinded, decentralized clinical investigation
- Patients with CT-confirmed pulmonary fibrosis and anxiety symptoms (GAD-7* score ≥ 5)
- Assessment of efficacy and safety at baseline, Weeks 3, 6, 9 and 12
- Primary endpoint: Change from baseline in anxiety symptom severity (GAD-7) at week 9
- Key secondary endpoints included change in health-related QoL as measured by KBILD**.
- Change in life satisfaction was explored using BBQ***

Study Design

Screening → Almee for 9 weeks; N=54 / Control (no intervention) for 9 weeks; N=54 → 3 weeks off-treatment follow-up

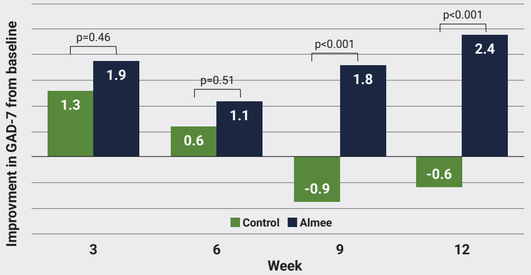
* Generalized Anxiety Disorder 7-item questionnaire on emotions, stress, and coping. Lower score = lower anxiety.

** King's Brief Interstitial Lung Disease, a validated 15-item, disease-specific questionnaire. Higher score = greater QoL

*** Brunnsviken Brief Quality of Life Inventory, a 12-item questionnaire assessing QoL in 6 areas (Leisure time, View on life, Creativity, Learning, Friends and Friendship, and View of self) on a 5-point scale, to supplement the disease-specific assessment of KBILD. The six key domains—Leisure, Outlook, Creativity, Learning, Friendships, and Self-Perception.Higher score = greater QoL

Result

Results on primary endpoint: change in GAD-7



Almee met its primary endpoint (at week 9) of anxiety reduction (p=0.0006)

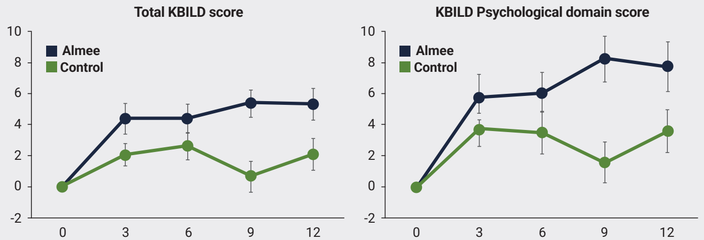
Analysis of change from baseline BBQ health scores and KBILD scores at week 9, observed data

Quality of Life Measure	Almee	Control	Difference	p-value
BBQ health scores	5.44	-1.06	6.50 (0.63-12.38)	0.0305
KBILD total score	5.09	2.09	3.01 (0.59-5.43)	0.0154
KBILD Psychological domain	8.23	2.71	5.51 (1.74-9.29)	0.0047
KBILD Breathlessness and Activities domain	4.20	1.24	2.96 (-1.30-7.22)	0.1710
KBILD Chest symptoms domain	5.82	3.32	2.50 (-3-35-8.34)	0.3984

Almee (N=47) vs Control (N=48)

Improvements in health-related QoL using KBILD

Including subgroups of patients on/off anxiolytics/ antidepressants and on/off antifibrotics

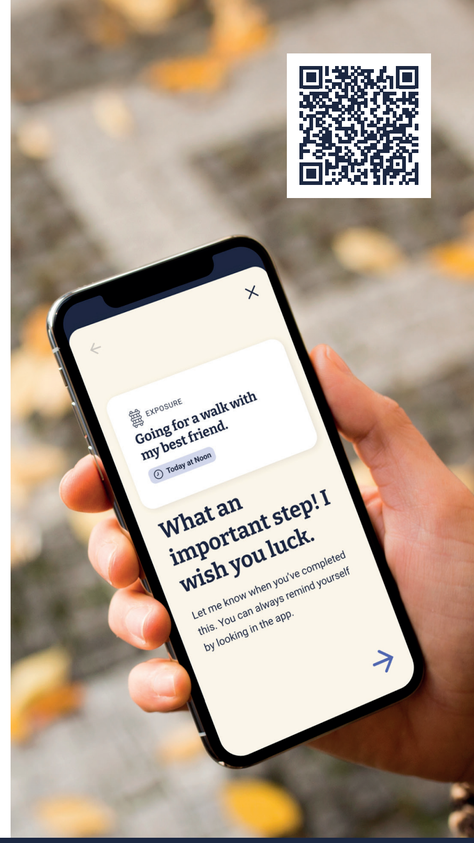


Change in K-BILD scores from baseline. Imputed data. N = 108. Lines represent mean values.

Change in KBILD total score:
- Treatment difference at week 9: 4.4 points (p = 0.0019)
- Treatment difference at week 12: 2.9 points (p = 0.0490)

Change in psychological domain score:
- Treatment difference at week 9: 6.5 points (p = 0.0015)
- Treatment difference at week 12: 4.0 points (p = 0.0667)

The 3 KBILD domains:
- Psychological
- Breathlessness and Activities
- Chest symptoms



Conclusions

- In addition to effects on health-related QoL, use of Almee improved general life satisfaction in patients with PF.
- Almee can be a valuable adjunct to comprehensive care in PF and lead to significant improvements in health-related QoL.
- Improvements in health-related QoL may lead to increased treatment persistence (refs 1–3).

References

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