

Reduction of Fibromyalgia Severity with a Digital Acceptance and Commitment Therapy

PRESENTER
 Michael J. Rosenbluth, PhD



Background

Fibromyalgia (FM) is a chronic pain disorder often accompanied by additional symptoms that negatively impact quality of life, including fatigue, sleep disturbance, difficulty concentrating, depression, and anxiety.

The complex clinical manifestations lead to high clinical and economic burden that worsens with greater FM severity.

Clinical guidelines recommend Cognitive Behavioral Therapy (CBT) as a stand alone or adjunctive treatment with level 1A evidence.¹⁻⁴

Acceptance and Commitment Therapy (ACT) is empirically supported for managing chronic pain, including FM.^{5,6}

This study assessed the effectiveness in reducing FM severity from a smartphone-based digital therapeutic (FM-ACT).

Methods

FM-ACT

FM-ACT (*Stanza*®, *Swing Therapeutics, Inc., San Francisco, CA*), is a FDA cleared, Class II prescription digital therapeutic that provides self-guided ACT for FM patients (Fig. 4).⁷

The program is composed of 8 core chapters along with reinforcement content to strengthen the learned skills. The core therapy is 3 months, followed by a maintenance period.

Each chapter consists of 4 to 6 therapy sessions, in which patients learn and practice core ACT skills related to processes of acceptance, values, present moment awareness, cognitive defusion, self as context, and committed action to build psychological flexibility.

The program also offers additional CBT-based interventions for chronic pain, including disease education, paced daily activities/exercise, and sleep.

Study Design

- The study was a secondary analysis of accumulated data from 3 trials (2 RCTs^{8,9} and 1 ongoing real-world study¹⁰).
- All participants who received FM-ACT treatment and had outcomes data available at Month 3 were included (N = 143).

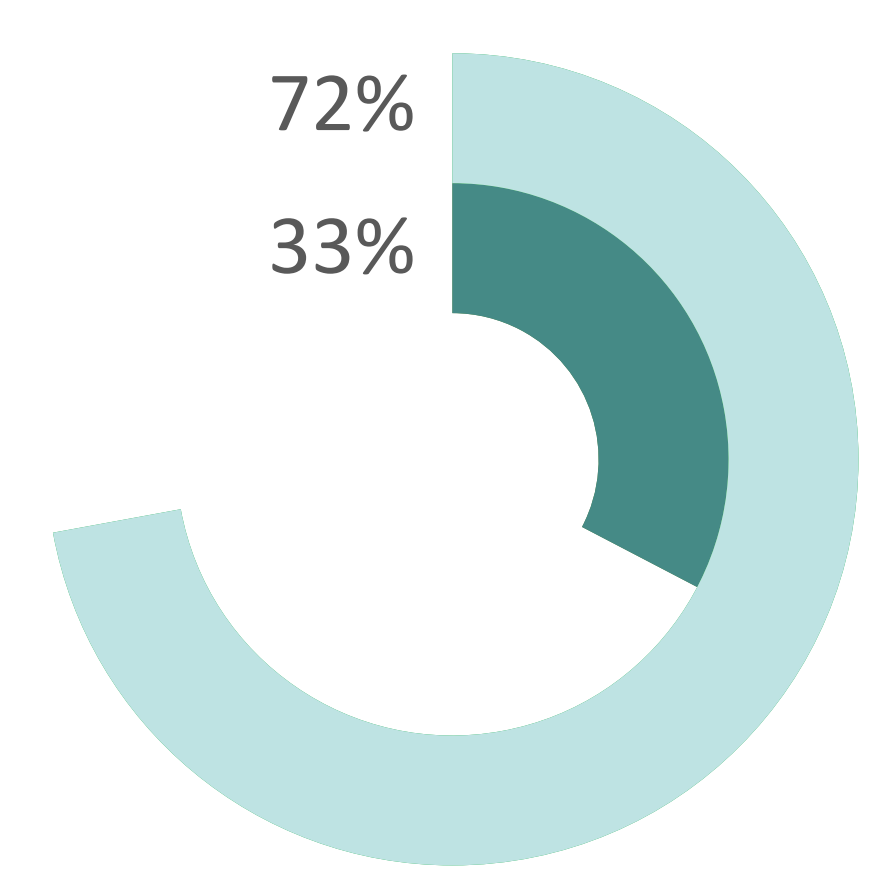
Data Collection and Analysis

- Baseline and Post-treatment (Month 3):
 - PGIC: Patient Global Impression of Change (Month 3 only)
 - FIQ-R: Revised Fibromyalgia Impact Questionnaire
 - Pain Intensity, Pain Interference, and Sleep Interference
 - BDI-II: Beck Depression Inventory II
- Improvement in FM-related well-being was assessed by PGIC response rate.
- Post-treatment changes in FM severity were evaluated on the clinical measures associated with different symptoms of FM (Table 1).
- Responders on a clinical measure were defined as participants who had baseline to Month 3 reduction of at least one severity level.

Table 1. Measures and score ranges used to define FM severity.

	Measure	No Impact/ Subclinical	Mild	Moderate	Severe
FM Impact	FIQ-R total	0	1 to < 39	39 to < 59	59 to 100
Pain	Pain Intensity NRS	0	1 to 3	4 to 7	8 to 10
	Pain Interference NRS	0	1 to 3	4 to 7	8 to 10
Sleep Problem	Sleep Interference NRS	0	1 to 3	4 to 7	8 to 10
Depression	BDI-II	0 to 13	14 to 19	20 to 28	29 to 63
Fatigue	BDI-II "tiredness & fatigue"	0	1	2	3

Key: BDI-II - Beck Depression Inventory; FIQ-R - Revised Fibromyalgia Impact Questionnaire; NRS - Numerical Rating Scale, a scale of 0 (no impact) - 10 (max severity) was used.



72% of participants responded on PGIC

Figure 2. % Participants responded on PGIC at Month 3.

FM severity reduced on all clinical measures and across baseline severity groups, especially among participants with greater baseline severity

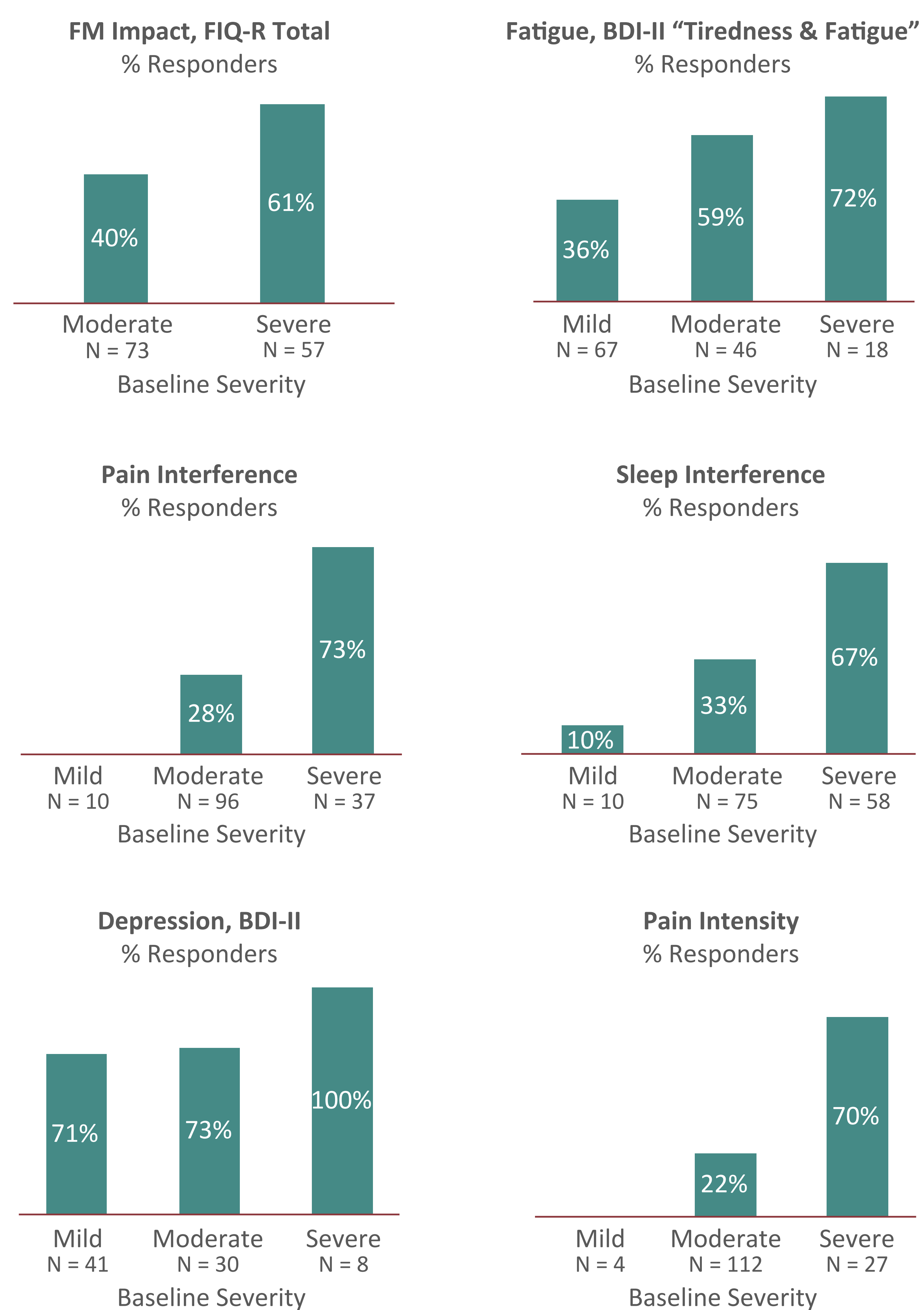


Figure 3. % Participants responded in each baseline severity group on the clinical measures. A response was defined as post-treatment transition to a lower severity category (e.g. moderate to mild) at month 3 compared to baseline.

Conclusion

The results demonstrated that FM-ACT treatment reduces severity on FM symptoms and improves well-being.

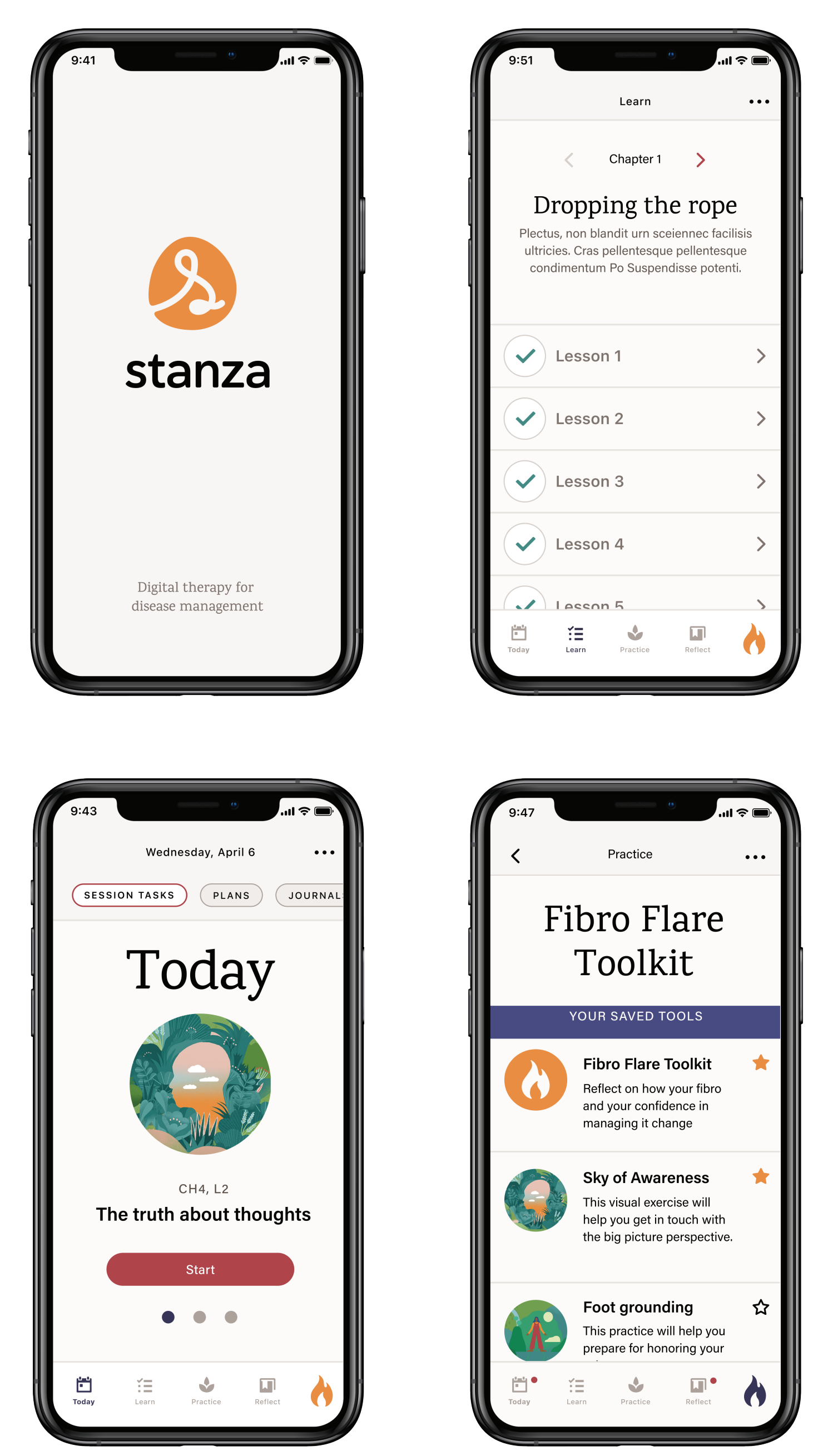


Figure 1. FM-ACT digital therapeutic application.

References

- [1] Clauw. JAMA. 2014; 311(15):1547-55
- [2] Häuser, et al. Nat Rev Dis Primers. 2015; 1:15022
- [3] Bernardy, et al. Eur J Pain. 2018; 22(2):242-60
- [4] Köllner, et al. Schmerz. 2012; 26(3):291-6
- [5] Feliu-Soler, et al. J Pain Res. 2018; 11:2145-59
- [6] McCracken, et al. BMJ. 2022; 376:e057212
- [7] Catella, et al. J Behav Med. 2023. Epub
- [8] SMART-FM, NCT05005351
- [9] PROSPER-FM, NCT05243511, Interim Analysis
- [10] REACT-FM, NCT05011162

Yifei Dai, PhD¹; Nicolette Vega, BA¹; Zunera Ghalib, BS¹; Kristen Guthrie BS¹; Allison Kraus, MA¹; R. Michael Gendreau, MD PhD²; Michael J. Rosenbluth, PhD¹; Juan V. Luciano, PhD³; Lance M. McCracken, PhD⁴; Andrea L. Chadwick, MD⁵; Brian Keefe, MD⁶

¹Swing Therapeutics, San Francisco, CA, USA
²Gendreau Consulting, LLC, Poway, CA, USA
³Dept of Clinical and Health Psychology, Universitat Autònoma de Barcelona, Bellaterra, ES
⁴Dept of Psychology, Uppsala University, Uppsala, SE
⁵Dept of Anesthesiology, Pain, and Perioperative Medicine, University of Kansas School of Medicine, Kansas City, KS
⁶Independent consultant

