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Prescription apps take off during lockdown

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Digital therapeutics are going from strength to strength during the pandemic.

Telemedicine in its many forms was on the upswing long before the Covid-19 pandemic occurred, but the outbreak has undoubtedly forced greater uptake of digital technologies. The latest prescription app to appear on the US market is Parallel, developed by Mahana Therapeutics, which gained FDA clearance on Monday as a way for irritable bowel syndrome patients to manage their condition.

Parallel is the seventh prescription app to go on sale in the US this year. And the speed and ease with which these products have reached market show the regulator's willingness to adopt new technology as a way to manage diseases without patients having to see doctors in person.

Parallel enables irritable bowel syndrome patients to receive a web-based cognitive behavioural therapy programme under which they are taught behavioural techniques to improve bowel habits, help develop stable healthy eating and exercise patterns, address unhelpful thoughts, manage stress and emotions, and focus on reducing symptoms and preventing relapse.

Approval was based on data from the 558-patient Actib trial, in which Parallel, previously called Regul8, was compared with higher-intensity CBT sessions delivered over the phone, and a third arm in which patients received treatment as usual, which did not include CBT.

At one year, 66% of the patients randomised to Parallel met Actib's primary endpoint, achieving a clinically meaningful reduction in the severity of their IBS as defined by a 50-point drop from baseline on the irritable bowel syndrome symptom severity score. This outcome was also seen in 73% of those in the telephone CBT arm and 44% of patients in the usual treatment group.

Keen

Despite Actib showing Parallel to be less effective than the phone option, the FDA waved the app through on the basis of it being better than standard therapy, showing how keen the agency is on these kinds of therapeutics.

A month ago it granted de novo clearance for an app that runs on the Apple Watch, designed to track the sleep patterns of PTSD patients, and help avoid them experiencing nightmares. After a learning period of around 10 days, the NightWare app senses the wearer's heart rate and movement; when it detects a potential nightmare, it will vibrate enough to interrupt the nightmare without waking the patient.

Both NightWare and Parallel received FDA de novo clearance. Three other apps, from Pear Therapeutics and

Orexo, reached market this year with no such clearance, thanks to the FDA having relaxed regulations for this type of software for the duration of the US's Covid-19 public health emergency.

After the state of emergency lifts, the makers of these apps will no longer be able to sell them, since they are considered a stopgap measure to help patients unable to visit their doctors as usual.

After that Orexo and Pear will have to submit de novo applications. But the apps that were given either de novo or 510(k) clearance this year received the FDA's blessing an average of 5.8 months after submission – much faster than the 10.2 month average for all de novos at the half-year point (*FDA keeps the new devices coming, July 16, 2020*). Even if they have to resubmit, Orexo and Pear will probably not have to wait long.

Digital therapeutics that reached the US market in 2020

Date	Company	Device name	Indication	Route	Review time (months)
Mar 23	Pear Therapeutics	Somryst	Insomnia	510(k) clearance	8.9
Apr 29	Pear Therapeutics	Pear-004	Schizophrenia	Temporary	N/A
Jun 15	Akili Interactive Labs	EndeavorRx	ADHD	De novo	2.0
Jul 2	Orexo	Deprexis	Depression	Temporary	N/A
Jul 15	Orexo	Vorvida	Alcohol misuse	Temporary	N/A
Nov 6	Nightware	Nightware Kit	PTSD nightmares	De novo	5.4
Nov 25	Mahana Therapeutics	Parallel	Irritable bowel syndrome	De novo	6.9

Source: EvaluateMedTech, FDA.