

FDA OKs virtual reality system to ease back pain

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A 3D virtual reality system to treat back pain was approved by the U.S.

Food and Drug Administration on Tuesday.

The EaseVRx system is a prescription device for at-home use that combines [cognitive behavioral therapy](#) and other behavioral methods to treat patients 18 and older with chronic lower back [pain](#).

"Millions of adults in the United States are living with chronic lower back pain that can affect multiple aspects of their daily life," said Dr. Christopher Loftus, acting director of the Office of Neurological and Physical Medicine Devices in the FDA's Center for Devices and Radiological Health.

"Pain reduction is a crucial component of living with chronic lower back pain. Today's authorization offers a [treatment option](#) for pain reduction that does not include [opioid pain medications](#) when used alongside other [treatment methods](#) for chronic lower back pain," Loftus said in an agency [news release](#).

Pain experts welcomed the approval.

"It is exciting to see virtual reality [VR] devices being utilized to treat chronic pain as these devices and software become more affordable and accessible to patients," said Dr. Yili Huang, director of pain management at Northwell Health's Phelps Hospital in Sleepy Hollow, N.Y.

"It is believed that VR helps treat pain by distraction, focus shifting away from the painful stimulus and helping the patient build the necessary skills to manage their own pain," he said. "The EaseVRx treatment program seems to have successfully combined all three of these methods to help patients treat pain.

"The study results are promising because not only did the treatment demonstrate a decrease in pain, but it also demonstrated a decrease in

pain interference with activity, mood, sleep and stress, indicators that this treatment can help patients not only improve pain, but more importantly, quality of life," Huang added.

The EaseVRx system includes a [virtual reality headset](#) and controller, and a "breathing amplifier" that directs a patient's breath toward the headset microphone for use in deep breathing exercises.

The system uses a number of cognitive behavioral therapy (CBT) methods to achieve pain relief, including deep relaxation, self-compassion, acceptance, visualization, attention-shifting and healthy movement, the FDA said in the release.

A treatment program includes 56 VR sessions that are 2 to 16 minutes long as part of a daily eight-week treatment program.

The FDA approval is based on a clinical trial that included 179 patients with chronic lower back pain assigned to one of two eight-week VR programs: the EaseVRx 3D program or a control 2D program that did not feature CBT methods.

At the end of treatment, 66% of EaseVRx participants reported a greater than 30% reduction in pain, compared to 41% of those in the control group. A greater than 50% pain reduction was reported by 46% of the EaseVRx users, compared with 26% of those in the control group, according to the FDA.

One, two and three months after treatment, all EaseVRx users still reported a 30% reduction in pain, which was higher than in the control group.

Nearly 21% of EaseVRx users reported discomfort with the headset and about 10% reported motion sickness and nausea, but there were no

[serious side effects](#) associated with the system, which is made by AppliedVR.

Huang pointed out that the study had some limitations.

"Although any safe, opioid-free pain [treatment](#) is a welcome addition during the opioid epidemic, it is important and somewhat disappointing to note that EaseVRx had no effect on opioid use in this study," he said.

"It is also important to note that the study subjects were mostly college-educated Caucasian women, and any patients with medical conditions that can cause nausea and dizziness were excluded," Huang said. "This means that we cannot assume that all patients from diverse backgrounds will have the same benefits."

More information: The American Academy of Family Physicians has more on [low back pain](#).

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