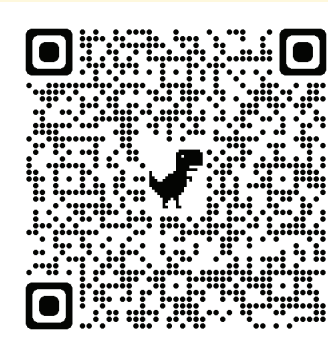




Digital Therapeutic Augmented Telehealth for Chronic Pain: Early Results at a Fibromyalgia Virtual Specialty Clinic

Dianne Shumay, PhD¹; Yifei Dai, PhD¹; Lora Black, PhD MPH²; Kristen Guthrie, BA¹; Allison Kraus, MA¹; Michael J. Rosenbluth, PhD¹; Lesley M. Arnold, MD³; Yvonne C. Lee, MD MMSc⁴; David A. Williams, PhD⁵; Andrea L. Chadwick, MD⁶

¹Swing Therapeutics, San Francisco, CA; ²Department of Psychiatry and Behavioral Health, The Ohio State University, Columbus, OH; ³College of Medicine, University of Cincinnati, Cincinnati, OH; ⁴Department of Medicine, Northwestern University Feinberg School of Medicine, Chicago, IL; ⁵Department of Anesthesiology, University of Michigan Medical School, Ann Arbor, MI; ⁶Department of Anesthesiology, Pain, and Perioperative Medicine, University of Kansas School of Medicine, Kansas City, KS

OBJECTIVE

To assess patient outcomes from treatment at a virtual fibromyalgia specialty clinic, inclusive of a prescription digital behavioral therapy

BACKGROUND

Clinical guidelines recommend inclusion of non-drug treatments for optimal management of Fibromyalgia (FM), including cognitive behavioral therapy (CBT).

Acceptance and Commitment Therapy (ACT), a form of CBT, is empirically validated for FM.^{1,2}

ACT guides patients through acceptance and mindfulness strategies for uncontrollable symptoms, as well as commitment and behavior change strategies to reduce symptom flares, increase quality of life, and improve physical and emotional functioning.

Despite strong clinical benefit, real-world adoption of CBT/ACT is limited to only 4.5% annually,³ largely due to availability of therapists.

A virtual specialty clinic was create to offer personalized, multi-modal treatments inclusive of a digital behavioral therapy (FM-ACT, Fig. 1).

METHODS

A chart review was performed at a FM virtual specialty clinic (*Swing Care*) on patients receiving care inclusive of FM-ACT between 12/2022 and 6/2023 (Fig. 2).

Data collected as part of the clinic protocol during the first 3 months of care were analyzed.

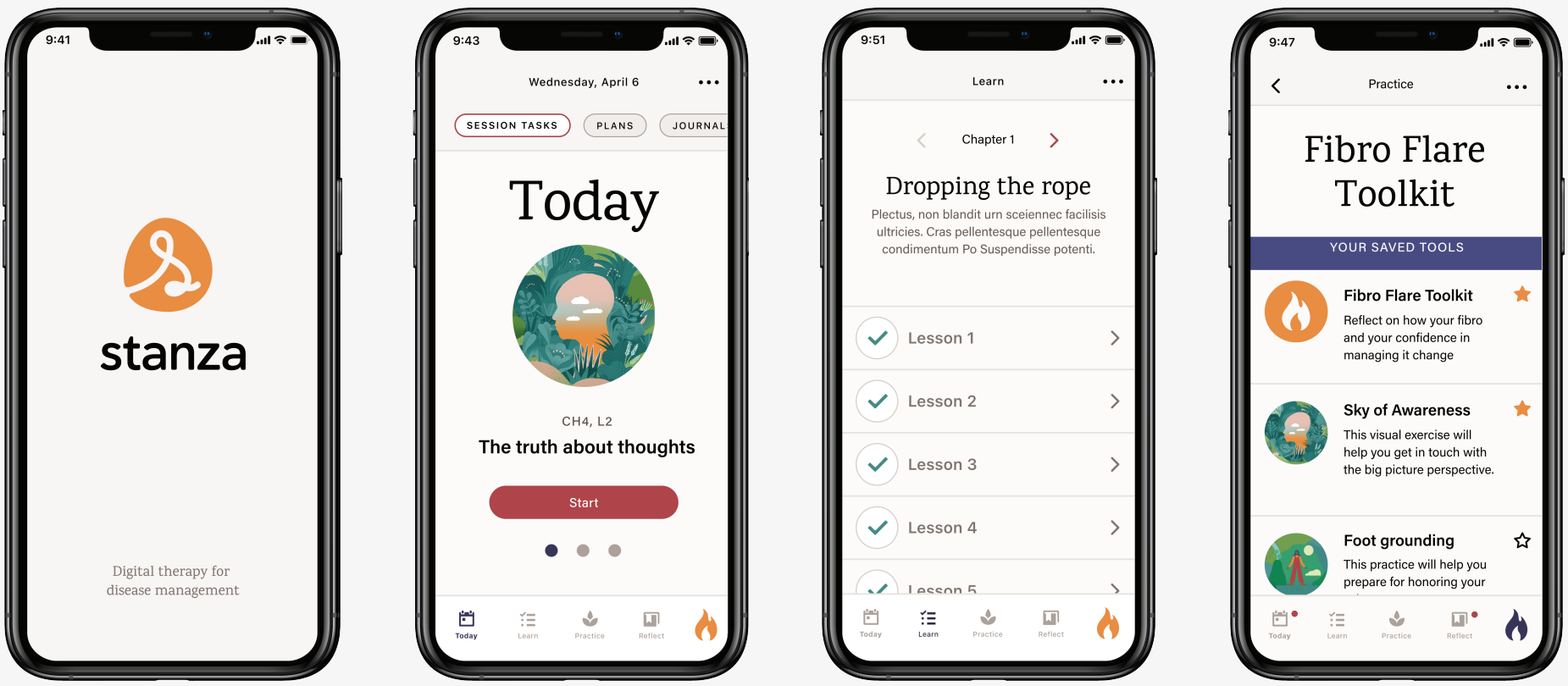


Figure 1. FM-ACT, a FDA cleared, class II digital behavioral therapy for treating FM symptoms (*Stanza*®, *Swing Therapeutics*, San Francisco, CA). An initial treatment consists of 3 months of structured ACT lessons, mindfulness practices, and activities to encourage paced exercise and behavior change, which can be continued after month 3 as therapy reinforcement.

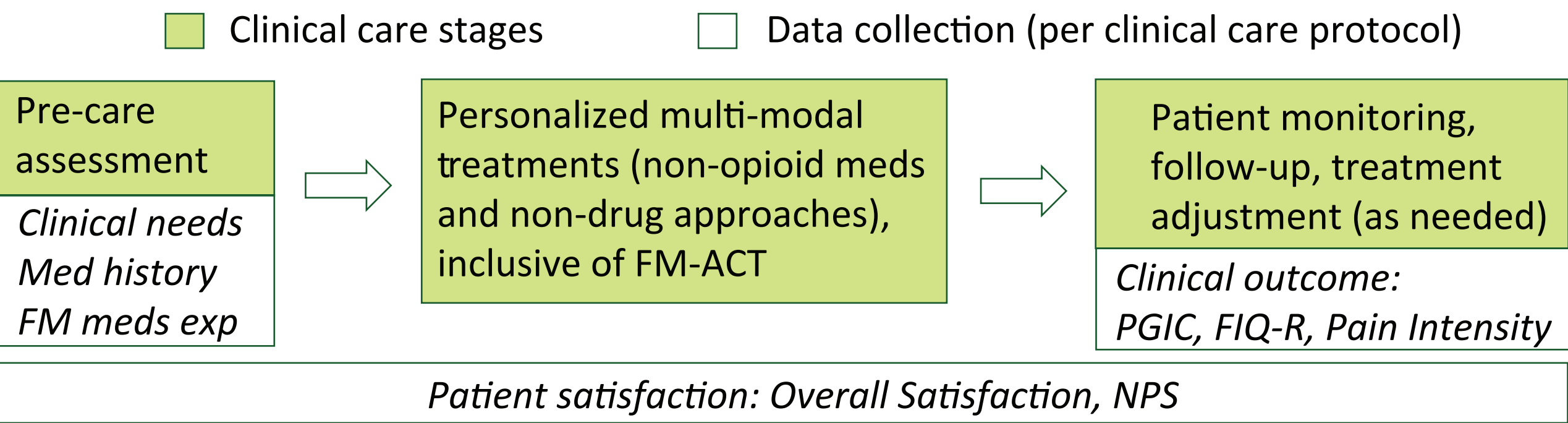


Figure 2. Patient care flow and data collection at the virtual clinic (*Swing Care* Provider Group, Covina, CA). The clinic was operating in Texas during the study time. Abbreviations: PGIC - Patient Global Impression of Change; FIQ-R - Revised Fibromyalgia Impact Questionnaire; NPS - Net Promoter Score.

Table 1. Patient characteristics.

Characteristics (N = 65)	
Gender, Female (n [%])	63 [98%]
Age (mean [SD])	52.2 [11.2]
Baseline FM Status (2016 Criteria)	
Widespread Pain Index (mean [SD])	12.1 [3.6]
Symptom Severity Score (mean [SD])	9.3 [1.8]
Fatigue, Moderate or Greater (n [%])	63 [97%]
Waking Unrefreshed, Moderate or Greater (n [%])	62 [95%]
Cognitive Symptoms, Moderate or Greater (n [%])	45 [69%]

Response to treatment started over 3 months

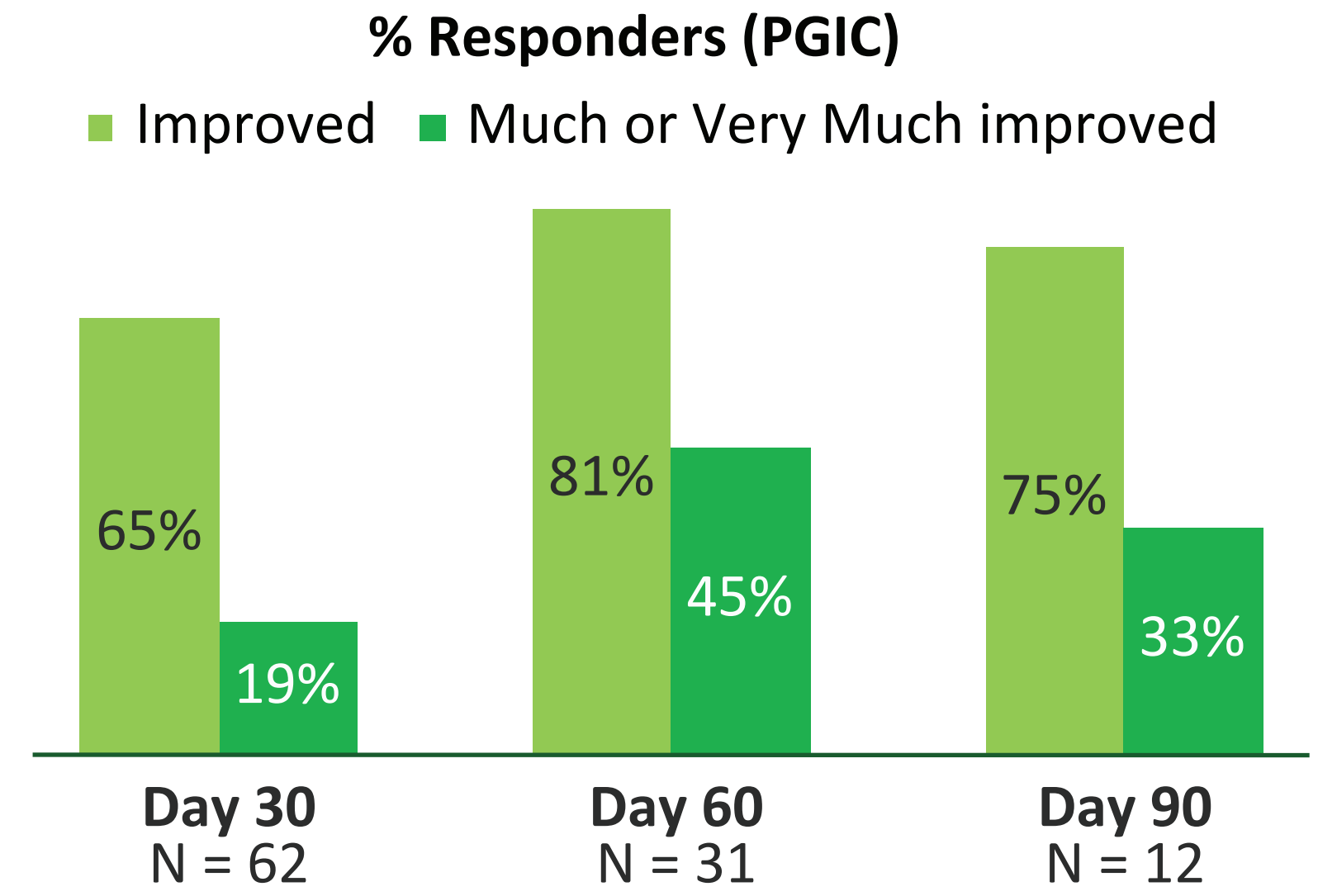


Figure 3. % patients improved (responders) on the Patient Global Impression of Change (PGIC).

FM severity reduced since Day 30

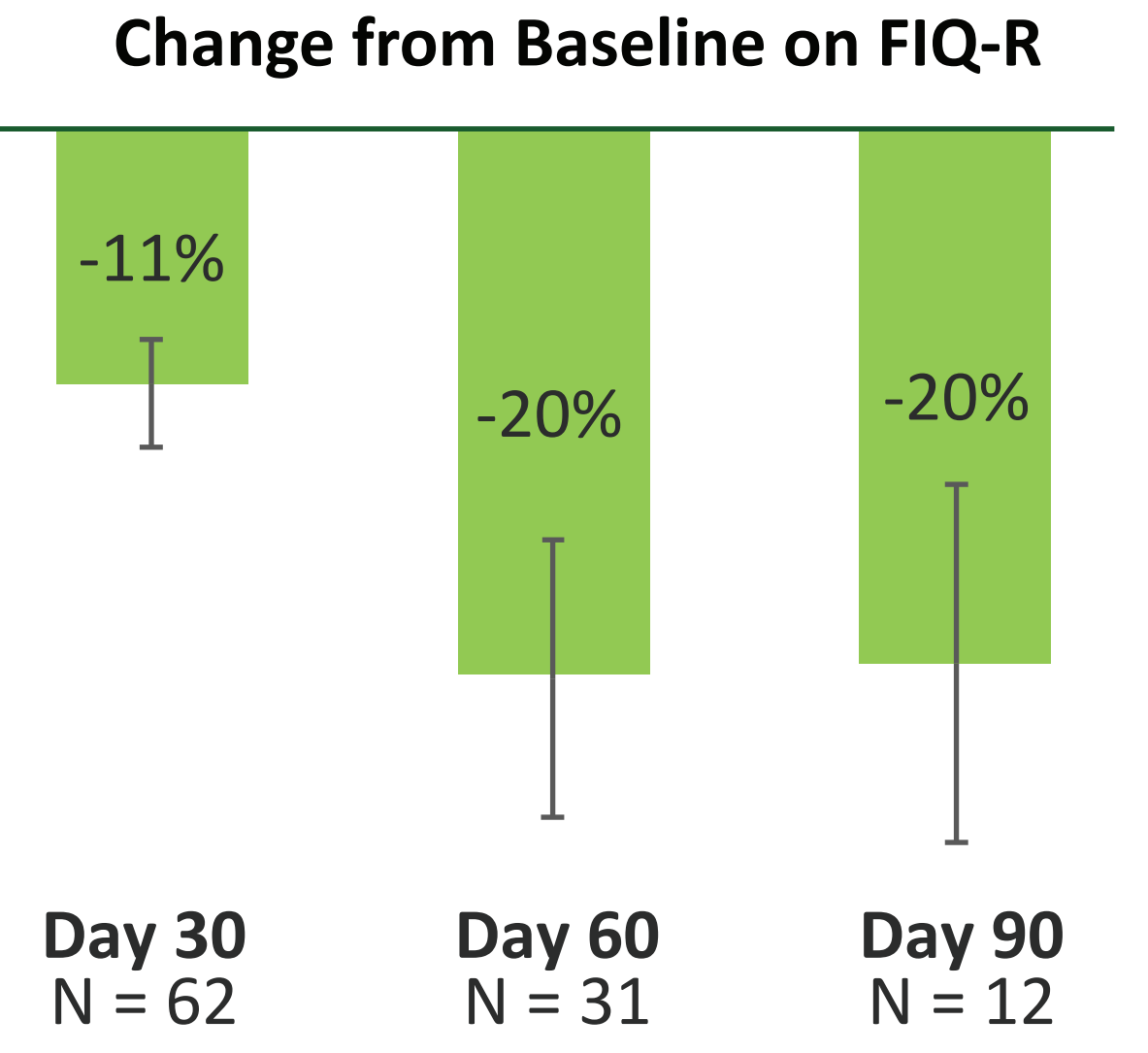


Figure 4. % change (mean and standard error) on the FIQ-R total score from baseline.

Improvements were shown from Day 30 to Day 90 across clinical measures

Table 2. % change from baseline.

Measure	Baseline Mean $\pm$ SD N = 65	Change from Baseline*		
		Day 30 N = 62	Day 60 N = 31	Day 90 N = 12
FIQ-R, total	68.9 $\pm$ 15.8	-11%	-20%	-20%
Function domain	19.2 $\pm$ 6.7	-5%	-13%	-8%
Impact domain	15.3 $\pm$ 4.6	-19%	-30%	-37%
Symptoms domain	34.8 $\pm$ 6.8	-9%	-19%	-20%
Weekly Pain Intensity	7.2 $\pm$ 1.9	-7%	-19%	-25%

*A negative value indicates improvement.

RESULTS

Pre-care assessment revealed substantial clinical unmet needs

- Top 3 symptoms (with prevalence): Fatigue (98%), Widespread pain (92%), Fibro Fog (difficulty concentrating, 85%)
- Top 3 coexisting conditions (with prevalence): Anxiety (83%), Depression (65%), Arthritis (63%)
- 96% of the patients engaged with the virtual clinic with substantial unmet needs (seeking new treatment option).
- In patients with FM medication experience, 80% reported dissatisfaction with medication due to ineffectiveness or side effects

Patients reported high satisfaction with clinical care and FM-ACT

% Patients Rated as NPS "Promoters"

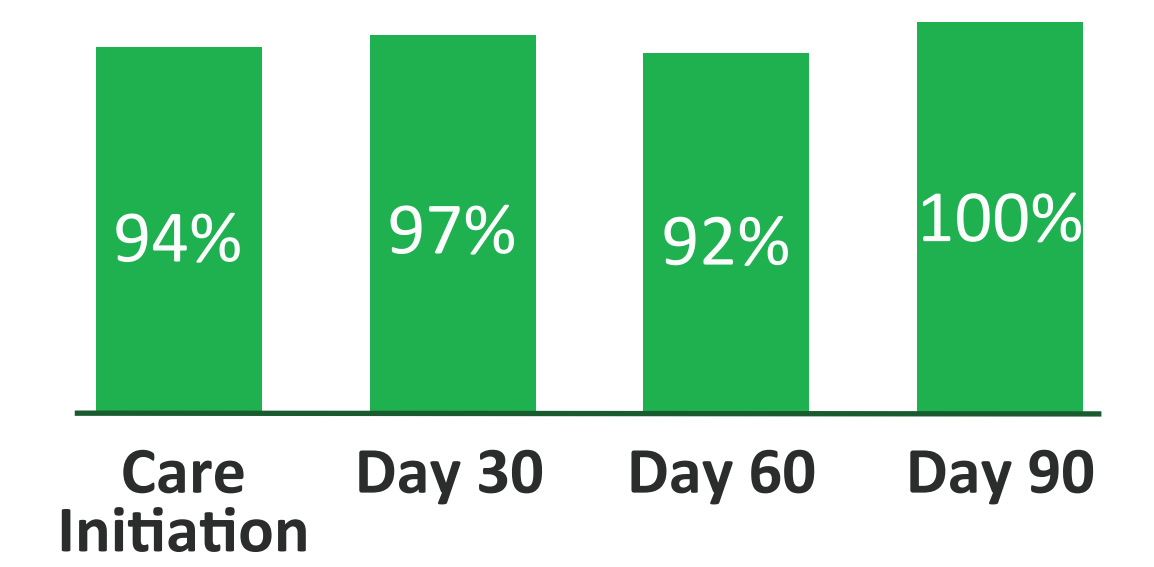


Figure 5. % "Promoters". The NPS was a 1-5 numeric rating scale to measure loyalty and satisfaction by determining how likely patients are to recommend the clinic to their friends and family ("promoter" = a rating of 5).

Value of Digital Therapeutic

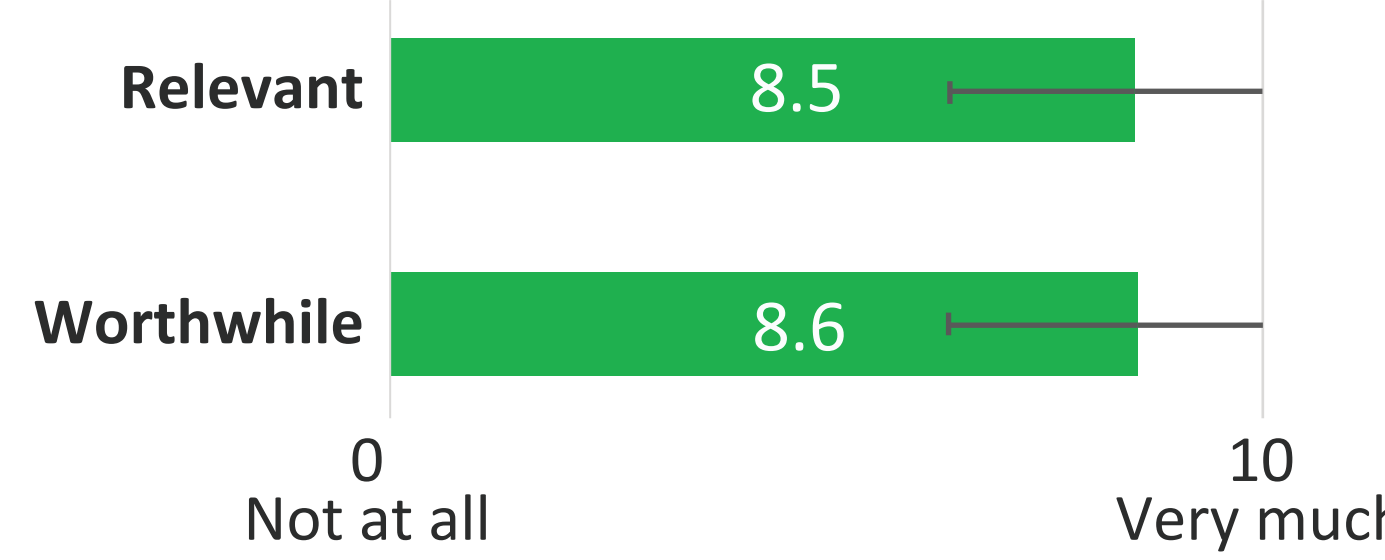


Figure 6. Patient rating on the value of FM-ACT's therapy content.

REFERENCES

- [1] Feliu-Soler A, et al. J Pain Res. 2018; 11:2145-59
- [2] McCracken LM, et al. BMJ. 2022; 376:e057212
- [3] Robinson et al. Pain Med. 2012; 13(10):1366-76

CONCLUSION

Improved FM outcomes and high satisfaction were observed among patients receiving care from a virtual specialty clinic inclusive of a digital behavioral therapy.