

Thinking Outside the (Pill) Box: Prescription Digital Therapeutics for MDD

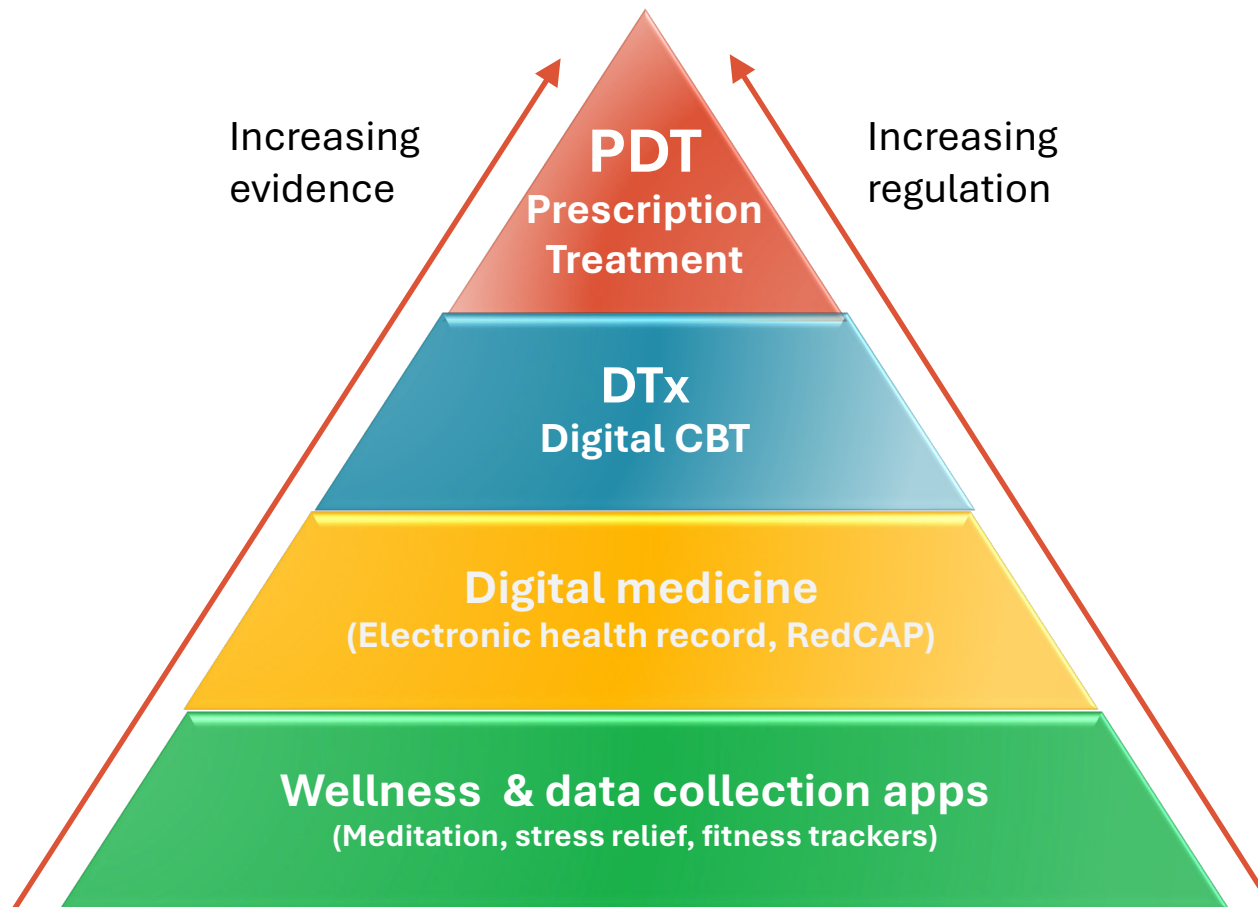


Supported by an independent educational grant
from Otsuka America Pharmaceutical, Inc.

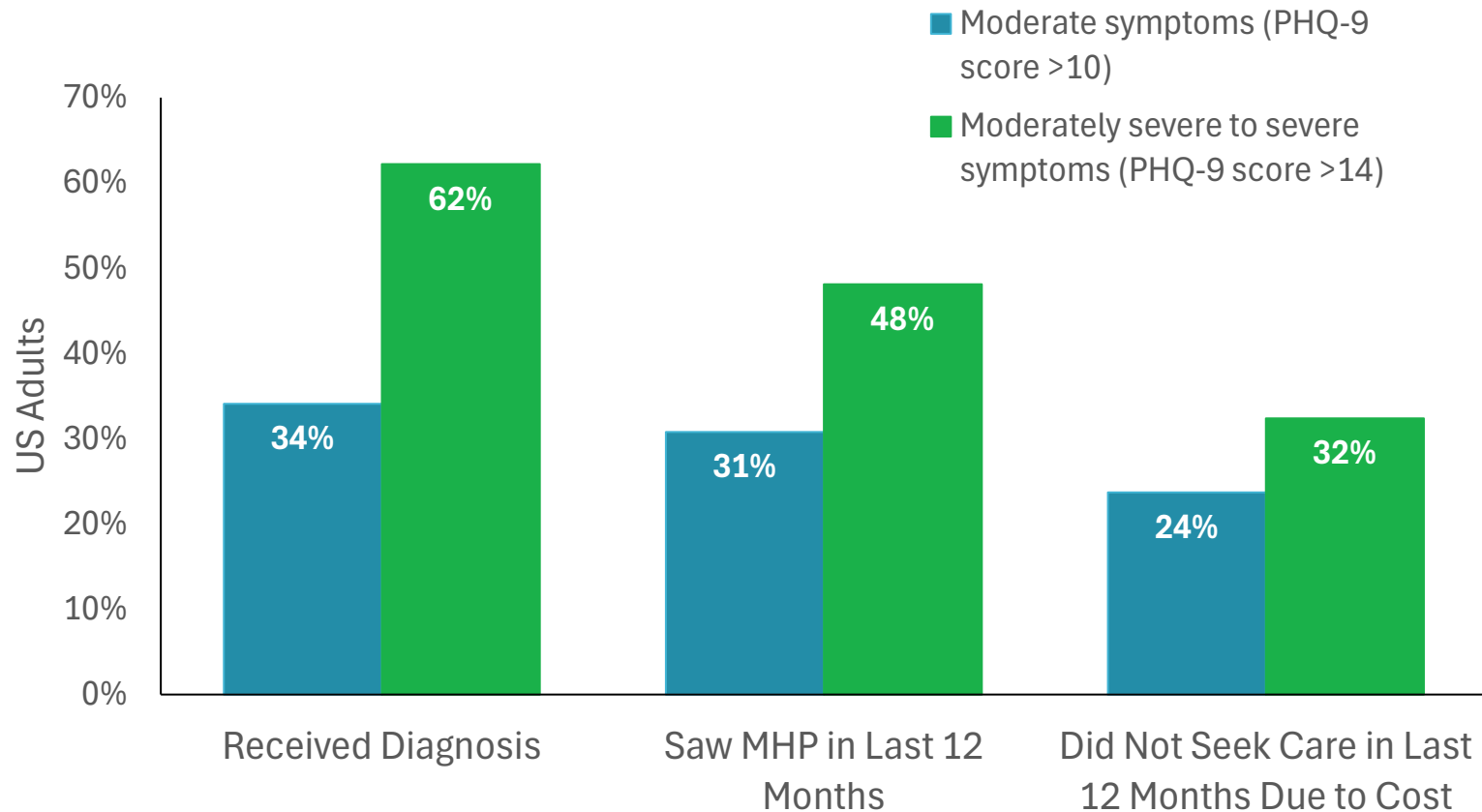
DIGITAL HEALTH				
(Apps anyone can download)		DIGITAL MEDICINE		
		(Cleared for measurement)	DTx	
			(Non-Rx treatment)	PDT (Rx treatments)
DEFINITIONS	<ul style="list-style-type: none"> • Lifestyle, wellness, health-related technology • Capture, store, transmit health data • Support life-science or clinical operations 	<ul style="list-style-type: none"> • Evidence-based technology • Measures and/or intervenes in the service of human health 	<ul style="list-style-type: none"> • Evidence-based therapeutic intervention to prevent, manage, or treat a medical condition 	<ul style="list-style-type: none"> • Evidence-based therapeutic intervention to prevent, manage, or treat a medical condition
Shared definition, different evidence and regulation				
CLINICAL EVIDENCE	<ul style="list-style-type: none"> • No evidence required 	<ul style="list-style-type: none"> • Clinical evidence required 	<ul style="list-style-type: none"> • Clinical evidence with real-world outcome data required 	<ul style="list-style-type: none"> • Meaningful clinical evidence of safety and efficacy for a specific indication from clinical trials
REGULATORY OVERSIGHT	<ul style="list-style-type: none"> • Not defined as a medical device • No regulatory oversight required 	<ul style="list-style-type: none"> • If classified and marketed as a medical device, clearance required • If used to develop medical products (eg, drugs, devices), regulatory acceptance by review body required 	<ul style="list-style-type: none"> • Review and clearance required to support any product claims of intended use, efficacy, and risk 	<ul style="list-style-type: none"> • FDA authorization (clearance or approval); must be prescribed by a licensed healthcare professional for one individual patient's use

DTx = Digital therapy; PDT = prescription digital therapeutic.

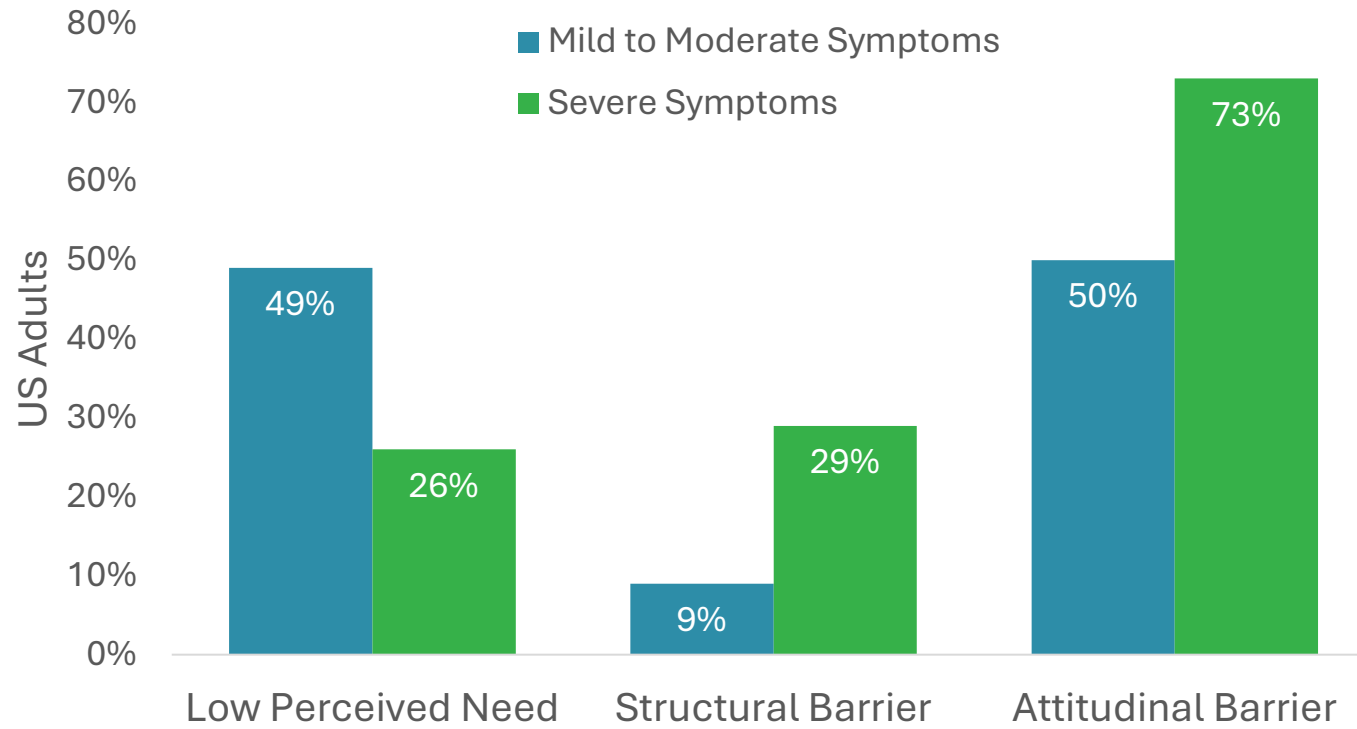
Digital Medicine Society. <https://dimesociety.org/access-resources/digital-healthcare-edition/>. Accessed March 26, 2025.



Over Half With Moderate Symptoms Did Not Access Care in Last Year and 1 of 3 Skipped Care Due to Cost



Stigma Keeps Over Half From Accessing Care and 1 in 3 with Severe Symptoms Face Structural Barriers



In a study of real-world data on SSRI Side Effects,
among 700 adults on SSRIs:



38% experienced side effects



25% found those side effects bothersome



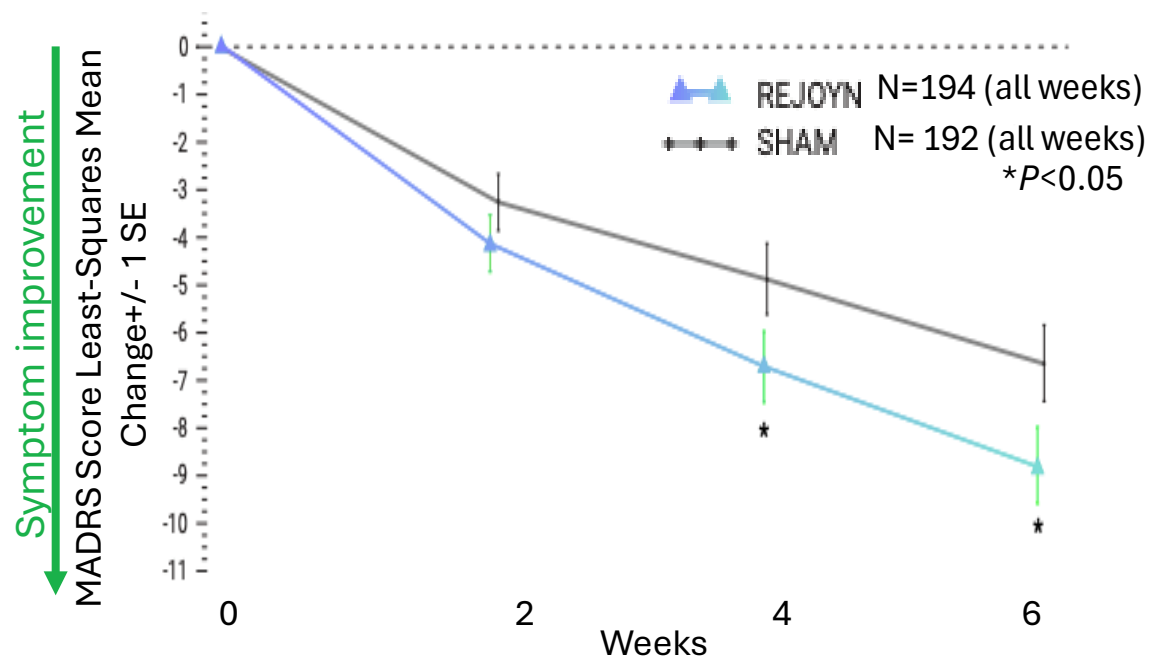
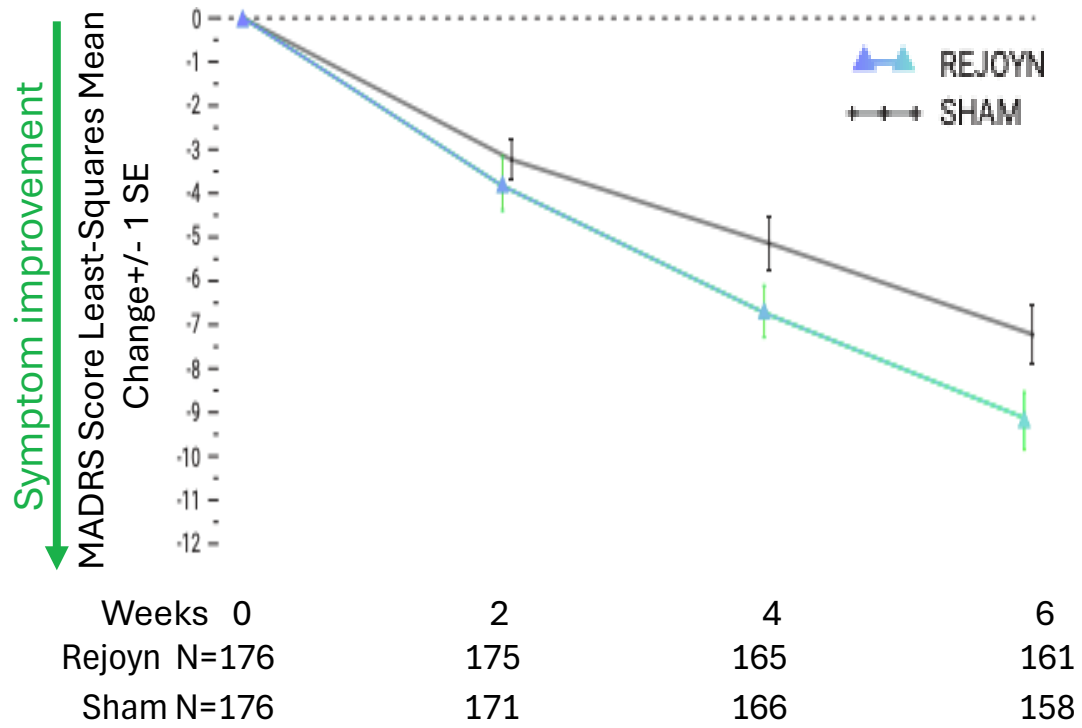
61% with side effects did not report them to
their prescriber

FDA-Authorized Prescription Digital Therapy for MDD





Statistically significant symptom reduction when considering all enrolled (ITT population)



>2 point greater decrease in MADRS score with Rejoyn (-8.78) vs sham (-6.66) (P=0.021; 95% CI: -3.93-0.32).

ITT = Intention to treat; MADRS = Montgomery-Asberg Depression Rating Scale; mITT = Modified intention to treat; SE = Standard error. Rejoyn. Otsuka Precision Health, Inc; 2024. Accessed April 2, 2025. <https://www.rejoynhcp.com/Clinician-Brief-Summary.pdf>

High Tolerability and High Adherence with PDT (Rejoyn)



88% of participants assigned to PDT adhered to treatment (≥ 12 of 18 sessions)



None of the reported adverse events were considered treatment-related



No discontinuations were related to adverse events

Practical Take-Aways

- ✓ **DTx can help address unmet needs** for MDD, including efficacy, tolerability and access, especially for patients with
 - ✓ Partial response
 - ✓ Side effects
 - ✓ Facing mental health professional shortages (~130 million patients)
- ✓ **PDTs are a subset of DTx** that have been **authorized as safe and effective by FDA** based on evidence from controlled, randomized clinical trials with publicly available data
- ✓ The **body of evidence** for the efficacy and safety of DTx **is growing** and mental health professionals should **consider embracing change** and **add these tools** to their **therapeutic armamentarium**

Questions?

