

# **The FDA Thinks This App Could Help People With Opioid Use Disorder Stay in Recovery**

Doctors gained an innovative new tool in their fight against the opioid addiction crisis this week. The FDA is giving the green light to a new mobile medical app called reSET-0, developed to help patients with opioid use disorder remain in outpatient treatment.

“As part of our efforts to address the misuse and abuse of opioids, we’re especially focused on new tools and therapies that can help more people with opioid use disorder successfully treat their addiction,” FDA Commissioner Scott Gottlieb, M.D., said in a press release this week. “Medical devices, including digital health devices like mobile medical apps, have the potential to play a unique and important role in contributing to these treatment efforts.”

**The goal of the app is to help people stay in recovery.**

The reSET-0 app is a prescription-only form of cognitive behavioral therapy (CBT) that is not indicated as a standalone treatment, but as a way to help patients in an intensive outpatient treatment program stay in treatment longer, according to the FDA. The app has been FDA-cleared, not FDA-approved, meaning it is similar enough to another legally

marketed device. In this case, that is the the original version of the reSET app that the FDA cleared in 2017, which was indicated for use with outpatient therapy to treat addiction related to alcohol, cocaine, marijuana, and stimulants, but not opioids.

“Often on the road to recovery, patients find their commitment to staying in treatment may wane,” Dr. Gottlieb said in the press release. “Providing Americans suffering from opioid use disorder with more options and proper support to address treatment challenges is key to helping them succeed.”

**After an individual diagnosed with opioid use disorder (OUD) is prescribed reSET-0, they download and install the product from the app store using an access code from their doctor.**

Then they begin the program, which consists of 67 different therapy lessons that use and build upon each other over the course of 12 weeks, Yuri Maricich, M.D., chief medical officer and head of clinical development for Pear Therapeutics, the company that developed the app, tells SELF.

The content of the app is largely grounded in a well-researched addiction-specific form of CBT, as Dr. Maricich describes it, called the Community Reinforcement Approach (CRA), which seeks to help people evaluate and rearrange their lifestyle and their environment (e.g. their social support system and family relationships) such that

sober living becomes more rewarding than substance abuse, as well as learn coping skills.

**The clinical trial found that patients who used the reSET-0 app stayed in treatment longer than those who didn't.**

In the peer-reviewed study, published in the Journal of Consulting and Clinical Psychology in 2014, the app was tested as an adjunct to two of the best evidence-based therapies available to treat opioid addiction: Medication-assisted treatment (MAT) and contingency management (CM). MAT is the use of certain medications—buprenorphine, in this case—to relieve the serious physical symptoms and powerful psychological cravings associated with opioid withdrawal, according to the Substance Abuse and Mental Health Services Administration (SAMHSA). CM is the use of motivational incentives to encourage abstinence, according to the National Institute on Drug Abuse (NIDA), like cash or vouchers. In this study, the participants were tested for opiates and cocaine three times a week and could earn a maximum of \$997.50.

All 170 participants in the study were enrolled in a 12-week treatment program based on CM and MAT, along with “minimal” therapist counseling (30 minutes every two weeks). About half of these participants also used the reSET-0 app, where they completed interactive lessons that typically include a CBT component and skill-building exercises. At the end of the 12 weeks, the app group saw an overall retention rate of 80.4

percent, compared to 64.1 percent for the no-app group. A specific portion of the app group also had more days of sobriety under their belts at the end of the trial (more on that in a bit).

Here's how the app works: Each lesson is composed of text, images, video, and audio, and takes about 15 to 20 minutes to complete. At the end of every lesson is a quiz to assess the user's fluency in that concept, Dr. Maricich explains; the patient must achieve 100 percent to move on. The first 31 modules are core lessons, intended to be returned to multiple times to reinforce key concepts, Dr. Maricich says. After successfully completing each quiz, the user gets to spin a prize wheel that will offer up either a congratulatory message on their progress or a small digital gift card. (It's essentially an algorithm-facilitated form of contingency management, Dr. Maricich explains.)

An example of a core lesson is learning skills to refuse drugs by analyzing situations in which they did, or almost did. Every time a patient relapses or is tempted to do so, the patient uses the lesson as an exercise to evaluate the specific circumstances—where they were, the time of day, their mood, the people they were with—to help them identify patterns in their own behavior and figure out what they could do differently next time. Mastering this concept within the app could come in handy for someone when they find themselves feeling vulnerable to relapse. “In a moment of difficulty or stress, they need to be able to quickly retrieve that skill and apply it in real life,” Dr. Maricich explains.

In addition to the educational component, the app helps facilitate communication between the physician and the patient

in between visits. The app has a feature for patients to self-report cravings and triggers, as well as record their use (or non-use) of buprenorphine, according to the press release, which the physician can monitor from a dashboard of their own. The doctor can also input the results of the patient's urinalysis; a negative drug test gives them another opportunity to spin the prize wheel, Dr. Maricich says (in addition to the voucher reward).

**While the app might help people stay in treatment, it hasn't been shown to actually reduce illicit drug use.**

Among people being treated for OUD for the first time, there was no statistical difference when it came to abstinence, according to the study, either when it came to their longest continuous abstinence (the longest period of time they went without using during the study), or total abstinence (the total amount of time they didn't use during the study).

Interestingly, the results were much more dramatic among people who had been treated for OUD at least one time before. For those people, the addition of the app to their treatment program on average increased their longest continuous abstinence (LCA) by 15.1 days (from 46 to 61.1), and their total abstinence (TA) by 17.8 days (from 54.8 to 72.6). The study authors theorized that people who had been in treatment before were able to build on the gains they made there.

But the FDA rejects the claim that the app is indicated to help reduce illicit drug use. “The FDA retains the right to consider the available data and determined that the data were not sufficient to support a claim of abstinence at this time,” Dr. Maricich says. Therefore, the company is required to include this limitation of use, Dr. Maricich explains: “reSET-0 has not been shown to decrease illicit drug use or improve abstinence in patients with OUD.”

And there are some significant study limitations, as the authors of the reSET-0 study point out. For instance, there is no data on how the participants fared after the 12-week study concluded—so it’s impossible to tell if the app made any meaningful impact over the long term. Another issue: The participants in the study were using a desktop version of the app in a computer in the clinic—not on their own phones and on their own time. It’s not clear if clinic attendance is necessary to make sure patients complete the lessons, the researchers point out. And with just 170 participants, the study is relatively small.

So for now, the FDA believes the evidence is lacking when it comes to reSET-0’s ability to help decrease drug use and increase abstinence—which really is the ultimate goal when treating substance abuse disorders. “Retention in treatment is always a good thing when it comes to addiction,” Timothy Brennan, M.D., director of the Addiction Institute at Mount Sinai West and Mount Sinai St. Luke’s Hospital, tells SELF. “But the end game is really to decrease drug use, and this hasn’t been shown to do that.”

# **Incorporating an app into the recovery model is exciting and potentially helpful, but it's not a solution just yet.**

“There’s increasing interest in digital therapeutics and tech-based interventions to treat substance use disorders, because they have the potential to reach a lot of people easily and efficiently,” Larissa Mooney, M.D., associate clinical professor of psychiatry at UCLA and director of the UCLA Addiction Medicine Clinic, tells SELF. “You want to use as many tools as you can to help the individual make progress towards recovery,” she says, emphasizing that an app like reSET-0 is just that—one tool.

“I think it’s a terrific idea to look at mobile tech and the internet as far as engaging people in treatment, because we certainly know people are on their phones for great periods of time,” Dr. Brennan says. “But yeah, I think we have a way to go in the efficacy of these apps.”

In other words: Doctors will welcome any help they can get in helping people overcome addiction, but nobody in the medical community is expecting Silicon Valley to come up with a quick fix for such a large and complex problem. “Addiction and biology and psychiatry—they don’t work that way,” Dr. Brennan explains. “We’re not going to hack our way through the opioid crisis.”

(Source: [www.Self.com](http://www.Self.com))

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