

Effectiveness of a Digital Acceptance and Commitment Therapy on Fatigue and Sleep Quality in Fibromyalgia: An Appraisal of Clinical Studies

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Background

Fatigue and sleep interference are among the most common and disabling symptoms associated with fibromyalgia (FM), negatively impacting patients' lives.

A smartphone-based, prescription digital therapeutic (FM-ACT) has been developed to deliver acceptance and commitment therapy (ACT), a guidelines-recommended behavioral therapy¹⁻⁴, to help patients better manage symptoms associated with FM.

Clinical benefits of FM-ACT have been demonstrated by randomized controlled trials (RCTs) in reducing FM severity and improving well-being.^{5,6}

This study reports an assessment of the clinical effect of FM-ACT on fatigue and sleep interference in patients with FM.

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 5).

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^{7,8} and 1 ongoing real-world study⁹).
- All participants who received FM-ACT treatment with outcome data available at Month 3 were included (N = 143).

Data Collection and Analysis

- Data were collected at Baseline and post-treatment at Month 3
- Baseline to Month 3 changes were assessed on clinical measures associated with fatigue and sleep interference (Table 1).
- % Improved participants were assessed in those with "moderate" to "severe" symptom at Baseline.

Table 1. Measures used to assess post-treatment improvement on fatigue and sleep.

	Measure	Data Source (N)
Fatigue	PROMIS Fatigue, T-score	2 RCTs (77)
	FIQ-R, "energy" item	All 3 trials (143)
	BDI-II, "tiredness & fatigue" item	All 3 trials (143)
Sleep	Sleep Interference NRS	All 3 trials (143)

PROMIS - Patient-Reported Outcomes Measurement Information System.
FIQ-R - Revised Fibromyalgia Impact Questionnaire. The "energy" item is an 11-level scale ranging from 0 (lots of energy) to 10 (no energy).
BDI-II - Beck Depression Inventory II. The "tiredness & fatigue" item is a 4-level scale ranging from 0 (No more tired than usual) to 3 (Too tired to do most things).
NRS - Numerical Rating Scale. The Sleep Interference NRS is an 11-level scale ranging from 0 (no interference) to 10 (max interference).

Average improvement on PROMIS Fatigue in both RCTs ≥ minimal important change¹⁰, with high % of participants meaningfully improved

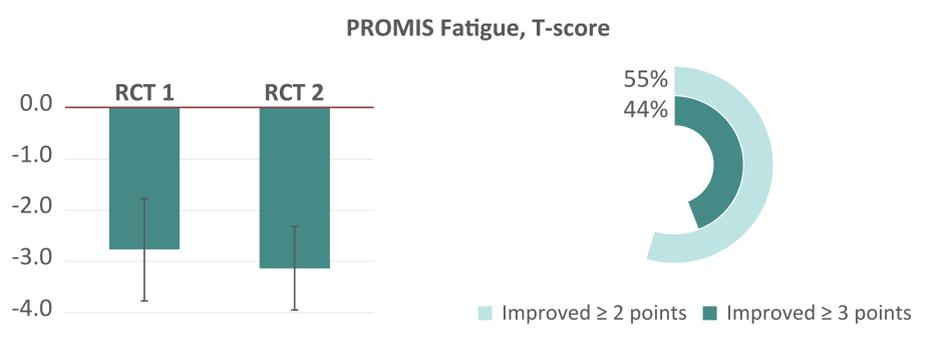
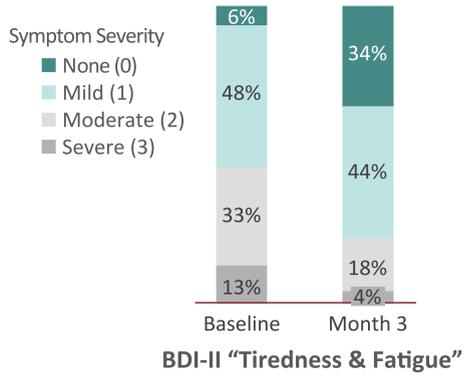


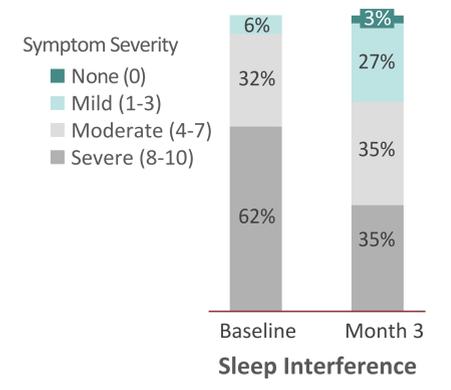
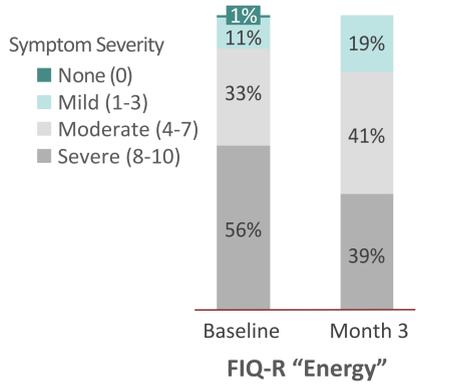
Figure 1. Change from baseline to Month 3 on PROMIS Fatigue T-score.

Figure 2. % participants responded on PROMIS Fatigue T-score (pooled from the 2 RCTs).



Participants experienced less fatigue and sleep interference after treatment

Figure 3. % Participants in each severity category at Baseline and Month 3.



Most participants with baseline moderate to severe symptoms improved

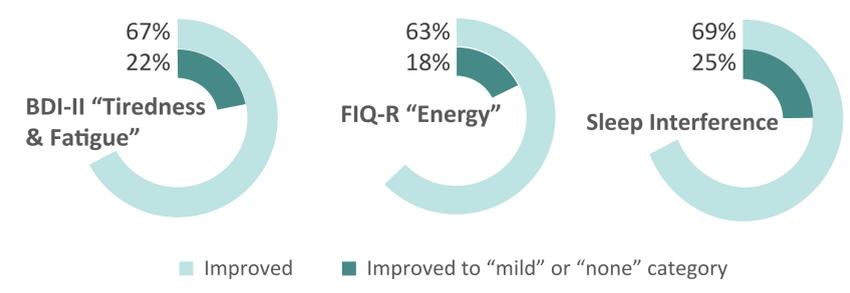


Figure 4. % Participants improved in those with moderate to severe symptom at baseline.

Conclusion

The findings demonstrated that FM-ACT improves outcomes on fatigue and sleep interference associated with FM.

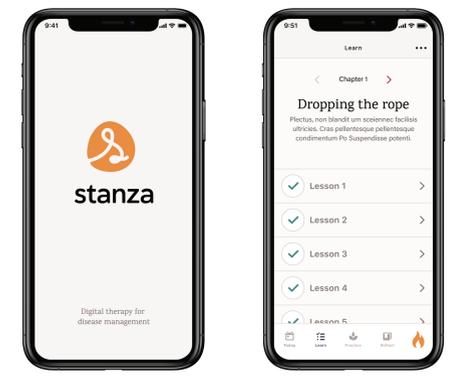


Figure 5. FM-ACT digital therapeutic application.

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