

# First US trial of varenicline for e-cigarette cessation shows positive results

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Benjamin Toll, Ph.D., Lisa Fucito, Ph.D., and colleagues developed a clinical trial for e-cigarette cessation that was meant to mimic real-world conditions. Credit: Medical University of South Carolina

The first U.S. trial of varenicline for e-cigarette cessation shows promising results and warrants larger-scale trials, the researchers say.

Researchers from Yale Cancer Center and MUSC Hollings Cancer Center published the [results](#) of their clinical trial of varenicline to help adults to stop using e-cigarettes in the *American Journal of Preventive Medicine* on May 16.

The results showed a significant disparity between the [placebo group](#) and the group receiving the medication. "We had a 15% difference in quit rates, with those in the medication group having a quit rate of 45%," said Lisa Fucito, Ph.D., lead author and director of the Tobacco Treatment Service at the Yale Cancer Center and Smilow Cancer Hospital.

Benjamin Toll, Ph.D., director of the Tobacco Treatment Program at MUSC Health and senior author on the study, said that the researchers designed the trial to mimic [real-world conditions](#) as much as possible—from the people who enrolled in the trial to the type of support they would likely receive from [primary care providers](#).

The publication of their results closely follows publication of a trial of cytisinicline for [e-cigarette](#) cessation. The two drugs work similarly. However, varenicline is already on the market in the U.S. in generic versions while cytisinicline has not yet received FDA approval and is not currently available for use by patients.

Varenicline, perhaps better known by the brand name Chantix, is FDA-approved to help adults to stop smoking [traditional cigarettes](#). But, despite the growing numbers of people who use e-cigarettes, there are no approved medication options to help them to stop using e-cigarettes.

"People can get to very high levels of nicotine exposure with these e-cigarette products, and they can use them near constantly throughout the day. So, the question we all have is, 'Can any pharmacotherapy stand up to this challenge?'" Fucito said.

It's a question of logistics. People who smoke cigarettes have to get a cigarette from the pack and light it. It's easy to track use. There are also natural stopping points—when the cigarette is finished, it must be snuffed out, and when the pack is used up, it must be thrown away and a new one purchased and opened before the person can smoke again.

E-cigarettes, however, can last for 5,000 or more puffs, making them harder to track intake but easier to use. Toll said he has patients who describe keeping their e-cigarettes under their pillows so they can vape right before going to sleep and then again immediately upon waking in the morning.

Previous studies have shown that a majority of people using e-cigarettes want to quit. But it's been unclear whether products used to stop smoking traditional combustible cigarettes would also work for e-cigarettes.

"We need more pharmacotherapy treatments to help address the really strong physical dependence that can develop from e-cigarette use. People undergo significant withdrawal when they try to stop, and that withdrawal is so unpleasant and hard to manage with just behavioral support alone," Fucito said.

A recent Italian study married pharmacotherapy with intense weekly behavioral counseling sessions, and the trial of cytisinicline also included weekly 10-minute sessions with trained counselors.

In this study, however, the researchers wanted to see how well the pharmacotherapy could work given typical health care conditions—meaning, the patient would likely get a brief discussion with a primary care provider along with a prescription and information about resources for quitting but no follow-up counseling sessions.

To recreate this, they developed a self-guided cessation booklet for

patients, with practical tools and tips for quitting. A licensed health care provider also met with each patient to inform them of how to use the medication, offer brief advice and instruct them to set a quit date for one to two weeks after starting the medication.

"We took a much lighter touch to reflect the behavioral support that you'd likely experience if you went to your doctor and asked for help with quitting e-cigarettes," Fucito said.

The study also included some patients with histories of depression. This was significant because Chantix, at one point, had a "black box warning" after reports linking the drug to psychiatric side effects. That warning was dropped in 2016 after a very large study showed the drug to be safe, but Toll and Fucito said the stigma of the warning remains in the minds of both health care providers and the general public.

"There's still some hesitancy to prescribe this very safe—now generic—drug, and it really shouldn't be that way," Toll said.

None of the participants in this study experienced [serious side effects](#), although a larger study would be needed to verify this finding. Most of the side effects were along the lines of nausea, insomnia or vivid dreams.

Another piece of good news—those who stopped vaping didn't boomerang back to cigarettes.

"If you have a former smoking history, one of the worries in the field is that you're going to go back to smoking when you quit vaping," Toll said. "And we did not find that."

On the other hand, one potential challenge that the researchers uncovered in the results indicated that people without a cigarette smoking history—in other words, those who have only ever used e-

cigarettes—might have a harder time quitting. That could be because that group is more likely to use e-cigarettes continuously throughout the day, therefore getting more nicotine into their systems.

Larger trials are needed to delve into these questions. But this trial, at least, should give health care providers some confidence in prescribing varenicline for patients trying to stop using e-cigarettes.

"We want people to come back to this medication," Fucito explained. "There are people who need help now and are likely to struggle to quit e-cigarettes on their own because the technology facilitates nicotine use on a level that we've never seen before."

**More information:** Lisa M. Fucito et al, Varenicline for E-Cigarette Cessation in Adults: A Preliminary Placebo-Controlled Randomized Trial, *American Journal of Preventive Medicine* (2024). [DOI: 10.1016/j.amepre.2024.04.007](https://doi.org/10.1016/j.amepre.2024.04.007)

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