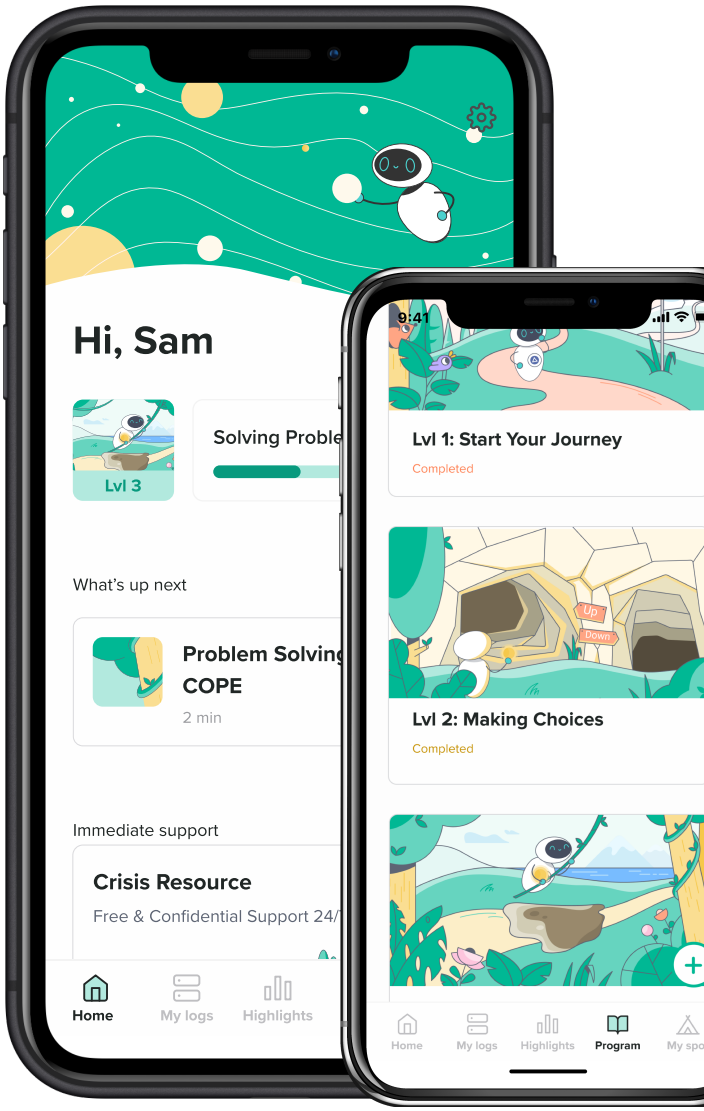
SparkRx

The first digital treatment for adolescent depression.

SparkRx is a digital therapeutic that provides an evidence-based adjunct treatment intervention for adolescents aged 13-22 with symptoms of depression.

Through a 5-week self-guided mobile app, SparkRx delivers the core components of face-to-face cognitive behavioral therapy[1] and includes the following features:

- Psychoeducation
- Activity Scheduling
- Mood Tracking
- Mindfulness
- Problem Solving
- Weekly Assessments



Available now, at no cost to patients[a]

Visit SparkRx.com to begin offering SparkRx to your patients today.

Footnotes

a SparkRx is being offered prior to FDA clearance, under the FDA's Enforcement Policy for Digital Health Devices During the COVID-19 Public Health Emergency. It is available for a limited time at no cost to patients or providers. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enforcement-policy-digital-health-devices-treating-psychiatric-disorders-during-coronavirus-disease

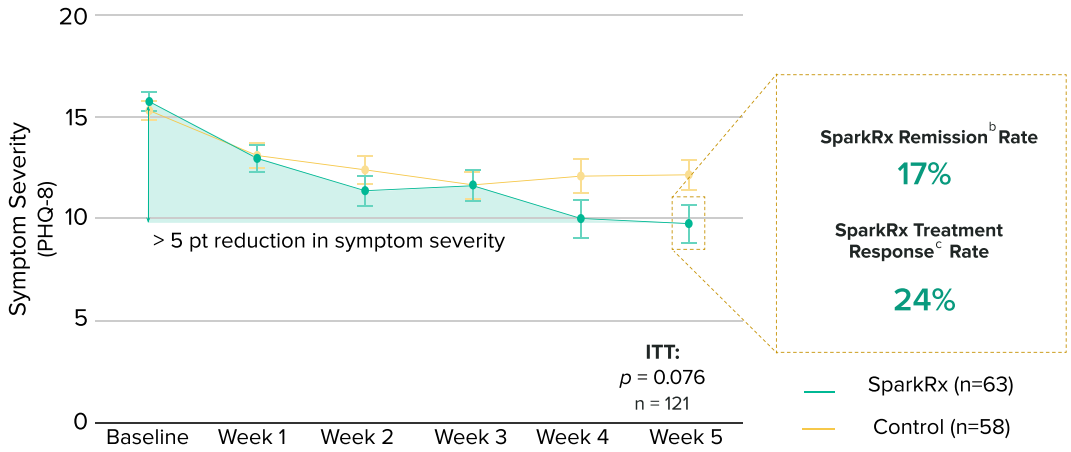
SparkRx

Supported by clinical data

SparkRx has been studied in a nationwide, randomized controlled trial (NCT04524598).

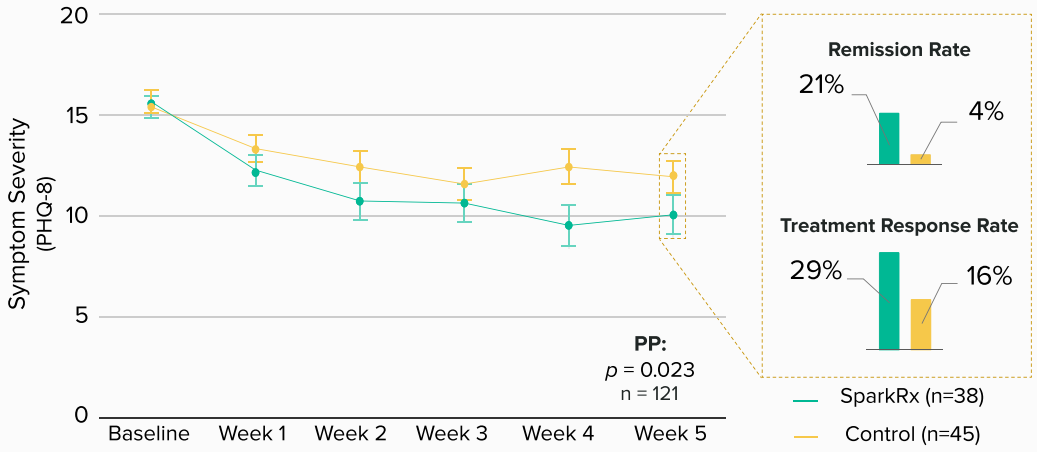
Participants who received SparkRx showed a **clinically significant reduction**[2,3] in depression symptoms. The intention-to-treat analysis comparing SparkRx to Control was not significant.

Intention-to-Treat Analysis



SparkRx led to a **statistically significant reduction** in depression symptoms compared to Control, p = 0.023, for participants who completed the program as recommended.

Per-Protocol Analysis



For Limbix's full clinical research summary visit **SparkRx.com**

Footnotes

b Remission defined as a post-intervention PHQ-8 score < 5.[4,6]

c Treatment response defined as a post-intervention PHQ score < 10 and 50% less than baseline PHQ score[4,5]

SparkRx

Visit SparkRx.com to begin offering SparkRx to your patients today

1

Sign up to offer SparkRx at SparkRx.com

Register with Limbix as a provider through a simple, secure web form. The form will ask for your name, NPI, and contact information.

2

Review the SparkRx Clinician Instructions for Use

After receiving your form, we will email you the Clinician Instructions for Use, which contains important safety information to help you determine which of your patients can benefit from using SparkRx.

3

Receive your SparkRx Provider Access Code

In the above email, you will also receive your unique SparkRx Access Code. You will give this code to your patients to allow them to create accounts in the app and begin their SparkRx journey!

The Limbix Provider Portal, coming soon, will allow you to monitor your patients' SparkRx progress. For more information, please email info@limbix.com

Here's what adolescents say about SparkRx

"It helped me know if I am putting effort into actually doing something - It brings me mindfulness with what I'm doing with the time throughout the day."

"...After using the app... I can take a step in a positive direction even if it's a small step. I know and can change my actions now to make me feel better because of the app."

"It helped me get coping techniques and know what to do when stressed. It helps me think more, like I see myself be more calm in situations that would stress me out normally."

SparkRx

Important Safety Information

Indications for Use

SparkRx is a digital therapeutic intended to provide a neurobehavioral intervention (Cognitive Behavioral Therapy - Behavioral Activation) in patients 13 to 22 years of age as adjunct treatment for symptoms of depression. SparkRx has not been cleared or approved by the U.S. Food and Drug Administration. During the COVID-19 public health emergency, SparkRx is being made available without a prescription under the FDA's emergency guidance for digital health devices for psychiatric disorders.

Warnings (for Clinicians)

SparkRx is not for emergency use. Please instruct patients to dial 911 or go to the nearest emergency room in the event of a medical emergency.

Patients should be clearly instructed not to use SparkRx to communicate severe, critical, or urgent information to their health care provider. Patients should also be informed that text they enter into SparkRx will not be monitored or reviewed by a health care provider.

SparkRx is not meant to be used as treatment without supervision of a health care provider. Please instruct your patients to contact you should they notice a worsening of symptoms or an increase in thoughts of suicide or self-harm.

SparkRx is not meant to be a substitution for any treatment or medication.

SparkRx is intended for patients whose primary language is English with a reading level of 5th grade or above, and who have access to an Android/iOS smartphone or tablet. SparkRx is intended only for patients who own a smartphone or tablet and are familiar with use of smartphone or tablet apps (applications).

SparkRx contains sensitive medical information. Please instruct patients to protect their information by password protecting their smartphone and tablet, and ensuring no one else may access their device.

SparkRx does not address concerns of active suicidal ideation with intent. SparkRx is not intended for the prevention of suicide attempts or self-harm behaviors. Patients with active suicidal ideation with intent or those who have had a past suicide attempt may still be given SparkRx to help treat depression but should not be given SparkRx to prevent, treat or mitigate active suicidal ideation with intent.

Patients with posttraumatic stress disorder (PTSD) who are currently experiencing marked alterations in arousal or reactivity associated with traumatic events may find that the level of exposure related to guided behavioral activation exacerbates symptoms.

References

1. McCauley, E., Gudmundsen, G., Schloredt, K., Martell, C., Rhew, I., Hubley, S., & Dimidjian, S. (2015). The Adolescent Behavioral Activation Program: Adapting Behavioral Activation as a Treatment for Depression in Adolescence. Journal of Clinical Child & Adolescent Psychology, 45(3), 291–304. https://doi.org/10.1080/15374416.2014.979933
2. Löwe, B., Unützer, J., Callahan, C. M., Perkins, A. J., & Kroenke, K. Monitoring depression treatment outcomes with the patient health questionnaire-9. Med Care, 42, 1194–1201 (2004).
3. Donkin, L., et al. Rethinking the dose-response relationship between usage and outcome in an online intervention for depression: randomized controlled trial. J Med Internet Res, 15, e231. 10.2196/jmir.2771 (2013).
4. Forman-Hoffman, V. L., et al. Significant reduction in depressive symptoms among patients with moderately-severe to severe depressive symptoms after participation in a therapist-supported, evidence-based mobile health program delivered via a smartphone app. Internet Interv, 25, 100408 (2021).
5. Kroenke, K., Spitzer, R. L., & Williams, J. B. The PHQ-9: validity of a brief depression severity measure. J Gen Intern Med, 16, 606–613 (2001).
6. Coley, R. Y., Boggs, J. M., Beck, A., Hartzler, A. L., & Simon, G. E. Defining success in measurement-based care for depression: A comparison of common metrics. Psychiatr Serv, 71, 312–318 (2020).